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Contents

Federal Register

Vol. 77, No. 172

Wednesday, September 5, 2012

Administrative Conference of the United States
NOTICES
Meetings:
Committees of Administrative Conference of United States, 54554–54555

Agriculture Department
See Forest Service
See National Agricultural Statistics Service
See Rural Utilities Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54555–54556

Alcohol, Tobacco, Firearms, and Explosives Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Environmental Information, 54610–54611
Student and Supervisor Training Validation Surveys, 54610

Antitrust Division
NOTICES
National Cooperative Research and Production Act:
IMS Global Learning Consortium, Inc., 54611
National Warheads and Energetics Consortium, 54611
ODVA, Inc., 54612
Petroleum Environmental Research Forum, 54612

Antitrust
See Antitrust Division

Bureau of Consumer Financial Protection
PROPOSED RULES
Appraisals for Higher-Risk Mortgage Loans, 54722–54775

Centers for Medicare & Medicaid Services
RULES
Administrative Simplification:
Adoption of Standard for Unique Health Plan Identifier; Addition to National Provider Identifier Requirements, etc., 54664–54720

Coast Guard
PROPOSED RULES
Regulated Navigation Areas:
Thames River Degaussing Range Replacement Operations; New London, CT, 54495–54499
Special Anchorage Areas:
Stockton Springs, ME, 54493–54495

Commerce Department
See Foreign-Trade Zones Board
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration
See Patent and Trademark Office

Commodity Futures Trading Commission
RULES
Commodity Pool Operator and Commodity Trading Advisor Regulations Resulting from Dodd-Frank Act, 54355–54360

Comptroller of the Currency
PROPOSED RULES
Appraisals for Higher-Risk Mortgage Loans, 54722–54775

Consumer Product Safety Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Requirements for Baby-Bouncers and Walker-Jumpers, 54567–54568

Defense Department
NOTICES
Meetings:
Defense Advisory Committee on Women in the Services, 54568–54569
Renewal of U.S. Naval Academy Board of Visitors, 54569–54570

Defense Nuclear Facilities Safety Board
NOTICES
Senior Executive Service Performance Review Board, 54570

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Assessing Program Performance, National Resource Center, Business and International Education, etc., 54571
Evaluation of the Carol M. White Physical Education Program, 54570–54571
Meetings:
President's Advisory Commission on Asian Americans and Pacific Islanders, 54572–54573
President's Board of Advisors on Historically Black Colleges and Universities, 54571–54572

Energy Department
See Energy Efficiency and Renewable Energy Office
See Federal Energy Regulatory Commission
See Western Area Power Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals; Correction, 54573

Energy Efficiency and Renewable Energy Office
NOTICES
Meetings:
State Energy Advisory Board, 54573

Environmental Protection Agency
RULES
Denials of Objections on Remand:
Natural Resources Defense Council, Dichlorvos (DDVP), 54402–54421

Nonconformance Penalties for On-Highway Heavy-Duty Diesel Engines, 54384–54402
Revisions of Five California Clean Air Act Title V Operating Permits Programs, 54382–54384
PROPOSED RULES
Microorganisms; General Exemptions from Reporting Requirements:
Revisions to Recipient Organisms Eligible for Tier I and Tier II Exemptions, 54499–54511
NOTICES
Proposed RCRA Prospective Purchaser Agreement:
Order on Consent and Covenant Not to Sue for a portion of the Delphi Flint West Site, a/k/a Chevy in the Hole in Flint, Genesee County, Michigan, 54576–54577

Executive Office for Immigration Review
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Notice of Appeal to Board of Immigration Appeals from Decision of a DHS Officer, 54612–54613

Executive Office of the President
See Presidential Documents

Federal Aviation Administration
RULES
Airworthiness Directives:
Eurocopter France Helicopters, 54353–54354
NOTICES
Meetings:
Research, Engineering and Development Advisory Committee, 54648
RTCA NextGen Advisory Committee, 54648–54649
Petitions for Exemptions; Summaries of Petitions Received, 54649–54650
Requests to Release Airport Property:
El Paso International Airport, El Paso, TX, 54650–54651
Study on the Use of Cell Phones On Board Aircraft, 54651

Federal Communications Commission
RULES
Facilitating the Use of Microwave for Wireless Backhaul and Other Uses etc., 54421–54434
PROPOSED RULES
Facilitating the Use of Microwave for Wireless Backhaul and Other Uses etc., 54511–54517
NOTICES
Meetings:
North American Numbering Council, 54577

Federal Emergency Management Agency
NOTICES
Emergency Declarations:
Louisiana; Amendment No. 1, 54599
Louisiana; Related Determinations, 54599
Mississippi; Amendment No. 1, 54599–54600
Mississippi; Related Determinations, 54600
Major Disaster Declarations:
New Mexico; Related Determinations, 54601–54602
Ohio; Related Determinations, 54600–54601
Oklahoma; Related Determinations, 54601

Federal Energy Regulatory Commission
NOTICES
Combined Filings, 54573–54574
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
KODE Novus II, LLC, 54574–54575
Initial Market-Based Rate Filings:
Frontier El Dorado Refining LLC, 54575

Federal Highway Administration
NOTICES
Draft Program Comment for Common Post-1945 Concrete and Steel Bridges, 54652–54655

Federal Reserve System
PROPOSED RULES
Appraisals for Higher-Risk Mortgage Loans, 54722–54775
NOTICES
Changes in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 54577–54578
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 54578

Fish and Wildlife Service
RULES
Endangered and Threatened Wildlife and Plants:
Determination of Endangered Status for Arctostaphylos franciscana (Franciscan manzanita) Throughout Its Range, 54434–54450
Migratory Bird Hunting:
Certain Federal Indian Reservations and Ceded Lands for 2012–13 Early Season, 54451–54463
PROPOSED RULES
Endangered and Threatened Wildlife and Plants:
90-Day Finding on a Petition to List the Eagle Lake Rainbow Trout, 54548–54553
Designation of Critical Habitat for Franciscan Manzanita, 54517–54548
NOTICES
Endangered Species Permit Applications, 54604–54605
Longworth Low-Effect Habitat Conservation Plan for the Morro Shoulderband Snail, Community of Los Osos, San Luis Obispo County, CA, 54605–54607

Foreign Claims Settlement Commission
NOTICES
Meetings; Sunshine Act, 54613

Foreign-Trade Zones Board
NOTICES
Reorganizations under Alternative Site Framework:
Foreign-Trade Zone 189, Kent, Ottawa, and Muskegon Counties, MI, 54558–54559

Forest Service
NOTICES
Meetings:
Central Montana Resource Advisory Committee, 54556–54557
Dixie Resource Advisory Committee, 54556
Eastern Idaho Resource Advisory Committee, 54557
Lassen County Resource Advisory Committee, 54556

General Services Administration
NOTICES
Maximum Per Diem Rates for the Continental United States, 54578

Health and Human Services Department
See Centers for Medicare & Medicaid Services

See National Institutes of Health
See Substance Abuse and Mental Health Services Administration

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency

Housing and Urban Development Department
NOTICES
Fair Housing Demonstrations:
Baltimore, MD, Standard Metropolitan Statistical Area, 54602–54604

Indian Affairs Bureau
NOTICES
Addition of Lands to Indian Reservations:
Dafter Parcel, Bay Mills Indian Community of Michigan, 54607
Sugar Parcel Lands, Bay Mills Indian Community of Michigan, 54607–54608

Industry and Security Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Offsets in Military Exports, 54559

Interior Department
See Fish and Wildlife Service
See Indian Affairs Bureau
See Land Management Bureau
See Surface Mining Reclamation and Enforcement Office

Internal Revenue Service
PROPOSED RULES
Allocation of Costs under the Simplified Methods, 54482–54490

International Trade Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Textile and Apparel Safeguard Actions on Imports from Korea, 54559–54561
Antidumping Duty Administrative Reviews; Results, Extensions, Amendments, etc.:
Certain Polyester Staple Fiber from Taiwan, 54561–54562
Certain Polyester Staple Fiber from the Republic of Korea, 54562–54563
Silicon Metal from the People's Republic of China, 54563–54565

Justice Department
See Alcohol, Tobacco, Firearms, and Explosives Bureau
See Antitrust Division
See Executive Office for Immigration Review
See Foreign Claims Settlement Commission
See Justice Programs Office
NOTICES
Lodging of Consent Decrees under the Toxic Substances Control Act, 54609–54610

Justice Programs Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Census of Juveniles on Probation, 54613–54614

Labor Department
See Labor Statistics Bureau

Labor Statistics Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54614–54615

Land Management Bureau
NOTICES
Meetings:
Southeast Oregon Resource Advisory Council, 54608
Public Land Orders:
Partial Withdrawal Revocation and Transfer of Administrative Jurisdiction, Kirtland Air Force Base, NM, 54608–54609
Requests for Nominations:
Carrizo Plain National Monument Advisory Council, CA, 54609

National Agricultural Statistics Service
NOTICES
Intent to Suspend the 2012 Census of Agriculture Content Testing, 54557–54558

National Credit Union Administration
PROPOSED RULES
Appraisals for Higher-Risk Mortgage Loans, 54722–54775

National Institutes of Health
NOTICES
Government-Owned Inventions; Availability for Licensing, 54578–54580
Meetings:
Center for Scientific Review, 54580–54584
National Institute of Biomedical Imaging and Bioengineering, 54581–54584
National Institute of Diabetes and Digestive and Kidney Diseases, 54582
NIH Guidelines for Research Involving Recombinant DNA Molecules; Final Action, 54584–54597

National Oceanic and Atmospheric Administration
NOTICES
Endangered and Threatened Species Recovery Plans; Availability, 54565–54566
Meetings:
Mid-Atlantic Fishery Management Council, 54566
Permits:
Endangered Species; File No. 16134, 54566–54567
Marine Mammals; File No. 15142, 54567

National Science Foundation
NOTICES
Meetings:
Astronomy and Astrophysics Advisory Committee, 54615

National Transportation Safety Board
NOTICES
Strategic Management Program Fiscal Year 2013–2016 Strategic Plan, 54615

Nuclear Regulatory Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54615–54618
Meetings; Sunshine Act, 54618
Receipt of Request for Action:
Exelon Generation Company, LLC, 54619

Patent and Trademark Office
RULES
CPI Adjustment of Patent Fees for Fiscal Year 2013, 54360–54367

Presidential Documents
EXECUTIVE ORDERS
Energy Efficiency; Acceleration of Investment in Industrial Facilities (EO 13624), 54777–54781
Servicemembers, Veterans, and Military Family Members, Mental Health Services; Access Improvement (EO 13625), 54783–54786

Rural Utilities Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54558

Securities and Exchange Commission
PROPOSED RULES
Elimination of Prohibition Against General Solicitation And General Advertising in Certain Offerings, 54464–54481
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54619–54620
Applications:
Pruco Life Insurance Company, et al., 54621–54626
Meetings; Sunshine Act, 54626
Self-Regulatory Organizations; Proposed Rule Changes:
BATS Exchange, Inc., 54633–54635
BATS–Y Exchange, Inc., 54630–54632
Chicago Board Options Exchange, Incorporated, 54626–54629
Financial Industry Regulatory Authority, Inc., 54636–54640
International Securities Exchange, LLC, 54629–54630
NASDAQ OMX PHLX LLC, 54635–54636
NASDAQ Stock Market LLC, 54640–54646

Social Security Administration
NOTICES
Social Security Acquiescence Ruling; Correction, 54646

State Department
NOTICES
Culturally Significant Objects Imported for Exhibition:
African Art, New York, and the Avant-Garde, 54647
Becoming Van Gogh, 54646–54647
Manet: Portraying Life, 54647–54648
Sicily; Art and Invention Between Greece and Rome, 54647
Meetings:
Shipping Coordinating Committee, 54648

Statistical Reporting Service
See National Agricultural Statistics Service

Substance Abuse and Mental Health Services Administration
NOTICES
Current List of Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards to Engage in Urine Drug Testing for Federal Agencies, 54597–54598

Surface Mining Reclamation and Enforcement Office
PROPOSED RULES
Alabama Regulatory Program, 54490–54491
Utah Regulatory Program, 54491–54493

Surface Transportation Board
NOTICES
Control:
Genesee and Wyoming Inc. of RailAmerica, Inc., et al., 54655–54659
Meetings:
Rail Energy Transportation Advisory Committee, 54659

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Surface Transportation Board

Treasury Department
See Comptroller of the Currency
See Internal Revenue Service
See United States Mint

United States Mint
NOTICES
Price for the 2012 Annual Uncirculated Dollar Coin Set, 54659–54660

Veterans Affairs Department
RULES
Service Dogs, 54368–54382
Sharing Information Between the Department of Veterans Affairs and the Department of Defense, 54367–54368
NOTICES
Privacy Act; Systems of Records, 54660–54661

Western Area Power Administration
NOTICES
Temporary Extensions of Transmission Service Rates:
Pacific Northwest-Pacific Southwest Intertie Project, 54575–54576

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 54664–54720

Part III
Bureau of Consumer Financial Protection, 54722–54775
Federal Reserve System, 54722–54775
National Credit Union Administration, 54722–54775
Treasury Department, Comptroller of the Currency, 54722–54775

Part IV
Presidential Documents, 54777–54781, 54783–54786

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.

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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:

13624 54779
13625 54783

12 CFR

Proposed Rules:

34 54722
164 54722
226 54722
722 54722
1026 54722
1222 54722

14 CFR

39 54353

17 CFR

4 54355

Proposed Rules:

230 54464
239 54464

26 CFR

Proposed Rules:

1 54482

30 CFR

Proposed Rules:

901 54490
944 54491

33 CFR

Proposed Rules:

110 54493
165 54495

37 CFR

1 54360
41 54360

38 CFR

1 54367
17 54368

40 CFR

70 54382
86 54384
180 54402

Proposed Rules:

725 54499

45 CFR

162 54664

47 CFR

101 54421

Proposed Rules:

101 54511

50 CFR

17 54434
20 54451

Proposed Rules:

17 (2 documents) 54517, 54548

Rules and Regulations

Federal Register

Vol. 77, No. 172

Wednesday, September 5, 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.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0354; Directorate Identifier 2010–SW–104–AD; Amendment 39–17165; AD 2012–17–02]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Eurocopter France (EC) Model SA–365N, SA–365N1, SA–366G1, AS–365N2, AS 365 N3, EC 155B, and EC155B1 helicopters. This AD was prompted by the discovery of a cracked main rotor mast nut. This condition, if not corrected, could lead to complete failure of the mast nut, resulting in failure of the rotor mast and loss of control of the helicopter. This AD will require replacing the main rotor mast nut with an airworthy main rotor mast nut to prevent this scenario.

DATES: This AD is effective October 10, 2012.

ADDRESSES: For service information identified in this AD, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, TX 75052, telephone (972) 641–0000 or (800) 232–0323, fax (972) 641–3775, or at *http://www.eurocopter.com/techpub.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

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 this AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Gary Roach, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 222–5110; email *gary.b.roach@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On April 4, 2012, at 77 FR 20319, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 to include an AD that would apply to all Eurocopter France (EC) Model SA–365N, SA–365N1, SA–366G1, AS–365N2, AS 365 N3, EC 155B, and EC155B1 helicopters. That NPRM proposed to require replacing the main rotor mast nut with an airworthy main rotor mast nut to prevent failure of the main rotor mast and subsequent loss of control of the helicopter.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD No.: 2006–0368R1, dated December 2, 2010, and corrected December 8, 2010 (AD 2006–0368R1), to correct an unsafe condition for the EC Model SA 365 N, SA 365 N1, AS 365 N2, AS 365 N3, SA 366 G1, EC 155 B, and EC 155 B1 helicopters.

EASA advises that a cracked (partially failed) main rotor mast nut was discovered during a complete overhaul of a main rotor mast. The start of the crack was related to circular scoring found in the nut threads. EASA states that this condition, if not corrected, ''could lead to complete failure of the mast nut, possibly resulting in failure of the rotor mast and consequent loss of control of the helicopter.'' To address this unsafe condition, EASA issued Emergency AD 2006–0368–E, dated December 6, 2006 (AD 2006–0368–E), to require repetitive inspections of the mast nut, and replacement of the nut if cracked. Since issuance of AD 2006–0368–E, EC has developed modification (MOD) 0762C42 to improve the strength of the mast nut by changing its material. Replacing mast nut part number (P/N) 360A31–1020–20 with mast nut P/N 365A31–2060–20 or 365A31–2060–21 (as applicable to helicopter type) ''constitutes an optional terminating action'' for the repetitive inspection requirements. For this reason, EASA issued AD 2006–0368R1 ''to inform which helicopters remain subject to inspections and replacement requirements'' of the AD.

Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM.

FAA's Determination

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us of the unsafe condition described in the EASA AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Differences Between This AD and the EASA AD

The EASA AD allows for either inspecting the mast nut at regular intervals or replacing the mast nut, while this AD requires replacing the mast nut. The EASA AD uses flight hours of the main rotor mast assembly, while this AD uses TIS of the helicopter.

Related Service Information

We reviewed EC Alert Service Bulletin (ASB) No. 62.00.23, Revision 1, for Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters; EC ASB 62.12, Revision 1, for Model SA–366G1 helicopters; and EC ASB 62A014, Revision 1, for Model EC 155B and EC155B1 helicopters, all dated October 27, 2010. The ASBs contain procedures

for repetitively inspecting the mast nut for a crack or failure. The ASBs remove any helicopter with MOD 0762C42 incorporated from the applicability of the ASB. EASA classified this ASB as mandatory and issued AD 2006–0368R1 to ensure the continued airworthiness of these helicopters.

Costs of Compliance

We estimate that this AD affects 30 helicopters of U.S. registry. We estimate that replacing the mast nut with an airworthy mast nut will require 32 work-hours, at an average labor cost of $85 per work-hour. Parts will cost about $3,100. Based on these costs, we estimate a total cost per helicopter of $5,820, and a total cost for the U.S. operator fleet of $174,600.

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 helicopters 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 to the extent that it justifies making a regulatory distinction; 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 an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

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):

2012–17–02 Eurocopter France Helicopters: Amendment 39–17165; Docket No. FAA–2012–0354; Directorate Identifier 2010–SW–104–AD.

(a) Applicability

This AD applies to Eurocopter France (EC) Model SA–365N, SA–365N1, SA–366G1, AS–365N2, AS 365 N3, EC 155B, and EC155B1 helicopters with a mast nut, part number (P/N) 360A31–1020–20, installed, certificated in any category.

(b) Unsafe Condition

This AD describes the unsafe condition as a cracked main rotor mast nut. This condition could result in failure of the rotor mast and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective October 10, 2012.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) For EC Models SA–365N, SA–365N1, AS–365N2, and AS 365 N3, prior to accumulating 1,650 hours time-in-service (TIS) or within the next 50 hours TIS, whichever occurs later, remove mast nut P/N 360A31–1020–20 and replace with an airworthy mast nut that has a P/N other than P/N 360A31–1020–20.

(2) For EC Model SA–366G1, prior to accumulating 990 hours TIS or within the next 30 hours TIS, whichever occurs later, remove mast nut P/N 360A31–1020–20 and replace with an airworthy mast nut that has a P/N other than P/N 360A31–1020–20.

(3) For EC Models EC 155B and EC155B1, prior to accumulating 660 hours TIS or within the next 50 hours TIS, whichever occurs later, remove mast nut P/N 360A31–1020–20 and replace with an airworthy mast nut that has a P/N other than P/N 360A31–1020–20.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Gary Roach, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 222–5110; email *gary.b.roach@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

(1) Eurocopter Alert Service Bulletin No. 62.00.23, No. 62.12, and No. 62A014, which are not incorporated by reference, contain additional information about the subject of this AD. All of the service bulletins are Revision 1 and all are dated October 27, 2010. For service information identified in this AD, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, TX 75052, telephone (972) 641–0000 or (800) 232–0323, fax (972) 641–3775, or at *http://www.eurocopter.com/techpub.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(2) The subject of this AD is addressed in in European Aviation Safety Agency AD No.: 2006–0368R1, dated December 2, 2010, and corrected December 8, 2010.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6300, main rotor drive system.

Issued in Fort Worth, Texas, on August 16, 2012.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–21262 Filed 9–4–12; 8:45 am]

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COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 4

RIN 3038–AD49

Amendments to Commodity Pool Operator and Commodity Trading Advisor Regulations Resulting From the Dodd-Frank Act

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rules.

SUMMARY: The Commodity Futures Trading Commission (Commission) is amending its regulations governing the operations and activities of commodity pool operators (CPOs) and commodity trading advisors (CTAs) in order to have those regulations reflect changes made to the Commodity Exchange Act (CEA) by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act).

DATES: *Effective Date:* November 5, 2012.

FOR FURTHER INFORMATION CONTACT: Barbara S. Gold, Associate Director, or Christopher W. Cummings, Special Counsel, Division of Swap Dealer and Intermediary Oversight, 1155 21st Street NW., Washington, DC 20581. Telephone number: 202–418–6700 and electronic mail: *bgold@cftc.gov* or *ccummings@cftc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. The Dodd-Frank Act

On July 21, 2010, President Obama signed the Dodd-Frank Act.[1] Title VII of the Dodd-Frank Act[2] amended the CEA[3] to establish a comprehensive new regulatory framework for swaps and security-based swaps. The goal of this legislation was to reduce risk, increase transparency, and promote market integrity within the financial system by, among other things: (1) Providing for the registration and comprehensive regulation of swap dealers (SDs) and major swap participants (MSPs); (2) imposing clearing and trade execution requirements on standardized derivative products; (3) creating robust recordkeeping and real-time reporting regimes; and (4) enhancing the Commission's rulemaking and enforcement authorities with respect to, among others, all registered entities and intermediaries subject to the oversight of the Commission. Among the changes made by the Dodd-Frank Act to the CEA were to include within the CPO definition the operator of a collective investment vehicle that trades swaps, and to include within the CTA definition a person who provides advice concerning swaps.[4]

B. The Proposed Amendments to Part 4

Part 4 of the Commission's regulations sets forth a comprehensive regulatory framework for the operations and activities of CPOs and CTAs. It includes disclosure, reporting and recordkeeping requirements for registered CPOs and CTAs, registration and compliance exemptions for CPOs and CTAs, and other provisions, including anti-fraud provisions, applicable to CPOs and CTAs, regardless of registration status. To ensure that the Part 4 regulations applied to CPOs and CTAs in the context of these intermediaries' involvement with swap transactions, on March 3, 2011, the Commission proposed certain amendments to Part 4 (Proposal).[5]

As the Commission explained in the Proposal, because many of the existing Part 4 regulations generally applied to CPOs and CTAs, they would continue to be applicable to CPOs and CTAs with respect to their swap activities without the need for amendment thereto. The Commission noted that in other instances, however, the text of certain existing Part 4 regulations was specific to activities involving futures contracts, commodity options, and off-exchange retail foreign currency (''commodity interests''), and it did not include, refer to or otherwise take account of swap activities. As the Commission stated: ''The Proposal [was] intended to clarify and ensure that the requirements governing the operations and activities of CPOs and CTAs continue to apply for these intermediaries in the context of their involvement with swap transactions.''[6] Accordingly, the Commission proposed to amend Regulations 4.7, 4.10, 4.22, 4.23, 4.24 4.30, 4.33 and 4.34 to include in each of these regulations a reference to swaps or swap activities.

II. Comments on the Proposal

The Commission received two comment letters on the Proposal,[7] each of which supported the Proposal. One of these letters stated that the Proposal ''should act to reduce risk and increase its transparency, and promote market integrity by ensuring that all entities are consistently regulated to the extent that their trading and other activities pertain to swaps.''[8] The other letter urged the Commission ''to work quickly and diligently on writing these rules and putting them in place as soon as possible.''[9]

III. The Final Regulations

In light of the supportive comments it received, with one exception the Commission is adopting the amendments to the Part 4 regulations it proposed. That exception concerns the proposed amendment to Regulation 4.10(a) that, *for the purposes of Part 4,* would have expanded the definition of the term ''commodity interest'' to include ''swaps.'' This proposal was superseded by a proposed amendment to Regulation 1.3(yy) that, *for the purposes of all of the Commission's regulations,* would define the term ''commodity interest'' to include ''swaps.''[10] Accordingly, the Commission is considering the proposed definition of the term ''commodity interest'' in connection with its consideration of the comment letters it received on its proposed amendment to Regulation 1.3(yy).

A. Adding ''Swap'' Terms to Part 4

As proposed, the Commission is inserting ''swap,'' ''swap transaction'' or a similar term at various regulations throughout Part 4. *See* the amendments to Regulations 4.23(a)(1), 4.24(g), (h)(1), and (i)(2) for CPOs and Regulations 4.34(g) and 4.34(i)(2) for CTAs. For

[1] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010). The text of the Dodd-Frank Act may be accessed through the Commission's Web site, *www.cftc.gov.*

[2] Pursuant to Section 701 of the Dodd-Frank Act, Title VII may be cited as the ''Wall Street Transparency and Accountability Act of 2010.''

[3] 7 U.S.C. 1 *et seq.* (2006). The Commission's regulations are found at 17 CFR part 1 *et seq.* (2012). Both the CEA and the Commission's regulations also may be accessed through the Commission's Web site.

[4] *See* Section 721(a) of the Dodd-Frank Act, which re-organized (and in some cases amended) existing definitions in, and added new definitions to, Section 1a of the CEA. The CPO and CTA definitions, as amended, are codified at CEA sections 1a(11) and 1a(12), respectively.

[5] 76 FR 11701.

[6] 76 FR 11701. Part 4 applies to CPOs with respect to their activities affecting pool participants and to CTAs with respect to their activities affecting clients. Depending on the nature of its activities, a CPO or CTA may also come within the definition of the term ''swap dealer'' or ''major swap participant'' in new CEA Section 1a(49) or 1a(33), respectively. As directed by the Dodd-Frank Act, the Commission has adopted new regulations that establish business conduct standards for SDs and MSPs. *See* 77 FR 9734 (Feb. 17, 2012). These new regulations apply to SDs and MSPs with respect to the counterparties with whom they transact swap business, and govern different activity than that to which the Part 4 regulations apply.

[7] These comment letters currently are available on the Commission's Web site.

[8] Comment letter from Chris Barnard (Mar. 29, 2011).

[9] Comment letter from Kyle Vandergrift (Apr. 20, 2011).

[10] *See* 76 FR 33066, 33069–70 (June 7, 2011).

example, Regulation 4.23(a)(1) is being amended to include ''swap type and counterparty'' in the itemized daily record that a CPO must make and keep with respect to a pool's commodity interest transactions.

At other Part 4 regulations, the Commission has included as proposed the term ''swap dealer'' among the persons for whom a CPO or CTA must provide information in its Disclosure Document and for whom a CPO must provide information in a pool's periodic Account Statement. *See* the amendments to Regulations 4.22(a)(3), 4.24(j)(1), (j)(3), (l)(1), and (l)(2) for CPOs and Regulations 4.34(j)(1), (j)(3), (k)(1) and (k)(2) for CTAs. For example, Regulations 4.24(j) and 4.34(j) are being amended to include SDs in the group of persons as to which conflicts of interest must be disclosed by CPOs and CTAs.

Similarly, the Commission has included as proposed ''a registered swap dealer'' among the persons listed in Regulation 4.7(a)(2) that do not have to satisfy a portfolio requirement in order to be a qualified eligible person (QEP), such that a CPO or CTA that has claimed relief under Regulation 4.7 may accept the SD as a pool participant or advisory client without regard to the size of its investment portfolio. As the Commission explained, ''this would be consistent with the current treatment of other financial intermediaries registered with the Commission (such as futures commission merchants [FCMs] and retail foreign exchange dealers [RFEDs]) as QEPs under Regulation 4.7(a)(2).'' [11]

B. Including Books and Records Relating to Swap Transactions within Part 4

The Commission has adopted as proposed amendments to Part 4 that require a CPO or CTA to make and keep certain books and records generated by the swap transactions in which it engages on behalf of not only its pool participants and clients, but also itself. *See* the amendments to Regulations 4.23(a)(7) and (b)(1) for CPOs and Regulations 4.33(a)(6) and (b)(1) for CTAs. The amendments to Regulations 4.23(a)(7) and 4.33(a)(6) require CPOs and CTAs to retain each acknowledgment of a swap transaction received from an SD. The amendments to Regulations 4.23(b)(1) and 4.33(b)(1) make clear that if a CPO or CTA was a counterparty to a swap transaction, then it would be subject to the swap data recordkeeping and reporting requirements of Part 45 of the Commission's regulations, as applicable.[12]

C. Regulation 4.30

Subject to certain exceptions, Regulation 4.30 provides that no CTA may solicit, accept or receive from an existing or prospective client funds, securities or other property in the trading advisor's name (or extend credit in lieu thereof) to purchase, margin, guarantee or secure any commodity interest of the client.

The Commission proposed to amend Regulation 4.30 by adding to the list of intermediaries then excepted from the foregoing prohibition—*i.e.,* registered FCMs, leverage transaction merchants and RFEDs—a registered SD in connection with a swap that was not cleared through a derivatives clearing organization. The Commission explained that this amendment to Regulation 4.30 was necessary ''[b]ecause swap dealers will generally fall within the statutory definition of CTA, and because a swap dealer engaging in uncleared swap transactions may be accepting funds or other property from its counterparties as variation and initial margin payments.'' [13]

Subsequently, the Commission amended Regulation 4.6 to provide therein for an exclusion from the definition of the term ''commodity trading advisor'' for an SD, *provided* the commodity interest and swap advisory activities of the SD are solely incidental to the conduct of its business as an SD.[14] Because not all SDs may always meet the ''solely incidental'' proviso, the Commission has determined to amend Regulation 4.30 as proposed, such that any registered SD who is a CTA is not subject to the regulation's operational prohibition.

D. Deleting Regulation 4.32

The Commission has deleted as proposed Regulation 4.32, which concerned trading by a registered CTA on or subject to the rules of a derivatives transaction execution facility (DTEF) for non-institutional customers. As the Commission explained:

> Section 734(a) of the Dodd-Frank Act repeals Section 5a of the CEA, which is the section establishing and providing for the regulation of DTEFs. Accordingly, because subsequent to the effective date of the Dodd-Frank Act Regulation 4.32 will no longer have a statutory basis or purpose, the Proposal would remove and reserve Regulation 4.32.[15]

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'') [16] requires federal agencies to consider the impact of those rules on small businesses.[17] A regulatory flexibility analysis or certification typically is required for ''any rule for which the agency publishes a general notice of proposed rulemaking pursuant to'' the notice-and-comment provisions of the Administrative Procedure Act, 5 U.S.C. 553(b).[18] The amendments to the Part 4 regulations contained herein will affect CPOs and CTAs. The Commission stated in the Proposal that:

> With respect to CPOs, the Commission previously has determined that a CPO is a small entity for the purpose of the RFA if it meets the criteria for an exemption from registration under Regulation 4.13(a)(2). Thus, because the Proposal applies to registered CPOs, the RFA is not applicable to it. As for CTAs, the Commission previously has stated that it would evaluate within the context of a particular rule proposal whether all or some affected CTAs would be considered to be small entities and, if so, the economic impact on them of the particular rule. In this regard, the Commission notes that the Proposal applies to registered CTAs. Moreover, the Proposal would not have a significant economic impact on any CPO or CTA who would be affected thereby, because it would merely bring within the current Part 4 regulatory structure of disclosure, reporting and recordkeeping information with respect to swap activities. It would not impose any additional operative requirements or otherwise direct or confine the activities of CPOs and CTAs.[19]

The Commission did not receive any comments regarding its RFA analysis in the Proposal. Accordingly, pursuant to 5 U.S.C. 605(b), the Chairman, on behalf of the Commission, certifies that the amendments to the Part 4 regulations being published today by this **Federal Register** release will not have a significant economic impact on a substantial number of small entities.

[11] 76 FR at 11702.

[12] *See* Regulation 45.2, which requires SDs and MSPs to keep full, complete and systematic records, together with all pertinent data and memoranda, of all activities relating to their business with respect to swaps, as prescribed by the Commission. (Non-SD and non-MSP counterparties subject to the Commission's jurisdiction have a similar requirement, but only with respect to each swap to which they are a counterparty.)

[13] 76 FR at 11702. In this regard, the Commission has proposed regulations addressing the circumstances in which non-bank SDs may be required or permitted to accept margin payments in uncleared swap transactions. *See* 76 FR 23732 (Apr. 28, 2011). Accordingly, this amendment to Regulation 4.30 should not be interpreted to impose or authorize any such margin requirements.

[14] *See* 77 FR 9734, 9739–40 (Feb. 17, 2012).

[15] 76 FR at 11702.

[16] 5 U.S.C. 601 *et seq.*

[17] By its terms, the RFA does not apply to ''individuals.'' *See* 48 FR 14933, n. 115 (Apr. 6, 1983).

[18] 5 U.S.C. 601(2), 603, 604 and 605.

[19] 76 FR at 11703.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA)[20] imposes certain requirements on Federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the PRA. The amendments to the Part 4 regulations will not require any new collection of information from any entity that is subject to them. Additionally, the Commission did not receive any comments regarding its PRA analysis in the Proposal. Accordingly, for purposes of the PRA, the Chairman, on behalf of the Commission, certifies that the amendments to the Part 4 regulations being published today by this **Federal Register** release will not impose any new reporting or recordkeeping requirements.

C. Cost-Benefit Analysis

Prior to the passage of the Dodd-Frank Act, the Part 4 regulations did not apply to swap-related activities. This pre-Dodd-Frank Act construct provides a useful reference point from which to compare the costs and benefits of the proposed regulations to the alternative where the Commission would not be taking any action to incorporate swap-related information into Part 4.

As a result of the Dodd-Frank Act including swap-related activities among the activities on which the CPO and CTA definitions are based, CPOs and CTAs who engage in swap-related activities are now subject to Part 4. In various places, however, the wording of particular provisions of Part 4 was incomplete or inconsistent in the context of CPOs and CTAs involved with swap transactions; there is no regulatory need for the prohibition in Regulation 4.30 against directly accepting margin payments to apply to an SD; and the subject matter of Regulation 4.32 (trading on DTEFs) was rendered moot by the Dodd-Frank Act. Under such a scenario, the costs to the public of inaction would be, in qualitative terms, failure to receive Part 4 disclosure, reporting and recordkeeping protections from their CPOs and CTAs with regard to their swap activities, an unnecessary burden on SDs, and regulatory text that is obsolete. The costs of these amendments, if any, will be minimal—limited to the costs associated with including information related to swaps in the Disclosure Documents, Account Statements and books and records already required of CPOs and CTAs under existing Part 4 regulations. Moreover, this information should be readily available to CPOs and CTAs. The costs cannot be feasibly quantified or estimated, because they will vary according to each registrant's internal processes and registration category. In contrast, the amendments will yield significant if unquantifiable benefit to the public, relative to inaction, by clarifying the application of Part 4 and the obligations of CPOs and CTAs to their participants and clients, respectively.

In the CEA,[21] Congress provided the Commission with the authority to promulgate regulations that, among other things, are reasonably necessary to effectuate any of the provisions or to accomplish any of the purposes of the CEA. In accordance with Section 15(a) of the CEA, it is in this post-Dodd-Frank Act environment that the Commission considers the costs and benefits of its actions before promulgating a regulation under the CEA or issuing an order.

Section 15(a) specifies that the costs and benefits shall be evaluated in light of the following five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations.

In light of the provisions of the Dodd-Frank Act that expand the ''commodity pool operator'' and ''commodity trading advisor'' definitions to include swap-related activities, these amendments incorporate into the existing Part 4 framework regulations to take account of the swap-related activities of CPOs and CTAs. Specifically, the amendments subject CPOs and CTAs when involved with swap transactions to the same Part 4 requirements that apply when they are involved with commodity interest transactions, to the extent regulations in place at the time of the enactment of the Dodd-Frank Act did not clearly do so.[22] The revision to Regulation 4.30 excepts SDs from the prohibition on accepting margin to treat them equivalently with FCMs and RFEDs. In addition, these amendments delete Regulation 4.32, pertaining to trading by registered CTAs on DTEFs, given the repeal by the Dodd-Frank Act of CEA Section 5a, which authorized such trading facilities.

In the Proposal the Commission sought public comment on the costs and benefits of its contemplated amendments to Part 4.[23] The Commission did not receive any comments in response to this request.

Section 15(a) Factors

(1) Protection of market participants and the public.

The Commission believes the amendments to the Part 4 regulations will provide protection to market participants and the public by requiring CPOs and CTAs to include information on swap intermediaries and activities in the disclosure, reporting and recordkeeping framework under Part 4. For example, Regulation 4.24(j) has provided protections to commodity pool participants by requiring their CPO to disclose any actual or potential conflict of interest with any FCM with whom their pool was required to maintain its account. The amendment to Regulation 4.24(j) the Commission has adopted will provide similar protections, by requiring the CPO to disclose any actual or potential conflict of interest with any SD with whom their pool maintains its swap positions.

(2) Efficiency, competitiveness, and financial integrity of the futures markets.

The Commission does not expect the amendments to Part 4 to have an impact on the efficiency, competitiveness and financial integrity of the commodity interest markets.

(3) Price Discovery.

The Commission does not expect the amendments to Part 4 to have an impact on the market's price discovery functions.

(4) Sound risk management practices.

The Commission does not expect the amendments to Part 4 to have an impact on risk management practices by CPOs, CTAs and other Commission registrants. However, the requirement that CPOs and CTAs account for SD, MSP and swap activities when complying with their disclosure, reporting and recordkeeping requirements under Part 4 will benefit prospective and actual pool participants and clients by ensuring that these participants and clients are afforded the same customer protections as participants and clients

[20] 44 U.S.C. 3501 *et seq.*

[21] *See* 7 U.S.C. 12(a)(5).

[22] As is explained above, when the Dodd-Frank Act extended the statutory definitions of the terms ''commodity pool operator'' and ''commodity trading advisor,'' those existing Part 4 regulations that applied generally to CPOs and CTAs became applicable to CPOs and CTAs captured by the expanded statutory definitions, without further amendment. Certain other existing Part 4 regulations, however, spoke specifically to activities involving commodity interests, but not to swap activities. Accordingly, this rulemaking amends this latter subset of Part 4 regulations by making them applicable to swap activities, thus closing the regulatory gap that would otherwise exist.

[23] 76 FR 11701, 11703.

in all other commodity pools and managed account programs.

(5) Other public interest considerations.

The Commission has not identified any other public interest considerations regarding the costs and benefits of the amendments to Part 4.

List of Subjects in 17 CFR Part 4

Advertising, Brokers, Commodity futures, Commodity pool operators, Commodity trading advisors, Customer protection, Reporting and recordkeeping requirements, Swaps.

For the reasons presented above, the Commission hereby amends Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 4—COMMODITY POOL OPERATORS AND COMMODITY TRADING ADVISORS

■ 1. The authority citation for Part 4 is revised to read as follows:

Authority: 7 U.S.C. 1a, 2, 6b, 6c, 6*l,* 6m, 6n, 6*o,* 12a and 23, as amended by Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (July 21, 2010).

■ 2. Section 4.7 is amended by adding paragraph (a)(2)(i)(C) to read as follows:

§ 4.7 Exemption from certain part 4 requirements for commodity pool operators with respect to offerings to qualified eligible persons and for commodity trading advisors with respect to advising qualified eligible persons.

* * * * *

(a) * * *

(2) * * *

(i) * * *

(C) A swap dealer registered pursuant to section 4s(a)(1) of the Act, or a principal thereof;

* * * * *

■ 3. Section 4.22 is amended by revising paragraph (a)(3) to read as follows:

§ 4.22 Reporting to pool participants.

(a) * * *

(3) The Account Statement must also disclose any material business dealings between the pool, the pool's operator, commodity trading advisor, futures commission merchant, retail foreign exchange dealer, swap dealer, or the principals thereof that previously have not been disclosed in the pool's Disclosure Document or any amendment thereto, other Account Statements or Annual Reports.

* * * * *

■ 4. Section 4.23 is amended by:

■ a. Revising paragraphs (a)(1) and (a)(7); and

■ b. Revising paragraph (b)(1), to read as follows:

§ 4.23 Recordkeeping.

* * * * *

(a) * * *

(1) An itemized daily record of each commodity interest transaction of the pool, showing the transaction date, quantity, commodity interest, and, as applicable, price or premium, delivery month or expiration date, whether a put or a call, strike price, underlying contract for future delivery or underlying physical, swap type and counterparty, the futures commission merchant and/or retail foreign exchange dealer carrying the account and the introducing broker, if any, whether the commodity interest was purchased, sold (including, in the case of a retail forex transaction, offset), exercised, expired (including, in the case of a retail forex transaction, whether it was rolled forward), and the gain or loss realized.

* * * * *

(7) Copies of each confirmation or acknowledgment of a commodity interest transaction of the pool, and each purchase and sale statement and each monthly statement for the pool received from a futures commission merchant, retail foreign exchange dealer or swap dealer.

* * * * *

(b) * * *

(1) An itemized daily record of each commodity interest transaction of the commodity pool operator and each principal thereof, showing the transaction date, quantity, commodity interest, and, as applicable, price or premium, delivery month or expiration date, whether a put or a call, strike price, underlying contract for future delivery or underlying physical, swap type and counterparty, the futures commission merchant or retail foreign exchange dealer carrying the account and the introducing broker, if any, whether the commodity interest was purchased, sold, exercised, or expired, and the gain or loss realized; *Provided, however,* that if the pool operator is a counterparty to a swap, it must comply with the swap data recordkeeping and reporting requirements of Part 45 of this chapter, as applicable.

* * * * *

■ 5. Section 4.24 is amended by:

■ a. Revising paragraph (g);

■ b. Revising paragraph (h)(1)(i);

■ c. Revising paragraph (*i*)(2)(xii);

■ d. Revising paragraphs (j)(1)(vi) and (j)(3); and

■ e. Revising paragraphs (l)(1)(iii), (l)(2) introductory text and (l)(2)(i), to read as follows:

§ 4.24 General disclosures required.

* * * * *

(g) *Principal risk factors.* A discussion of the principal risk factors of participation in the offered pool. This discussion must include, without limitation, risks relating to volatility, leverage, liquidity, counterparty creditworthiness, as applicable to the types of trading programs to be followed, trading structures to be employed and investment activity (including retail forex and swap transactions) expected to be engaged in by the offered pool.

(h) * * *

(1) * * *

(i) The approximate percentage of the pool's assets that will be used to trade commodity interests, securities and other types of interests, categorized by type of commodity or market sector, type of swap, type of security (debt, equity, preferred equity), whether traded or listed on a regulated exchange market, maturity ranges and investment rating, as applicable;

* * * * *

(i) * * *

(2) * * *

(xii) Any costs or fees included in the spread between bid and asked prices for retail forex or, if known, swap transactions; and

* * * * *

(j) * * *

(1) * * *

(vi) Any other person providing services to the pool, soliciting participants for the pool, acting as a counterparty to the pool's retail forex or swap transactions, or acting as a swap dealer with respect to the pool.

* * * * *

(3) Included in the description of such conflicts must be any arrangement whereby a person may benefit, directly or indirectly, from the maintenance of the pool's account with the futures commission merchant and/or retail foreign exchange dealer and/or from the maintenance of the pool's swap positions with a swap dealer, or from the introduction of the pool's account to a futures commission merchant and/or retail foreign exchange dealer and/or swap dealer by an introducing broker (such as payment for order flow or soft dollar arrangements) or from an investment of pool assets in investee pools or funds or other investments.

* * * * *

(l) * * *

(1) * * *

(iii) The pool's futures commission merchants and/or retail foreign exchange dealers and/or swap dealers and its introducing brokers, if any.

(2) With respect to a futures commission merchant and/or retail

foreign exchange dealer and/or swap dealer or an introducing broker, an action will be considered material if:

(i) The action would be required to be disclosed in the notes to the futures commission merchant's, retail foreign exchange dealer's, swap dealer's or introducing broker's financial statements prepared pursuant to generally accepted accounting principles;

* * * * *

■ 6. Section 4.30 is revised to read as follows:

§ 4.30 Prohibited activities.

(a) Except as provided in paragraph (b) of this section, no commodity trading advisor may solicit, accept or receive from an existing or prospective client funds, securities or other property in the trading advisor's name (or extend credit in lieu thereof) to purchase, margin, guarantee or secure any commodity interest of the client.

(b) The prohibition in paragraph (a) of this section shall not apply to:

(1) A futures commission merchant that is registered as such under the Act;

(2) A leverage transaction merchant that is registered as a commodity trading advisor under the Act;

(3) A retail foreign exchange dealer that is registered as such under the Act; or

(4) A swap dealer that is registered as such under the Act, with respect to funds, securities or other property accepted to purchase, margin, guarantee or secure any swap that is not cleared through a derivatives clearing organization.

§ 4.32 [Removed and Reserved]

■ 7. Section 4.32 is removed and reserved.

■ 8. Section 4.33 is amended by:

■ a. Revising paragraph (a)(6); and

■ b. Revising paragraph (b)(1), to read as follows:

§ 4.33 Recordkeeping.

* * * * *

(a) * * *

(6) Copies of each confirmation or acknowledgment of a commodity interest transaction, and each purchase and sale statement and each monthly statement received from a futures commission merchant, a retail foreign exchange dealer or a swap dealer.

* * * * *

(b) * * *

(1) An itemized daily record of each commodity interest transaction of the commodity trading advisor, showing the transaction date, quantity, commodity interest, and, as applicable, price or premium, delivery month or expiration date, whether a put or a call, strike price, underlying contract for future delivery or underlying physical, swap type and counterparty, the futures commission merchant and/or retail foreign exchange dealer carrying the account and the introducing broker, if any, whether the commodity interest was purchased, sold (including, in the case of a retail forex transaction, offset), exercised, expired (including, in the case of a retail forex transaction, whether it was rolled forward), and the gain or loss realized; *Provided, however,* that if the trading advisor is a counterparty to a swap, it must comply with the swap data recordkeeping and reporting requirements of Part 45 of this chapter, as applicable.

* * * * *

■ 9. Section 4.34 is amended by:

■ a. Revising paragraph (g);

■ b. Revising paragraph (i)(2);

■ c. Revising paragraph (j)(3); and

■ d. Revising paragraphs (k)(1)(iii), (k)(2) introductory text and (k)(2)(i), to read as follows:

§ 4.34 General disclosures required.

* * * * *

(g) *Principal risk factors.* A discussion of the principal risk factors of this trading program. This discussion must include, without limitation, risks due to volatility, leverage, liquidity, and counterparty creditworthiness, as applicable to the trading program and the types of transactions and investment activity expected to be engaged in pursuant to such program (including retail forex and swap transactions, if any).

* * * * *

(i) * * *

(2) Where any fee is determined by reference to a base amount including, but not limited to, ''net assets,'' ''gross profits,'' ''net profits,'' ''net gains,'' ''pips'' or ''bid-asked spread,'' the trading advisor must explain how such base amount will be calculated. Where any fee is based on the difference between bid and asked prices on retail forex or swap transactions, the trading advisor must explain how such fee will be calculated;

* * * * *

(j) * * *

(3) Included in the description of any such conflict must be any arrangement whereby the trading advisor or any principal thereof may benefit, directly or indirectly, from the maintenance of the client's commodity interest account with a futures commission merchant and/or retail foreign exchange dealer, and/or from the maintenance of the client's swap positions with a swap dealer or from the introduction of such account through an introducing broker (such as payment for order flow or soft dollar arrangements).

(k) * * *

(1) * * *

(iii) Any introducing broker through which the client will be required to introduce its account to the futures commission merchant and/or retail foreign exchange dealer and/or swap dealer.

(2) With respect to a futures commission merchant, retail foreign exchange dealer, swap dealer or introducing broker, an action will be considered material if:

(i) The action would be required to be disclosed in the notes to the futures commission merchant's, retail foreign exchange dealer's, swap dealer's or introducing broker's financial statements prepared pursuant to generally accepted accounting principles;

* * * * *

Dated: Issued in Washington, DC, on August 23, 2012, by the Commission.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

Appendices to Amendments to Commodity Pool Operator and Commodity Trading Advisor Regulations Resulting From the Dodd-Frank Act—Commission Voting Summary and Statements of Commissioners

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Sommers, Chilton, O'Malia and Wetjen voted in the affirmative; no Commissioner voted in the negative.

Appendix 2—Statement of Chairman Gary Gensler

I support the final rule to amend certain provisions of Part 4 of the Commission's regulations regarding the operations and activities of commodity pool operators (CPOs) and commodity trading advisors (CTAs). The amendments ensure that CFTC regulations with regard to CPOs and CTAs reflect changes made to the Commodity Exchange Act by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act).

Consistent with Dodd-Frank's expansion of the CPO and CTA definitions to include those involved in swaps and advising on swaps, the final amendments require swaps information to be included in the disclosure, reporting and recordkeeping obligations that currently exist for CPOs and CTAs under Part 4. Such information will enhance customer

protections by increasing the transparency of CPO and CTA swap activities to their pool participants and clients.

[FR Doc. 2012–21606 Filed 9–4–12; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 41

[PTO–C–2011–0007]

RIN 0651–AC55

CPI Adjustment of Patent Fees for Fiscal Year 2013

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office or USPTO) is adjusting certain patent fee amounts for fiscal year 2013 to reflect fluctuations in the Consumer Price Index (CPI). The patent statute provides for the annual CPI adjustment of patent fees set by statute to recover the higher costs associated with doing business as reflected by the CPI.

DATES: This final rule is effective on October 5, 2012.

FOR FURTHER INFORMATION CONTACT: Gilda Lee by email at *Gilda.Lee@uspto.gov,* by telephone at (571) 272–8698, or by fax at (571) 273–8698.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose: Section 41(f) of Title 35 of the United States Code provides the USPTO with the authority to adjust certain statutory patent fees to reflect fluctuations during the preceding twelve months in the Consumer Price Index (CPI). The purpose of this provision is to allow the USPTO to recover higher costs of providing services as reflected by the CPI. This final rule sets forth which fees will be adjusted and how the adjustment is calculated based on the current fluctuation in the CPI over the twelve months preceding this notice.

Summary of Major Provisions: The USPTO is adjusting certain patent fees in accordance with 35 U.S.C. 41(f), as amended by the Consolidated Appropriations Act (Pub. L. 108–447, 118 Stat. 2809 (2004)) and the Leahy-Smith America Invents Act (Pub. L. 112–29). The fee increase helps the USPTO to meet its strategic goals and maintain effective and efficient operation of the patent system.

Costs and Benefits: This rulemaking is not economically significant as that term is defined in Executive Order 12866 (Sept. 30, 1993).

Background

Statutory Provisions: Patent fees are set by or under the authority provided in 35 U.S.C. 41, 119, 120, 132(b), 156, 157(a), 255, 302, 311, 376, section 532(a)(2) of the Uruguay Round Agreements Act (URAA) (Pub. L. 103–465, § 532(a)(2), 108 Stat. 4809, 4985 (1994)), and section 4506 of the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106–113, 113 Stat. 1501, 1501A–565 (1999)). For fees paid under 35 U.S.C. 41(a) and (b) and 132(b), independent inventors, small business concerns, and nonprofit organizations who meet the requirements of 35 U.S.C. 41(h)(1) are entitled to a fifty-percent reduction.

The USPTO published a notice proposing to adjust the patent fees charged under 35 U.S.C. 41(a) and (b) for fiscal year 2013 to reflect fluctuations in the CPI on May 14, 2012.

The fiscal year 2005 Consolidated Appropriations Act (section 801 of Division B) provided that 35 U.S.C. 41(a), (b), and (d) shall be administered in a manner that revises patent application fees (35 U.S.C. 41(a)) and patent maintenance fees (35 U.S.C. 41(b)), and provides for a separate filing fee (35 U.S.C. 41(a)), search fee (35 U.S.C. 41(d)(1)), and examination fee (35 U.S.C. 41(a)(3)) during fiscal years 2005 and 2006. See Public Law 108–447, 118 Stat. 2809, 2924–30 (2004). The Omnibus Appropriations Act, 2009, extended the patent and trademark fee provisions of the fiscal year 2005 Consolidated Appropriations Act through September 30, 2011. See Public Law 112–4, 125 Stat. 6 (2011); Public Law 111–322, 124 Stat. 3518 (2010); Public Law 111–317, 124 Stat. 3454 (2010); Public Law 111–290, 124 Stat. 3063 (2010); Public Law 111–242, 124 Stat. 2607 (2010); Public Law 111–224, 124 Stat. 2385 (2010); Public Law 111–117, 123 Stat. 3034 (2009); Public Law 111–8, 123 Stat. 524 (2009); Public Law 111–6, 123 Stat. 522 (2009); Public Law 111–5, 123 Stat. 115 (2009); Public Law 110–329, 122 Stat. 3574 (2008); Public Law 110–161, 121 Stat. 1844 (2007); Public Law 110–149, 121 Stat. 1819 (2007); Public Law 110–137, 121 Stat. 1454 (2007); Public Law 110–116, 121 Stat. 1295 (2007); Public Law 110–92, 121 Stat. 989 (2007); Public Law 110–5, 121 Stat. 8 (2007); Public Law 109–383, 120 Stat. 2678 (2006); Public Law 109–369, 120 Stat. 2642 (2006); and Public Law 109–289, 120 Stat. 1257 (2006). The Leahy-Smith America Invents Act, enacted September 16, 2011, codified the patent and trademark fee provisions of the fiscal year 2005 Consolidated Appropriations Act.

Section 11 of the Leahy-Smith America Invents Act provides for a surcharge of fifteen percent, rounded by standard arithmetic rules, on all fees charged or authorized by 35 U.S.C. 41(a), (b), and (d)(1), as well as by 35 U.S.C. 132(b). Section 11 of the Act provides that this fifteen percent surcharge is effective ten days after the date of enactment (*i.e.*, September 26, 2011). Section 11 also provides that this fifteen percent surcharge shall terminate, with respect to a fee to which the surcharge applies, on the effective date of the setting or adjustment of that fee pursuant to the exercise of the authority under section 10 of the Act for the first time with respect to that fee. Section 10 fee-setting will be implemented in a future separate rulemaking.

As for this rulemaking, Section 41(f) of Title 35, United States Code, provides that fees established under 35 U.S.C. 41(a) and (b) may be adjusted on October 1, 1992, and every year thereafter, to reflect fluctuations in the Consumer Price Index over the previous twelve months. If the annual change in CPI is one percent or less, no fee adjustment for CPI fluctuations will be pursued.

This CPI increase will be implemented on October 1, 2012. This interim increase in fees is necessary to allow the USPTO to meet its strategic goals within the time frame outlined in the FY 2013 President's Budget. The interim fee increase is a bridge to provide resources until the USPTO exercises its fee-setting authority and develops a new fee structure that will provide sufficient financial resources in the long term. An adequately funded USPTO will optimize the administration of the U.S. intellectual property system, and thereby move innovation to the marketplace more quickly, creating and sustaining U.S. jobs and enhancing the health and living standards of Americans.

Fee Adjustment Level: The patent statutory fees established by 35 U.S.C. 41(a) and (b) are adjusted to reflect the most recent fluctuations occurring during the twelve-month period prior to publication of the final rule implementing this CPI adjustment, as measured by the Consumer Price Index for All Urban Consumers (CPI–U). The Office of Management and Budget (OMB) has advised that in calculating these fluctuations, the USPTO should use CPI–U data as determined by the Secretary of Labor, which is found at

''*http://www.bls.gov/cpi/*''. In accordance with the above description of the statutory fee adjustment, the USPTO is adjusting patent statutory fee amounts based on the Administration's CPI–U for the twelve-month period ending June 30, 2012.

The fees other than small entity patent statutory fees have been adjusted based on the June 2011 to June 2012 annual CPI–U increase of 1.7%. These fee amounts were then rounded by applying standard arithmetic rules so that the resulting amounts will be consistent to the user. Fees for other than a small entity of $100 or more were rounded to the nearest $10. Fees of less than $100 were rounded to the nearest even number so that any comparable small entity fee will be a whole number. The small entity fee amounts are 50% of the other than small entity fee amounts.

General Procedures: Any fee amount adjusted by the final rule that is paid on or after the effective date of the fee adjustment enacted by the final rule is subject to the new fees in effect. The amount of the fee to be paid for a given item will be determined by the time of filing of that item with the Office. The time of filing will be determined either according to the date of receipt in the Office (37 CFR 1.6) or the date reflected on a proper Certificate of Mailing or Transmission, where such a certificate is authorized under 37 CFR 1.8. Use of a Certificate of Mailing or Transmission is not authorized for items that are specifically excluded from the provisions of 37 CFR 1.8. Items for which a Certificate of Mailing or Transmission under 37 CFR 1.8 is not authorized include, for example, filing of national and international applications for patents. *See* 37 CFR 1.8(a)(2).

Patent-related correspondence delivered by the ''Express Mail Post Office to Addressee'' service of the United States Postal Service (USPS) is considered filed or received in the USPTO on the date of deposit with the USPS. See 37 CFR 1.10(a)(1). The date of deposit with the USPS is shown by the ''date-in'' on the ''Express Mail'' mailing label or other official USPS notation.

To ensure clarity in the implementation of the new fees, a discussion of specific sections is set forth below.

Discussion of Specific Rules

37 CFR 1.16 National application filing, and examination fees: Section 1.16, paragraphs (a) through (e), (h) through (j) and (o) through (s), is revised to adjust fees established therein to reflect fluctuations in the CPI–U. See Table 1.

37 CFR 1.17 Patent application and reexamination processing fees: Section 1.17, paragraphs (a)(1) through (a)(5), (l), and (m), is revised to adjust fees established therein to reflect fluctuations in the CPI–U. See Table 1.

37 CFR 1.18 Patent post allowance (including issue) fees: Section 1.18, paragraphs (a) through (c), is revised to adjust fees established therein to reflect fluctuations in the CPI–U. See Table 1.

37 CFR 1.20 Post issuance fees: Section 1.20, paragraphs (c)(3)–(c)(4), and (d) through (g), is revised to adjust fees established therein to reflect fluctuations in the CPI–U. See Table 1.

37 CFR 1.492 National stage fees: Section 1.492, paragraphs (a), (c)(2), (d) through (f) and (j), is revised to adjust fees established therein to reflect fluctuations in the CPI–U. See Table 1.

37 CFR 41.20 Fees: Section 41.20, paragraphs (b)(1) through (b)(3), is revised to adjust fees established therein to reflect fluctuations in the CPI–U. See Table 1.

Fee Amount Adjustments: Table 1 shows the adjusted patent statutory fee amounts and fee adjustments based on the June 2011 to June 2012 annual CPI–U increase of 1.7%. The other than small entity fee amounts have been adjusted by 1.7%. These fee amounts were then rounded by applying standard arithmetic rules. Fees for other than a small entity of $100 or more were rounded to the nearest $10. Fees of less than $100 were rounded to the nearest even number. The small entity fee amounts are 50% of the large entity fee amounts.

TABLE 1—FEE ADJUSTMENT CALCULATIONS BASED ON CPI-U ADJUSTMENT OF 1.7%

37 CFR	Fee title	Current fee amount	New fee amount	Fee adjustment
1.16(a)(1)	Filing of Utility Patent Application (on or after 12/8/2004)	$380 Small Entity (SE) $190	$390 SE $195	$10 SE $5
1.16(a)(1)	Filing of Utility Patent Application (electronic filing for small entities) (on or after 12/8/2004).	$95	$98	$3
1.16(b)(1)	Filing of Design Patent Application (on or after 12/8/2004)	$250 SE $125	$250 SE $125	$0 SE $0
1.16(b)(1)	Filing of Design Patent Application (Continued Prosecution Application) (on or after 12/8/2004).	$250 SE $125	$250 SE $125	$0 SE $0
1.16(c)(1)	Filing of Plant Patent Application (on or after 12/8/2004)	$250 SE $125	$250 SE $125	$0 SE $0
1.16(d)	Provisional Application Filing	$250 SE $125	$250 SE $125	$0 SE $0
1.16(e)(1)	Filing of Reissue Patent Application (on or after 12/8/2004)	$380 SE $190	$390 SE $195	$10 SE $5
1.16(e)(1)	Filing of Reissue Patent Application (CPA) (on or after 12/8/2004)	$380 SE $190	$390 SE $195	$10 SE $5
1.16(h)	Independent Claims in Excess of Three	$250 SE $125	$250 SE $125	$0 SE $0
1.16(h)	Reissue Independent Claims in Excess of Three	$250 SE $125	$250 SE $125	$0 SE $0
1.16(i)	Claims in Excess of Twenty	$60 SE $30	$62 SE $31	$2 SE $1
1.16(i)	Reissue Total Claims in Excess of Twenty	$60 SE $30	$62 SE $31	$2 SE $1
1.16(j)	Multiple Dependent Claims	$450 SE $225	$460 SE $230	$10 SE $5

TABLE 1—FEE ADJUSTMENT CALCULATIONS BASED ON CPI-U ADJUSTMENT OF 1.7%—Continued

37 CFR	Fee title	Current fee amount	New fee amount	Fee adjustment
1.16(o)	Utility Patent Examination	$250 SE $125	$250 SE $125	$0 SE $0
1.16(p)	Design Patent Examination	$160 SE $80	$160 SE $80	$0 SE $0
1.16(q)	Plant Patent Examination	$200 SE $100	$200 SE $100	$0 SE $0
1.16(r)	Reissue Patent Examination	$750 SE $375	$760 SE $380	$10 SE $5
1.16(s)	Utility Application Size Fee—For each additional 50 sheets that exceeds 100 sheets.	$310 SE $155	$320 SE $160	$10 SE $5
1.16(s)	Design Application Size Fee—For each additional 50 sheets that exceeds 100 sheets.	$310 SE $155	$320 SE $160	$10 SE $5
1.16(s)	Plant Application Size Fee—For each additional 50 sheets that exceeds 100 sheets.	$310 SE $155	$320 SE $160	$10 SE $5
1.16(s)	Reissue Application Size Fee—For each additional 50 sheets that exceeds 100 sheets.	$310 SE $155	$320 SE $160	$10 SE $5
1.16(s)	Provisional Application Size Fee—For each additional 50 sheets that exceeds 100 sheets.	$310 SE $155	$320 SE $160	$10 SE $5
1.17(a)(1)	Extension for Response within First Month	$150 SE $75	$150 SE $75	$0 SE $0
1.17(a)(2)	Extension for Response within Second Month	$560 SE $280	$570 SE $285	$10 SE $5
1.17(a)(3)	Extension for Response within Third Month	$1,270 SE $635	$1,290 SE $645	$20 $10
1.17(a)(4)	Extension for Response within Fourth Month	$1,980 SE $990	$2,010 SE $1,005	$30 SE $15
1.17(a)(5)	Extension for Resonse within Fifth Month	$2,690 SE $1,345	$2,730 SE $1,365	$40 SE $20
1.17(l)	Petition to Revive Unavoidably Abandoned Application	$620 SE $310	$630 SE $315	$10 SE $5
1.17(m)	Petition to Revive Unintentionally Abandoned Application	$1,860 SE $930	$1,890 SE $945	$30 SE $15
1.18(a)	Utility Issue	$1,740 SE $870	$1,770 SE $885	$30 SE $15
1.18(a)	Reissue Issue	$1,740 SE $870	$1,770 SE $885	$30 SE $15
1.18(b)	Design Issue	$990 SE $495	$1,010 SE $505	$20 SE $10
1.18(c)	Plant Issue	$1,370 SE $685	$1,390 SE $695	$20 SE $10
1.20(c)(3)	Reexamination Independent Claims in Excess of Three	$250 SE $125	$250 SE $125	$0 SE $0
1.20(c)(4)	Reexamination Total Claims in Excess of Twenty	$60 SE $30	$62 SE $31	$2 SE $1
1.20(d)	Statutory Disclaimer	$160 SE $80	$160 SE $80	$0 SE $0
1.20(e)	First Stage Maintenance	$1,130 SE $565	$1,150 SE $575	$20 SE $10
1.20(f)	Second Stage Maintenance	$2,850 SE $1,425	$2,900 SE $1,450	$50 SE $25
1.20(g)	Third Stage Maintenance	$4,730 SE $2,365	$4,810 SE $2,405	$80 SE $40
1.492(a)	Filing of PCT National Stage Application	$380 SE $190	$390 SE $195	$10 SE $5
1.492(b)(3)	PCT National Stage Search Search Report Prepared and Provided to USPTO.	$490 SE $245	$500 SE $250	$10 SE $5
1.492(b)(4)	PCT National Stage Search—All Other Situations	$620 SE $310	$630 SE $315	$10 SE $5
1.492(c)(2)	PCT National Stage Examination—All Other Situations	$250 SE $125	$250 SE $125	$0 SE $0
1.492(d)	Independent Claims in Excess of Three	$250 SE $125	$250 SE $125	$0 SE $0
1.492(e)	Total Claims in Excess of Twenty	$60 SE $30	$62 SE $31	$2 SE $1
1.492(f)	Multiple Dependent Claims	$450 SE $225	$460 SE $230	$10 SE $5
1.492(j)	PCT National Stage Application Size Fee	$310 SE $155	$320 SE $160	$10 SE $5
41.20(b)(1)	Notice of Appeal	$620 SE $310	$630 SE $315	$10 SE $5

TABLE 1—FEE ADJUSTMENT CALCULATIONS BASED ON CPI-U ADJUSTMENT OF 1.7%—Continued

37 CFR	Fee title	Current fee amount	New fee amount	Fee adjustment
41.20(b)(2) ..	Filing a Brief in Support of an Appeal	$620 SE $310	$630 SE $315	$10 SE $5
41.20(b)(3) ..	Request for Oral Hearing	$1,240 SE $620	$1,260 SE $630	$20 SE $10

Comment and Response to Comment: The USPTO published a notice proposing to adjust the patent fees charged under 35 U.S.C. 41(a) and (b) for fiscal year 2013 to reflect fluctuations in the CPI. The Office received one comment in response to the proposed rule. The commenter supports the proposed CPI adjustment of fees for FY 2013 as an interim fee increase until the USPTO exercises its fee-setting authority under Section 10 of the AIA. However, because of the significant administrative burdens on corporations and patent law firms to adjust their internal systems for paying fees and correctly advising clients of fee increases, it is suggested there should not be more than one fee adjustment per year. The commenter suggests that in future years, CPI adjustments and Section 10 adjustments should be timed so as to avoid having two separate adjustments in the same year. The Office's response is patent fees are being set under 35 U.S.C. 41(a) and (b) to ensure proper funding for effective operations. As previously discussed, this interim increase in fees is necessary to allow the USPTO to meet its strategic goals within the time frame outlined in the FY 2013 President's Budget. In the future, the USPTO does not anticipate routinely adjusting patent fees more than once per fiscal year.

Rulemaking Considerations

Final Regulatory Flexibility Analysis

The Office has prepared the following Final Regulatory Flexibility Analysis.

1. *Description of the reasons that action by the agency is being considered:* The USPTO is adjusting the patent fees set under 35 U.S.C. 41(a) and (b) to ensure proper funding for effective operations. The patent fee CPI adjustment under 35 U.S.C. 41(f) is a routine adjustment that has generally occurred on an annual basis when necessary to recover the higher costs of USPTO operations that occur due to the increase in the price of products and services.

2. *Statement of the objectives of, and legal basis for, the final rule:* Patent fees are set by or under the authority provided in 35 U.S.C. 41, 119, 120, 132(b), 156, 157(a), 255, 302, 311, 376, section 532(a)(2) of the URAA, and 4506 of the AIPA. The objective of the change is to adjust patent fees set under 35 U.S.C. 41(a) and (b) as an annual, routine step in order to recover the higher costs of USPTO operations as reflected by the CPI. 35 U.S.C. 41(f) provides that fees established under 35 U.S.C. 41(a) and (b) may be adjusted every year to reflect fluctuations in the CPI over the previous twelve months.

3. *Statement of Significant Issues Raised by the Public Comments in Response to the IRFA and the Office's Response to Such Issues:* The Office received no comments concerning the Initial Regulatory Flexibility Act analysis.

4. *Description and estimate of the number of affected small entities:* The Small Business Administration (SBA) small business size standards applicable to most analyses conducted to comply with the Regulatory Flexibility Act are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with fewer than a maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System (NAICS) code. The USPTO, however, has formally adopted, with SBA approval, an alternate size standard as the size standard for the purpose of conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations. *See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations,* 71 FR 67109 (Nov. 20, 2006), 1313 *Off. Gaz. Pat. Office* 60 (Dec. 12, 2006). This alternate small business size standard is the previously established size standard that identifies the criteria entities must meet to be entitled to pay reduced patent fees. See 13 CFR 121.802. If patent applicants identify themselves on the patent application as qualifying for reduced patent fees, the USPTO captures this data in the Patent Application Location and Monitoring (PALM) database system, which tracks information on each patent application submitted to the USPTO.

Unlike the general SBA small business size standards set forth in 13 CFR 121.201, USPTO's approved alternative size standard is not industry-specific. Specifically, the USPTO definition of small business concern for Regulatory Flexibility Act purposes is a business or other concern that: (1) Meets the SBA's definition of a ''business concern or concern'' set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) Whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition. *See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations,* 71 FR at 67112 (November 20, 2006), 1313 *Off. Gaz. Pat. Office* at 63 (December 12, 2006).

The changes in this final rule will apply to any small entity that files a patent application, or has a pending patent application or unexpired patent. The changes in this final rule will specifically apply when an applicant or patentee pays an application filing or national stage entry fee, search fee, examination fee, extension of time fee, notice of appeal fee, appeal brief fee, request for an oral hearing fee, petition to revive fee, issue fee, or patent maintenance fee.

The USPTO has been advised that a number of small entity applicants and patentees do not claim small entity status for various reasons. *See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations,* 71 FR at 67110 (November 20, 2006), 1313 *Off. Gaz. Pat. Office* at 61 (December 12, 2006). Therefore, the USPTO is also considering all other entities paying patent fees to be small entities as well in an effort to capture the impact on all

small entity applicants whether they claim that status or not. While the USPTO does not record the number of small entity filers in a given year, the USPTO estimates that in FY 2011, of the patent fees where a small entity discount is available, 3,980,519 patent fees were paid, out of which 1,190,558 fees claimed the small entity discount.

5. *Description of the reporting, recordkeeping and other compliance requirements of the final rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record:* This final rule does not require any reporting or recordkeeping or incorporate other compliance requirements. This final rule only adjusts patent fees (as discussed previously) to reflect changes in the CPI.

6. *Description of any significant alternatives to the final rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the rule on small entities:* The alternative of not adjusting patent fees would have a lesser economic impact on small entities, but would not accomplish the stated objectives of the applicable statutes. The USPTO is making a small adjustment to patent fees, under 35 U.S.C. 41(f), to ensure proper funding for effective operations in light of changes in the CPI. The patent fee CPI adjustment is a routine adjustment that has generally occurred on an annual basis to recover the higher costs of USPTO operations that occur due to increases in the price of products and services. This CPI adjustment helps the Office maintain effective operations and decrease patent pendency levels.

7. *Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the final rule:* The USPTO is the sole agency of the United States Government responsible for administering the provisions of Title 35, United States Code, pertaining to examination and granting patents. Therefore, no other Federal, state, or local entity shares jurisdiction over the examination and granting of patents and there are no duplicative, overlapping or conflicting rules.

Other countries, however, have their own patent laws, and an entity desiring a patent in a particular country must make an application for patent in that country, in accordance with the applicable law. Although the potential for overlap exists internationally, this cannot be avoided except by treaty (such as the Paris Convention for the Protection of Industrial Property, or the Patent Cooperation Treaty (PCT)). Nevertheless, the USPTO believes that there are no other duplicative or overlapping rules.

B. Executive Order 13132 (Federalism)

This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

C. Executive Order 12866 (Regulatory Planning and Review)

This rulemaking has been determined to be significant for purposes of Executive Order 12866 (Sept. 30, 1993), as amended by Executive Order 13258 (Feb. 26, 2002), and Executive Order 13422 (Jan. 18, 2007).

D. Executive Order 13563 (Improving Regulation and Regulatory Review)

The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13175 (Tribal Consultation)

This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

F. Executive Order 13211 (Energy Effects)

This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

G. Executive Order 12988 (Civil Justice Reform)

This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

H. Executive Order 13045 (Protection of Children)

This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

I. Executive Order 12630 (Taking of Private Property)

This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

J. Congressional Review Act

Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the USPTO has submitted a report containing the final rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the Government Accountability Office. The changes in this final rule will not result in an annual effect on the economy of 100 million dollars 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. Therefore, this final rule is not a ''major rule'' as defined in 5 U.S.C. 804(2).

K. Unfunded Mandates Reform Act of 1995

The changes in this final rule do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded

Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

L. National Environmental Policy Act

This rulemaking will not have any effect on the quality of environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

M. National Technology Transfer and Advancement Act

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are inapplicable because this rulemaking does not contain provisions which involve the use of technical standards.

N. Paperwork Reduction Act

This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The collections of information involved in this final rule have been reviewed and approved by OMB. The Office is not resubmitting information collection requests to OMB for its review and approval at this time but will update the fee amounts for existing information collection requirements associated with the information collections under OMB control numbers 0651–0016, 0651–0021, 0651–0024, 0651–0031, 0651–0032, 0651–0033, 0651–0063, and 0651–0064. The USPTO will submit to OMB fee revision changes for OMB control numbers 0651–0016, 0651–0021, 0651–0024, 0651–0031, 0651–0032, 0651–0033, 0651–0063, and 0651–0064 at the time these collections are submitted to OMB for renewal.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control number.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of information, Inventions and patents, Reporting and record keeping requirements, Small businesses.

37 CFR Part 41

Administrative practice and procedure, Inventions and patents, Lawyers.

For the reasons set forth in the preamble, 37 CFR parts 1 and 41 are to be amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

■ 2. Section 1.16 is amended by revising paragraphs (a) through (e), (h) through (j), and (o) through (s) to read as follows:

§ 1.16 National application filing, search, and examination fees.

(a) Basic fee for filing each application under 35 U.S.C. 111 for an original patent, except design, plant, or provisional applications:

(1) For an application filed on or after December 8, 2004:

By a small entity (§ 1.27(a)) if the application is submitted in compliance with the Office electronic filing system (§ 1.27(b)(2)):	$98.00
By a small entity (§ 1.27(a))	$195.00
By other than a small entity	$390.00

(b) Basic fee for filing each application for an original design patent:

(1) For an application filed on or after December 8, 2004:	
By a small entity (§ 1.27(a))	$125.00
By other than a small entity	$250.00

(c) Basic fee for filing each application for an original plant patent:

(1) For an application filed on or after December 8, 2004:	
By a small entity (§ 1.27(a))	$125.00
By other than a small entity	$250.00

(d) Basic fee for filing each provisional application:

By a small entity (§ 1.27(a))	$125.00
By other than a small entity	$250.00

(e) Basic fee for filing each application for the reissue of a patent:

(1) For an application filed on or after December 8, 2004:	
By a small entity (§ 1.27(a))	$195.00
By other than a small entity	$390.00

* * * * *

(h) In addition to the basic filing fee in an application, other than a provisional application, for filing or later presentation at any other time of each claim in independent form in excess of 3:

By a small entity (§ 1.27(a))	$125.00
By other than a small entity	$250.00

(i) In addition to the basic filing fee in an application, other than a provisional application, for filing or later presentation at any other time of each claim (whether dependent or independent) in excess of 20 (note that § 1.75(c) indicates how multiple dependent claims are considered for fee calculation purposes):

By a small entity (§ 1.27(a))	$31.00
By other than a small entity	$62.00

(j) In addition to the basic filing fee in an application, other than a provisional application, that contains, or is amended to contain, a multiple dependent claim, per application:

By a small entity (§ 1.27(a))	$230.00
By other than a small entity	$460.00

* * * * *

(o) Examination fee for each application filed under 35 U.S.C. 111 on or after December 8, 2004, for an original patent, except design, plant, or provisional applications:

By a small entity (§ 1.27(a))	$125.00
By other than a small entity	$250.00

(p) Examination fee for each application filed on or after December 8, 2004, for an original design patent:

By a small entity (§ 1.27(a))	$80.00
By other than a small entity	$160.00

(q) Examination fee for each application filed on or after December 8, 2004, for an original plant patent:

By a small entity (§ 1.27(a))	$100.00
By other than a small entity	$200.00

(r) Examination fee for each application filed on or after December 8, 2004, for the reissue of a patent:

By a small entity (§ 1.27(a))	$380.00
By other than a small entity	$760.00

(s) Application size fee for any application under 35 U.S.C. 111 filed on or after December 8, 2004, the specification and drawings of which exceed 100 sheets of paper, for each additional 50 sheets or fraction thereof:

By a small entity (§ 1.27(a))	$160.00
By other than a small entity	$320.00

* * * * *

■ 3. Section 1.17 is amended by revising paragraphs (a), (l), and (m) to read as follows:

§ 1.17 Patent application and reexamination processing fees.

(a) Extension fees pursuant to § 1.136(a):

(1) For reply within first month:	
By a small entity (§ 1.27(a))	$75.00
By other than a small entity	$150.00
(2) For reply within second month:	
By a small entity (§ 1.27(a))	$285.00
By other than a small entity	$570.00
(3) For reply within third month:	
By a small entity (§ 1.27(a))	$645.00
By other than a small entity	$1,290.00
(4) For reply within fourth month:	
By a small entity (§ 1.27(a))	$1,005.00

By other than a small entity $2,010.00
(5) For reply within fifth month:
By a small entity (§ 1.27(a)) $1,365.00
By other than a small entity $2,730.00

* * * * *

(l) For filing a petition for the revival of an unavoidably abandoned application under 35 U.S.C. 111, 133, 364, or 371, for the unavoidably delayed payment of the issue fee under 35 U.S.C. 151, or for the revival of an unavoidably terminated reexamination proceeding under 35 U.S.C. 133 (§ 1.137(a)):

By a small entity (§ 1.27(a)) $315.00
By other than a small entity $630.00

(m) For filing a petition for the revival of an unintentionally abandoned application, for the unintentionally delayed payment of the fee for issuing a patent, or for the revival of an unintentionally terminated reexamination proceeding under 35 U.S.C. 41(a)(7) (§ 1.137(b)):

By a small entity (§ 1.27(a)) $945.00
By other than a small entity $1,890.00

* * * * *

4. Section 1.18 is amended by revising paragraphs (a) through (c) to read as follows:

§ 1.18 Patent post allowance (including issue) fees.

(a) Issue fee for issuing each original patent, except a design or plant patent, or for issuing each reissue patent:

By a small entity (§ 1.27(a)) $885.00
By other than a small entity $1,770.00

(b) Issue fee for issuing an original design patent:

By a small entity (§ 1.27(a)) $505.00
By other than a small entity $1,010.00

(c) Issue fee for issuing an original plant patent:

By a small entity (§ 1.27(a)) $695.00
By other than a small entity $1,390.00

* * * * *

■ 5. Section 1.20 is amended by revising paragraphs (c)(3), (c)(4), and (d) through (g) to read as follows:

§ 1.20 Post issuance fees.

* * * * *

(c) * * *

(3) For filing with a request for reexamination or later presentation at any other time of each claim in independent form in excess of 3 and also in excess of the number of claims in independent form in the patent under reexamination:

By a small entity (§ 1.27(a)) $125.00
By other than a small entity $250.00

(4) For filing with a request for reexamination or later presentation at any other time of each claim (whether dependent or independent) in excess of 20 and also in excess of the number of claims in the patent under reexamination (note that § 1.75(c) indicates how multiple dependent claims are considered for fee calculation purposes):

By a small entity (§ 1.27(a)) $31.00
By other than a small entity $62.00

* * * * *

(d) For filing each statutory disclaimer (§ 1.321):

By a small entity (§ 1.27(a)) $80.00
By other than a small entity $160.00

(e) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond four years, the fee being due by three years and six months after the original grant:

By a small entity (§ 1.27(a)) $575.00
By other than a small entity $1,150.00

(f) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond eight years, the fee being due by seven years and six months after the original grant:

By a small entity (§ 1.27(a)) $1,450.00
By other than a small entity $2,900.00

(g) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond twelve years, the fee being due by eleven years and six months after the original grant:

By a small entity (§ 1.27(a)) $2,405.00
By other than a small entity $4,810.00

* * * * *

6. Section 1.492 is amended by revising paragraphs (a), (b)(3), (b)(4), (c)(2), (d) through (f) and (j) to read as follows:

§ 1.492 National stage fees.

* * * * *

(a) The basic national fee for an international application entering the national stage under 35 U.S.C. 371 if the basic national fee was not paid before December 8, 2004:

By a small entity (§ 1.27(a)) $195.00
By other than a small entity $390.00

(b) * * *

(3) If an international search report on the international application has been prepared by an International Searching Authority other than the United States International Searching Authority and is provided, or has been previously communicated by the International Bureau, to the Office:

By a small entity (§ 1.27(a)) $250.00
By other than a small entity $500.00

(4) In all situations not provided for in paragraphs (b)(1), (b)(2), or (b)(3) of this section:

By a small entity (§ 1.27(a)) $315.00
By other than a small entity $630.00

(c) * * *

(2) In all situations not provided for in paragraph (c)(1) of this section:

By a small entity (§ 1.27(a)) $125.00
By other than a small entity $250.00

(d) In addition to the basic national fee, for filing or on later presentation at any other time of each claim in independent form in excess of 3:

By a small entity (§ 1.27(a)) $125.00
By other than a small entity $250.00

(e) In addition to the basic national fee, for filing or on later presentation at any other time of each claim (whether dependent or independent) in excess of 20 (note that § 1.75(c) indicates how multiple dependent claims are considered for fee calculation purposes):

By a small entity (§ 1.27(a)) $31.00
By other than a small entity $62.00

(f) In addition to the basic national fee, if the application contains, or is amended to contain, a multiple dependent claim, per application:

By a small entity (§ 1.27(a)) $230.00
By other than a small entity $460.00

* * * * *

(j) Application size fee for any international application for which the basic national fee was not paid before December 8, 2004, the specification and drawings of which exceed 100 sheets of paper, for each additional 50 sheets or fraction thereof:

By a small entity (§ 1.27(a)) $160.00
By other than a small entity $320.00

PART 41—PRACTICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

■ 7. The authority citation for 37 CFR part 41 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 3(a)(2)(A), 21, 23, 32, 41, 134, 135.

■ 8. Section 41.20 is amended by revising paragraph (b) to read as follows:

§ 41.20 Fees.

* * * * *

(b) *Appeal fees.* (1) For filing a notice of appeal from the examiner to the Board:

By a small entity (§ 1.27(a) of this title) $315.00
By other than a small entity $630.00

(2) In addition to the fee for filing a notice of appeal, for filing a brief in support of an appeal:

By a small entity (§ 1.27(a) of this title) $315.00

By other than a small entity $630.00

(3) For filing a request for an oral hearing before the Board in an appeal under 35 U.S.C. 134:

By a small entity (§ 1.27(a)) $630.00
By other than a small entity $1,260.00

Dated: August 31, 2012.

Deborah S. Cohn,

Commissioner for Trademarks, United States Patent and Trademark Office.

[FR Doc. 2012–21974 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AN95

Sharing Information Between the Department of Veterans Affairs and the Department of Defense

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document adopts as final, without change, the interim final rule published in the **Federal Register** on October 20, 2011. This final rule removes a Department of Veterans Affairs (VA) regulatory restriction on the sharing of certain medical information with the Department of Defense (DoD) that is not required by the applicable statute and is inconsistent with the intent and purpose of that statute.

DATES: *Effective Date:* September 5, 2012.

FOR FURTHER INFORMATION CONTACT: Stephania Griffin, Veterans Health Administration Privacy Officer (10P2C1), Health Information Governance, Office of Informatics and Analytics, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave. NW., Washington, DC 20420, (704) 245–2492. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Section 7332(a)(1) of title 38, United States Code, affords special protection against the disclosure of VA medical ''[r]ecords of the identity, diagnosis, prognosis, or treatment of any patient or subject which are maintained in connection with the performance of any program or activity (including education, training, treatment, rehabilitation, or research) relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia.'' However, an exception in section 7332(e) states: ''The prohibitions of this section shall not prevent any interchange of records—(1) within and among those components of [VA] furnishing health care to veterans, or determining eligibility for benefits under this title; or (2) between such components furnishing health care to veterans and the Armed Forces.''

VA implemented section 7332(e) in 38 CFR 1.461(c)(1); however, in so doing, we imposed an additional restriction on the scope of information that may be exchanged between VA and DoD, limiting it to only ''information pertaining to a person relating to a period when such person is or was subject to the Uniform Code of Military Justice.'' This restriction was narrower than the statutory restriction, and it impeded VA's ability to share with DoD important medical information pertaining to veterans and to coordinate their care and treatment. Further, the restriction impeded VA's ability to fully engage in Presidential- and Congressional-supported interoperability initiatives with DoD, such as electronic health record initiatives. This regulatory limitation was not intended to have these negative results on VA's ability to provide comprehensive high-quality health care to veterans and, where applicable, to support DoD in similarly caring for servicemembers and military retirees.

On October 20, 2011, VA published in the **Federal Register,** at 76 FR 65133, an interim final rule that amended 38 CFR 1.461(c)(1) to better conform to authority granted to VA by Congress. Interested persons were invited to submit comments on or before December 19, 2011, and we received a total of 3 comments. All of the issues raised by the commenters are addressed below.

Two commenters stated general concerns regarding access to electronic medical records by DoD and the security of those records from inappropriate disclosure or access. VA is committed to the appropriate protection, use, and disclosure of information maintained and exchanged by VA in the course of official business and to ensuring the security of that information. The amendment to 38 CFR 1.461(c)(1) allows VA to fulfill Congress' clear intention that VA and DoD engage in the exchange of records, but does not affect the requirement of 38 U.S.C. 7332(e)(2) that limits VA disclosures to components of DoD that are ''furnishing health care to veterans.'' We do not make any changes based on these comments.

One commenter asserted that this regulation would create a breach of confidentiality by allowing DoD to access a veteran's health information without authorization by the veteran. However, the commenter also agreed that it is important that VA and DoD have access to veterans' medical information to ensure continuity of care, safety, and for the provision of benefits. This regulation will ensure that this access is provided for those reasons by removing a specific restriction that was not required by the statutory authority. In addition, VA will continue to comply with all other applicable laws and regulations regarding access to medical records, including those that limit the use and disclosure of information to specifically authorized disclosures. We do not make any changes based on this comment.

One commenter suggested that additional language be included in the final rule to prevent the misuse of information ''for unintended, alterative [sic] purposes beyond medical care.'' Otherwise, disclosure of information for purposes other than medical care ''may deter veterans from seeking care and/or disability compensation'' from VA. The suggested language focuses on the intended use of the information accessed under the rule. As we noted above, the amendment to the rule complies with the section 7332 limitations on the nature and purpose of information to be disclosed. Health care professionals, such as those accessing information through this provision, are already duty-bound to access health information consistent with law and professional standards. This rule does not limit or otherwise affect the enforcement of those laws and professional standards. Because we believe the suggested language is redundant of existing protections and because other laws and regulations govern such use and disclosure, we decline to further amend the regulation. We do not make any changes based on this comment.

Based on the rationale set forth here, and in the interim final rule, we adopt the interim final rule as a final rule without any changes.

Effect of Rulemaking

The Code of Federal Regulations, as revised by this final rule, represents the exclusive legal authority on this subject. No contrary rules or procedures are authorized. All VA guidance will be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

This 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 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 rule will not directly affect any small entities; only individuals could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 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, 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) unless OMB waives such review, 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 final rule 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 the 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 one year. This rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are: 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; and 64.013, Veterans Prosthetic Appliances.

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 August 29, 2012, for publication.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Archives and records, Cemeteries, Claims, Courts, Crime, Flags, Freedom of information, Government contracts, Government employees, Government property, Infants and children, Penalties, Privacy, Reporting and recordkeeping requirements, Security measures.

Dated: August 30, 2012.

Robert C. McFetridge,

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

PART 1—GENERAL PROVISIONS

■ Accordingly, the interim final rule amending 38 CFR part 1, which was published at 76 FR 65133 on October 20, 2011, is adopted as a final rule without changes.

[FR Doc. 2012–21816 Filed 9–4–12; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AN51

Service Dogs

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its regulations concerning veterans in need of service dogs. Under this final rule, VA will provide to veterans with visual, hearing, or mobility impairments benefits to support the use of a service dog as part of the management of such impairments. The benefits include assistance with veterinary care, travel benefits associated with obtaining and training a dog, and the provision, maintenance, and replacement of hardware required for the dog to perform the tasks necessary to assist such veterans.

DATES: *Effective Date:* This rule is effective October 5, 2012.

FOR FURTHER INFORMATION CONTACT: Lynnette Nilan, RN, MN, Patient Care Services, (10P4), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (406) 422–4476. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: On June 16, 2011, VA published in the **Federal Register** (76 FR 35162) a proposed rule to amend VA regulations to broaden and clarify current benefits to veterans with guide dogs, and to establish new benefits related to service dogs. Pursuant to 38 U.S.C. 1714(b) and (c), VA may provide to veterans enrolled under 38 U.S.C. 1705 guide dogs trained for the aid of people who are blind and service dogs trained for the aid of the hearing impaired or persons with a spinal cord injury or dysfunction or other chronic impairment that substantially limits mobility. Under section 1714(d), VA is also authorized to provide certain travel expenses related to the provision of such dogs.

In 1961, VA promulgated 38 CFR 17.118(a) (recodified as current 38 CFR 17.154(a) in 1996) restating the statutory language, which at that time limited VA's authority to the provision of guide dogs for blind veterans. In 2001, Congress amended section 1714 to authorize VA to provide service dogs for veterans with other disabilities. See Department of Veterans Affairs Health Care Programs Enhancement Act of 2001, Public Law 107–135, title II, § 201. This rule implements that authority and establishes a single regulation relating to the provision of guide and service dog benefits by VA.

Interested persons were invited to submit comments to the proposed rule on or before August 15, 2011, and we received 98 comments. All of the issues raised by the commenters that concerned at least one portion of the

rule can be grouped together by similar topic, and we have organized our discussion of the comments accordingly. For the reasons set forth in the proposed rule and below, we are adopting the proposed rule as final, with changes, explained below, to proposed § 17.148(b)(2), (d), (d)(1)(ii), and (d)(3) and § 17.154.

Definition of ''Service Dogs''

Section 17.148(a) defines ''service dogs'' as ''guide or service dogs prescribed for a disabled veteran under [§ 17.148].'' Multiple commenters argued that this definition is circular, and further contended that the omission of mental health impairments in § 17.148(b)(1) violates basic protections set forth in regulations implementing the Americans with Disabilities Act of 1990 (ADA). See 28 CFR 36.104 (specifically recognizing service dogs trained to assist individuals with mental impairments and defining ''service animal'' to mean ''any dog that is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability''). These commenters advocated that VA should use the definition of ''service animal'' set forth in the regulations implementing the ADA. We make no changes based on these comments.

The requirements in the ADA and regulations implementing the ADA are applicable only to ''public entities,'' and Federal Government agencies such as VA are not included in the ADA definition of a public entity. See 42 U.S.C. 12131(1). Thus, the specific requirements set forth in the ADA are not applicable to VA. Although this does not prevent VA from adopting, through regulation, a definition of ''service animal'' consistent with 28 CFR 36.104, it would be inappropriate to do so for the purposes of the programs regulated by this rule. The ADA and its implementing regulations exclusively address the issue of access to public facilities by individuals with disabilities, whereas the purpose of this rule is to authorize benefits to a veteran with a service dog. Access is not discussed in § 17.148 or § 17.154. Conversely, the ADA and its implementing regulations are neither controlling nor informative with regard to the administration of benefits to veterans with service dogs. The definition of ''service dogs'' in § 17.148(a) is reasonable because it is not overly broad for the purpose of the rule, and is appropriate to effectuate Congressional intent. Cf. 38 U.S.C. 1714(c) (providing authority for 38 CFR 17.148 and authorizing VA to ''provide service dogs trained for the aid of'' those veterans with hearing impairments, mobility impairments, etc., but not addressing access to VA facilities by persons accompanied by service dogs). The concerns from commenters were that § 17.148 ''reinvents the wheel'' by establishing a new definition for a term that is already defined in Federal regulation, and further that § 17.148 was unlawful under such regulation. However, as discussed above, the ADA definition of ''service animal'' is not applicable, and also is not helpful in determining the circumstances under which VA will provide the benefits described in § 17.148.

Commenters asserted that VA should use the term ''assistance animal'' instead of ''service dog'' because, they assert, the term ''service dog'' is understood more narrowly in the service dog industry to refer only to those dogs that assist with mobility impairments, whereas § 17.148(a) defines ''service dogs'' to mean dogs that aid with mobility impairments, visual impairments, and hearing impairments. By contrast, commenters stated that ''assistance animal'' is an industry term that encompasses dogs that assist with mobility, visual, and hearing impairments, and in turn should be used by VA in § 17.148(a). We make no changes based on these comments.

We disagree that every person in the service dog industry would understand what an ''assistance animal'' is in the way described by the commenter. Moreover, our regulations are written for a broader audience than those who may own or train service dogs, to include VA employees who administer benefits in accordance with our regulations. We believe that ''assistance animal'' in fact could be interpreted to have multiple colloquial meanings, and specifically may be likely to suggest that VA will provide benefits for animals other than dogs. We do not believe, as suggested by commenters, that our use of the term ''service dogs'' to encompass guide dogs for visual impairments and service dogs for hearing and mobility impairments would confuse veterans seeking benefits under the rule. Most importantly, § 17.148(a) clearly defines the term and states that the definition therein applies ''[f]or the purposes of'' § 17.148. In applying for this benefit, veterans would be expected to understand that the regulatory definition applies, and not any other definition that may be set forth elsewhere or understood in common parlance.

The Rule Does Not Deny Access of Any Service Dog to VA Health Care Facilities

Multiple commenters contended that the certificate requirement in § 17.148(c)(1) as proposed would violate their access rights under the regulations implementing the ADA. See 28 CFR 36.302 (stating that ''[a] public accommodation shall not require documentation, such as proof that the animal has been certified, trained, or licensed as a service animal''). We reiterate that this rulemaking does not address the issue of access to VA health care facilities by individuals accompanied by service dogs, and will not be used to determine whether a particular service dog will be allowed to enter a VA facility. Comments that allege unlawful violations of access rights or raise other issues relating to access to VA facilities, therefore, are beyond the scope of this rule. Therefore, we make no changes based on these comments. A certificate is required under § 17.148(c)(1) only to enable the veteran to receive service dog benefits, but is not required to gain entry to VA facilities. This rulemaking does not permit or prohibit the access of service dogs to VA health care facilities.

Access to VA facilities by service dogs accompanying individuals with disabilities is controlled by 40 U.S.C. 3103, which states: ''Guide dogs or other service animals accompanying individuals with disabilities and especially trained and educated for that purpose shall be admitted to any building or other property owned or controlled by the Federal Government on the same terms and conditions, and subject to the same regulations, as generally govern the admission of the public to the property.'' 40 U.S.C. 3103(a). The VA regulation that currently controls the access of animals to VA facilities is found at 38 CFR 1.218(a)(11), and we are in the process of amending § 1.218(a)(11) to be fully compliant with 40 U.S.C. 3103(a).

The Exclusion of Benefits for Mental Health Service Dogs Is Not Unlawful

Multiple commenters asserted that the exclusion of benefits to mental health service dogs is unlawfully discriminatory because it creates a different standard for treatment options between those veterans with mental health impairments and those veterans without mental health impairments. One commenter specifically alleged that not providing benefits for service dogs that mitigate the effects of mental health illnesses, while providing benefits for service dogs that mitigate the effects of

other impairments, may be a violation of Section 504 of the Rehabilitation Act (Section 504). Section 504 provides:

> No otherwise qualified individual with a disability in the United States, as defined in section 705(20) of this title, shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service.

29 U.S.C. 794(a).

We agree that the benefits administered under this rule are subject to Section 504, but disagree that not providing benefits for mental health service dogs violates Section 504. VA is not restricting service dog benefits based on disability. VA is providing benefits to both physically and mentally disabled veterans for the same purpose, which is to provide assistance for the use of a particular device (a service dog) when a service dog is clinically determined to be the optimal device to help a veteran manage a visual impairment, a hearing impairment, or a chronic impairment that substantially limits mobility. All veterans will receive equal consideration for benefits administered for these service dogs, provided all other criteria in § 17.148 are met, regardless of accompanying mental health diagnosis. Veterans diagnosed with a hearing or visual impairment will certainly not be deemed ineligible for service dog benefits because they also have a mental health impairment. We also note that mobility impairments under § 17.148 are not specifically limited to traumatic brain injuries or seizure disorders in § 17.148(b)(3). Some commenters misinterpreted the rule to contain such a limitation and argued that other mental impairment may produce mobility impairment. To clarify, if a veteran's mental impairment manifests in symptoms that meet the definition of ''chronic impairment that substantially limits mobility'' in § 17.148(b)(3) and a service dog is clinically determined to be the optimal device to manage that mobility impairment, then such a veteran will be awarded service dog benefits. The rule does not prevent such individualized assessments of veterans with mental health impairments, as long as the service dog would be evaluated as a device to mitigate the effects of a visual, hearing, or mobility impairment. If this requirement is met, VA would not deny service dog benefits simply because the service dog may also assist with mental impairment that does not cause a limitation identified in § 17.148(b).

The rule prevents the administration of benefits for a dog to mitigate the effects of a mental illness that are not related to visual, hearing, or mobility impairments, but this restriction is not discriminating based on the fact that a veteran has a mental disability. This restriction is based on a lack of evidence to support a finding of mental health service dog efficacy. In contrast, VA's shared national experience has been to directly observe positive clinical outcomes related to the use of service dogs and increased mobility and independent completion of activities for veterans with visual, hearing, and mobility impairments. Our observations are bolstered by the existence of nationally established, widely accepted training protocols for such dogs that enable the dogs to perform a variety of tasks directly related to mitigating sensory and mobility impairments (such as alerting to noise, opening doors, turning on light switches, retrieving the telephone, picking up objects, etc.). We are unaware of similarly vetted and accepted training protocols for mental health service dogs, or how assistance from such dogs could be consistently helpful for veterans to mitigate mental health impairments.

Although we do not disagree with some commenters' subjective accounts that mental health service dogs have improved the quality of their lives, VA has not yet been able to determine that these dogs provide a medical benefit to veterans with mental illness. Until such a determination can be made, VA cannot justify providing benefits for mental health service dogs.

Several commenters asserted that limiting § 17.148 to veterans diagnosed as having visual, hearing, or substantial mobility impairments violates 38 U.S.C. 1714, which was amended in 2009 to authorize VA to provide ''service dogs trained for the aid of persons with mental illnesses, including post-traumatic stress disorder, to veterans with such illnesses who are enrolled under section 1705 of this title.'' 38 U.S.C. 1714(c)(3). Though multiple commenters stressed that this rule's exclusion of mental health service dogs violates 38 U.S.C. 1714(c)(3), we reiterate as stated in the proposed rule that under the statutory language VA may provide or furnish a guide dog to a veteran but we are not required to do so. See 38 U.S.C. 1714 (c)(1)–(3) (noting that ''[t]he Secretary may, in accordance with the priority specified in section 1705 of this title, provide'' [service dogs]). As we explained in the proposed rule, this rulemaking expands part 17 of 38 CFR, which already addressed guide dogs for the blind, to now authorize benefits for hearing disabled and substantially mobility impaired veterans, because we have an adequate basis of clinical experience and evidence to suggest service dog efficacy for veterans with these impairments. Therefore, we make no changes based on the above comments.

The Exclusion of Benefits for Mental Health Service Dogs Is Not Unreasonable

Commenters contended that VA is acting against its own practices in administering benefits by requiring completion of a congressionally mandated service dog study prior to determining whether to administer mental health service dog benefits. Commenters asserted that while most VA regulations only rely on medical judgment or medical need to justify the provision of medical benefits, in this instance VA is without reason requiring a higher standard of clinical evidence. As stated by one commenter:

> VA's position that it can only act here in accord with a solid scientific evidence base is not in accord with its own practice. In most instances involving medical benefits, VA regulations rely simply on medical judgment, ''medical need,'' or a determination that providing the service is ''necessary.''

This is not an accurate statement. Current VA regulations do not discuss whether there is evidence to support the provision of a particular therapy or treatment method, but this does not support the inference that our regulations discount the need for evidence to support the provision of such therapy or treatment. Indeed, if we ultimately determine that mental health dogs are appropriate treatment tools for mental health impairments, we will amend our regulations to authorize benefits for such dogs. VA is currently evaluating the efficacy of mental health service dogs, pursuant to the National Defense Authorization Act for Fiscal Year 2010, Public Law 111–84, § 1077(a) (2009) (the NDAA), which states that ''the Secretary of Veterans Affairs shall commence a three-year study to assess the benefits, feasibility, and advisability of using service dogs for the treatment or rehabilitation of veterans with physical or mental injuries or disabilities, including post-traumatic stress disorder.'' All participants in this study are veterans with mental health disabilities who are receiving service dog benefits similar to those described in this rulemaking, but the service dogs for these veterans assist specifically with the effects of mental illness.

Although the NDAA provided that effectiveness of dogs for physical disabilities could additionally be evaluated in the study, we have chosen to limit this study's focus to mental health disabilities. However, we do not believe this limitation supports commenters' assertions that VA is creating an unreasonable double standard with regard to the need for clinical evidence, prior to administering benefits for mental health service dogs. The NDAA study is limited to veterans with mental health illness because VA has already determined from a clinical standpoint that service dogs are effective for assisting veterans with physical disabilities and mobility impairments. Moreover, we believe that the use of the word ''or'' in the NDAA makes the focus of the service dog study discretionary, and further that Congress clearly intended that VA must specifically evaluate the efficacy of mental health service dogs: ''The Secretary shall ensure that at least half of the participants in the study are veterans who suffer primarily from a mental health injury or disability.'' Public Law 111–84, § 1077(c)(4). There is no similar criterion in the law to compel that any portion of the participants must be veterans who suffer primarily from a physical injury or disability.

Though many commenters asserted that there is sufficient clinical evidence that VA could presently use to support administering mental health service dog benefits, the only evidence submitted in support of this assertion were anecdotal accounts of subjective benefits, including: Decreased dependence on medications; increased sense of safety or decreased sense of hyper-vigilance; increased sense of calm; and the use of the dog as a physical buffer to keep others at a comfortable distance. Again, we do not discount commenters' personal experiences, but we cannot reasonably use these subjective accounts as a basis for the administration of VA benefits. This is the precise reason VA is currently gathering evidence in the NDAA study—to determine how, exactly, service dogs may perform specific tasks or work that mitigates the effects of mental health disabilities.

Finally, we respond to multiple commenters' concerns with the manner in which VA is currently conducting the mandatory NDAA study. Essentially, these commenters stated that VA's conducting of the study is unreasonable because either the methodology is flawed, or VA's service dog organization partners in the study are inappropriate. Particularly, commenters alleged that VA has partnered exclusively with Assistance Dogs International (ADI) and ADI-accredited organizations in conducting the study, and further that ADI is not a proponent of psychiatric service dogs; such commenters accused VA of making adverse determinations regarding the efficacy of mental health service dogs before the study is complete. Generally, we find these comments to be beyond the scope of this rule, because VA is not basing any decisions in this rulemaking on any outcomes of the mandatory study, as the study has not yet been completed. However, we will note that VA has not partnered exclusively with ADI or ADI-accredited organizations to conduct the mandatory study. All relevant Federal requirements concerning research studies were followed by VA as relates to this study; an abstract of the study to include listed eligibility and exclusion parameters is available for public viewing at *http://clinicaltrials.gov/ct2/show/study/NCT01329341.* Therefore, we make no changes based on the above comments.

Service Dogs Must Be Certified by ADI or International Guide Dog Federation (IGDF) for Veterans With Visual, Hearing, or Substantial Mobility Impairments To Receive Benefits

Multiple commenters argued that VA should remove the requirement in § 17.148(c) as proposed that a service dog complete ADI training and be ADI certified before a veteran with a substantial mobility impairment can begin receiving benefits under § 17.148(d). These commenters put forth many reasons in support of removing this requirement, which we will specifically address in the following discussion. We make no changes to the rule based on these comments. In administering service dog benefits, VA must ensure that tested and proven criteria regarding service dog training and behavior are in place to ensure the integrity of the service dog benefits administered, and the safety of veterans and others who might come in contact with the veteran or the dog. There are no Federal standards for service dog training that we can apply, and VA does not have the expertise to design its own accreditation program or standards. ADI and IGDF are national, industry-recognized organizations with established and proven training criteria. Commenters offered many anecdotal observations concerning the quality and reliability of non-ADI organizations to train service dogs, but no commenters offered concrete, supportive evidence to persuade us that there are any organizations other than ADI or IGDF that have an established history and national credibility such that they should be recognized in § 17.148(c).

The reliance on ADI and IGDF accreditation is no different than our reliance on other nationally standardized criteria to ensure safe, high quality health care across all settings. For instance, VA relies on the Centers for Medicare and Medicaid Services (CMS) Resident Assessment Instrument/Minimum Data Set as the comprehensive assessment for all veterans in VA Community Living Centers (long term care facilities). See Veterans Health Administration (VHA) Directive 2008–007. In addition, VA requires States to rely on this tool for veterans in State homes receiving per diem payments from VA for the provision of nursing home care. See 38 CFR 51.110(b)(1)(i). Similarly, VA relies on and enforces by regulation National Fire Protection Association (NFPA) safety standards in all VA community residential care facilities, contract facilities for outpatient and residential treatment services for veterans with alcohol or drug dependence or abuse disabilities, and State homes. See 38 CFR 17.63, 17.81(a)(1), 17.82(a)(1), and 59.130(d)(1). We rely on various private, State, and local certifications concerning professional expertise. See, e.g., 38 CFR 3.352(b) (predicating aid and attendance allowance on need for care from health-care professional licensed to practice by a State or political subdivision thereof), § 17.81(a)(3) (conditioning VA authority to contract with residential treatment facilities that are ''licensed under State or local authority''), § 17.900 (recognizing certification of health care providers issued by, inter alia, The Joint Commission as well as specified government organizations including CMS). Thus, VA reliance on the recognized expertise of a public or private organization is not uncommon, nor is it illegal or questionable, so long as the basis for the reliance is well-reasoned and articulated.

Despite the negative comments that asserted that ADI is an inefficient organization or is inadequate in some respects, other commenters recognized that there are no other national organizations that perform a similar function, and that there are very few individuals who can accurately assess the quality of a service dog's training. Some commenters praised ADI, stating that ADI certification is ''the best route to go'' and that the requirement will ensure that VA is not paying for dogs of ''questionable value to our vet[eran]s.'' If at some point in the future we discover an efficient way to assess the quality of training provided by non-ADI

and non-IGDF dog providers, we will of course amend the rule; however, at this time, ADI and IGDF accreditation is the best guarantee we have that our veterans will be provided with safe, high quality service dogs.

We now specifically address comments that requiring certification from an ADI-accredited organization effectively creates a sole source contract, in violation of the general requirement for open and fair competition in Federal Acquisition Regulations. See 48 CFR 6.101. Multiple commenters further alleged that § 17.148(c) as proposed would violate a ''performance-based'' assessment requirement under Federal Acquisition Regulations for service contracts, because it emphasizes the source of service dog training rather than the result of that training. See 48 CFR 37.600 et seq. Without discussing under what circumstances VA may be permitted to enter into sole source contracts, we clarify for commenters that VA is not contracting with ADI or IGDF generally or with any ADI-accredited or IGDF-accredited organization to purchase service dogs for veterans under this rule. There is no fiscal conflict of interest or violation of Federal Acquisition Regulations because the rule does not authorize any financial arrangement whatsoever with ADI or IGDF.

Multiple commenters stated that the ADI limitation in § 17.148(c) is inefficient and ineffective for veterans by asserting that, compared to non-ADI organizations: There are not enough ADI-accredited organizations around the United States to meet veteran demand for service dogs; the cost to purchase ADI-certified service dogs is prohibitive; and the wait to receive a service dog from an ADI-accredited organization is too long. We make no changes based on these comments.

We acknowledge that not all States have registered ADI-accredited or IGDF-accredited organizations; however, § 17.148(d)(3) does provide for the reimbursement of travel expenses associated with the training a veteran must complete as offered by an ADI-accredited or IGDF-accredited organization. Therefore, there will be no out of pocket travel costs for veterans who must travel out of state to obtain a dog after a service dog is prescribed. Thus, we do not believe the absence of ADI-accredited or IGDF-accredited organizations in a particular State will serve as a barrier to obtaining a service dog.

Regarding the cost to obtain a service dog, we did not receive any concrete evidence from commenters that non-ADI accredited or non-IGDF accredited organizations are on average less expensive. Rather, commenters offered anecdotal claims that non accredited organizations are less expensive in some cases. A few commenters asserted that non-ADI accredited and non-IGDF accredited providers have less overhead costs because those organizations do not have to spend money to acquire or maintain accreditation. The ADI accreditation fee is $1000.00 paid every 5 years, with annual fees of approximately $50.00. The cost of IGDF accreditation is a one-time fee of $795, with an annual fee of $318 and a per unit fee of $39.45. We do not believe that these costs would necessitate an increased cost being passed to veterans specifically. ADI accreditation and IGDF accreditation are the only reasonable means we have of ensuring that an organization is using tested, standardized training and behavior criteria prior to a service dog being placed with a veteran. We view the cost of ADI and IGDF accreditation, therefore, as necessary and reasonable in order to ensure that we administer benefits in a safe and consistent manner. We clarify for one commenter that VA only intends to recognize those service dog organizations that have full membership in ADI or IGDF, or that are fully ADI or IGDF accredited, versus those organizations in the process of becoming ADI or IGDF accredited. This is consistent with our goal of ensuring VA only administers benefits for use of high quality service dogs that were subject to standardized training protocols.

Regarding the wait time to obtain a dog, commenters did not provide evidence to support that on average ADI-accredited organizations take longer than non-ADI accredited organizations to place service dogs with veterans. Many commenters instead provided anecdotal accounts of non-ADI organizations not utilizing ADI-specific training, and in turn training dogs faster than ADI organizations. Non-ADI organizations that facilitate ''owner training'' were especially noted by commenters as being faster and more effective for veterans, whereby the veteran would directly train the service dog. Again, we do not believe that we should administer benefits under the rule unless we can ensure that the service dogs for which we pay benefits are all subject to the same set of tested standards, to ensure safety and consistent quality. We do not believe this level of safety and quality can be met without accreditation based on nationally applicable criteria. This practice follows the same process VA uses with every other product, device, or treatment modality provided to our veterans.

Some commenters argued that VA could use other nationally recognized, performance based tests instead of requiring ADI certification to demonstrate that service dogs are safe and appropriately trained to mitigate effects of substantial mobility impairments. These commenters stated that submission to VA of a service dog's performance on a Public Access Test (PAT) or the American Kennel Club's Canine Good Citizen (CGC) test, in combination with statements indicating the level of the service dog's training and confirming the dog's good health, would provide sufficient objective evidence that service dogs are suitable for provision of benefits under the rule. Nationally recognized temperament tests such as a PAT or the CGC may indicate whether a service dog is stable and unobtrusive to the public to justify access (and, again, § 17.148 does not concern access), but these tests do not communicate the level of a service dog's specific training, or whether the service dog should be prescribed for a veteran as an assistive device. An accompanying statement submitted to VA that subjectively attests to a service dog's training is similarly inadequate, as VA seeks to administer benefits uniformly under the rule and therefore must ensure that all service dogs are subject to the same performance based standards. We make no changes based on these comments.

One commenter expressed support of VA's decision to specifically include seizure disorder as a covered impairment, and requested that VA more clearly indicate in the final rule which tasks a service dog may complete for such an eligible veteran. We reiterate that we require ADI and IGDF certification specifically because VA does not have the expertise, experience, or resources to develop independent criteria. For this reason, we make no changes to the rule to provide specific examples of tasks which any service dog may perform for a veteran. ADI has developed training protocols for service dogs to complete work and tasks for impairments as described in the rule, to include seizure disorders.

Finally, multiple commenters contended that VA could adopt independent training programs to internally produce service dogs for veterans, versus relying on certificates from external ADI-accredited service dog organizations. One commenter stated that VA should initiate an independent training program whereby veterans with post traumatic stress

disorder (PTSD) participate in training service dogs for the intended beneficiaries of this rule, i.e., veterans with visual, hearing, or substantial mobility impairments. This commenter compared such an internal training program to a program developed by the Denver VA Medical Center and Denver VA Regional Office in 2009, called ''Operation Freedom,'' in which veterans assisted in advancing dogs through CGC test training for 6 weeks as a component of the veterans' mental health treatment plans. After completion of this 6 week basic obedience training program, the dogs were trained by an external ADI-accredited organization in a rigorous 7 month regimen to become service dogs, and were placed with other veterans with disabilities. The initial pairing of the dogs with veterans during basic obedience training, as a treatment modality for mental health illnesses, provided those veterans with opportunities in skills development and community reintegration. Particularly, the program provided a bridge to community involvement through a meaningful volunteer opportunity that served other disabled veterans.

Though VA is not opposed to such training opportunities as a component of a treatment plan for a particular veteran, Operation Freedom is not an example of an independent and internal training program to train or produce service dogs for veterans. As the commenter correctly stated, the dogs involved in Operation Freedom were actually trained to become service dogs by an external ADI-accredited organization, over an extended period of time and subject to ADI standards as adopted and applied by that organization. We additionally clarify that even the initial basic obedience training that veterans assisted in providing to dogs was not provided on VA property, but rather on the property of the ADI-accredited organization, because the goal of Operation Freedom was to provide community reintegration opportunities for participating veterans as part of those veterans' treatment plans. The goal of Operation Freedom was ultimately not to produce service dogs for veterans, and we therefore do not find this example as provided by the commenter to be illustrative as to what VA should enact with regards to independent and internal service dog training programs. As stated previously, because VA does not have the expertise, experience, or resources to develop independent training criteria or otherwise train or produce service dogs for veterans, we require that service dogs be trained and placed with veterans by ADI-accredited and IGDF-accredited organizations. However, this in no way limits any veteran's personal choice to undertake any training experiences with any service dog organization, nor does it prevent VA from conducting programs similar to Operation Freedom. The commenter also noted potential cost savings for VA to conduct internal service dog training programs that employ PTSD veterans, but as explained earlier VA is not purchasing service dogs from ADI-accredited or IGDF-accredited organizations, and such cost comparisons are therefore not relevant. We make no changes based on the above comments.

One additional commenter suggested that instead of requiring ADI certification, that VA should hire professional service dog trainers to join rehabilitation therapy departments (e.g., to join Occupational and Physical Therapy departments) as VA staff, and that this would enable VA to professionally train service dogs at a higher output and with less cost than paying for ADI-certified service dogs. We make no changes based on this comment, as such cost considerations are not relevant because VA is not purchasing service dogs. VA does not have the expertise, experience, or resources to develop independent training criteria, and VA will not adopt or initiate internal training programs, as this would effectively make VA act as a professional service dog certifying body. VA's lack of expertise in this area is exactly why we have mandated ADI or IGDF certification.

To Qualify for Benefits, a Service Dog Must Be ''Optimal'' for the Veteran

Under § 17.148(b)(2), we require that the service dog must be the ''optimal'' device for the veteran to manage his or her impairment and live independently, and service dog benefits will not be provided if other assistive means or devices would provide the same level of independence as a service dog. Several commenters asserted that the use of one assistive device does not necessarily obviate the need for other assistive devices, and therefore that § 17.148(c) as proposed should not be used to exclude the prescription of a service dog if other devices may assist the veteran. We agree in part with the comments, but make no change to the regulation because the regulation does not prevent veterans from using multiple assistive devices.

For purposes of § 17.148(b)(2), an eligible veteran may be prescribed both a service dog and another assistive device, as long as each provides a distinct type of assistance, or if, without each of the devices, the veteran would be unable to complete tasks independently. For instance, for a veteran with a mobility impairment that is characterized by loss of balance and subsequent falls, both a balance cane and a service dog might assist a veteran with balance and walking; the cane might be optimal for assistance with walking, but the service dog may be the optimal means for that veteran to regain a standing position and stabilize after a fall. In such a case, the service dog may be prescribed to the veteran, as well as the balance cane. Similarly, a veteran with multiple impairments may be prescribed assistive devices to assist with one impairment and a service dog to assist with another. The ''optimal'' limitation in § 17.148(b)(2) will not limit the prescription of a service dog when necessary for the veteran to manage the impairment and live independently, but it will prevent the provision by VA of multiple assistive devices that serve the same purpose. By avoiding duplication of benefits in this manner, we maximize the amount of resources available to veterans and ensure that benefits are provided in a responsible manner.

Commenters stated that the ''optimal'' criterion in § 17.148(b)(2) as proposed would be used to ensure that service dogs are prescribed as assistive devices only as a ''last resort.'' A service dog is not a ''last resort'' in the sense inferred by the commenters. VA will not use the ''optimal'' requirement in such a way as to deprive any veteran of an assistive device that would best mitigate the effects of a veteran's impairment and provide the veteran the highest level of independence. The rule is designed, however, to promote the use of service dogs only when it is clinically determined that other devices will not adequately enable the veteran to live independently. This rationale of promoting service dogs secondary to other assistive devices is not without reason. A service dog is a long term commitment that requires tremendous dedication and effort on the part of the veteran, as well as significant costs—only part of which would be paid for by VA under § 17.148. A service dog must be fed, exercised, groomed, nursed when ill, and integrated into the veteran's family as a necessary partner in the veteran's daily life. If the extent of the veteran's mobility impairment is such that the only tasks requiring assistance are picking up or reaching items, then a device that is not a service dog that fully accomplishes these tasks is not only sufficient, but also is not unduly burdensome for the veteran. We

make no changes based on these comments.

Commenters argued that the rule should contain additional criteria that would objectively measure a veteran's level of independence between different devices, instead of the single ''optimal'' criterion. We believe, however, that because these are clinical determinations based on ''medical judgment'' under § 17.148(b)(2), additional criteria are unnecessary and unhelpful. Therefore, we make no changes based on these comments. It is clear in § 17.148(b)(2) that devices, including a service dog, will be clinically evaluated to determine which are necessary and most beneficial for the veteran to manage an impairment and live independently. We stressed the importance of this clinical determination in the proposed rule:

> VA does not intend to allow cost or any other factors to discourage the use of new technologies and equipment to maximize the independence of veterans. We believe that providing VA with discretion to choose between a service dog or assistive technology based on medical judgment rather than cost-effectiveness would ensure that VA's patients receive the highest quality of care that the VA-system can provide.

76 FR 35163.

One commenter additionally noted that the above rationale from the proposed rule presumed that higher cost technologies offer a higher standard of care. We clarify that the intent of this rationale was to support VA's use of clinical judgment to determine what device allows the veteran to function most independently, and not have such a determination influenced by factors such as cost.

Some commenters asserted that while another device may provide the exact same functions in mitigating the effects of mobility impairments as a service dog, service dogs nonetheless should be considered optimal and be prescribed because they uniquely provide certain ancillary benefits, including: Subjective feelings of increased personal comfort and understanding; an increased sense of purpose for the veteran in having to care for a living thing; an increased sense of self-esteem and overall psychological well-being; and improved social and community reintegration skills. We do not dispute these subjective accounts from commenters; however, we believe Congress authorized VA to provide service dogs to veterans with disabilities as a means of mitigating the effects of a disability—and not for the purpose of companionship or emotional support. Therefore, we make no changes based on these comments. The authorizing statute links the provision of service dogs to their having been trained ''for the aid of'' veterans with hearing impairments, mobility impairments, etc.; the statute does not suggest that ancillary benefits are to be considered. 38 U.S.C. 1714(c). Therefore, § 17.148 does not authorize benefits based on ancillary benefits that service dogs may provide but that are not specific to mitigating the effects of a veteran's disability, and which are not the product of specific training. Though dogs may generally tend to engender in their owners subjective feelings of improved well being, this is not the intended effect of service dog assistance under 38 U.S.C. 1714(c) or § 17.148.

As proposed, the determination that the service dog is ''optimal'' for the veteran under § 17.148(b)(2) was to be made by a VA clinician using medical judgment. Multiple commenters objected to this standard, for various reasons. Chiefly, commenters claimed that a VA clinician would not have the requisite expertise related to service dogs to properly compare their unique characteristics and benefits to other assistive devices. Instead, these commenters asserted that the decision-making process should involve either a local evaluation board or interdisciplinary team, in which prosthetic staff and other rehabilitative therapy staff is represented. We agree, and have amended the first sentence of § 17.148(b)(2) from the proposed rule to require ''[t]he VA clinical team that is treating the veteran for such impairment'' to assess whether it is appropriate to prescribe a service dog for that veteran. The ''VA clinical team'' will include, by virtue of being the clinical staff that is treating the veteran for the qualifying visual, hearing, or mobility impairment, the veteran's primary healthcare provider, and any other relevant specialty care providers and professional staff, to include prosthetic and rehabilitative therapy staff. Thus, the first sentence of § 17.148(b)(2) now reads: ''The VA clinical team that is treating the veteran for such impairment determines based upon medical judgment that it is optimal for the veteran to manage the impairment and live independently through the assistance of a trained service dog.''

We also recognize that ensuring that VA clinical staff is knowledgeable regarding service dog utilization is critical to the successful partnering of veterans with service dogs. VA is developing and will disseminate educational tools and training opportunities that will assist VA clinical staff to obtain this knowledge. In preparation for the effective date of this rulemaking, we have drafted clinical practice recommendations and have produced a video presentation for dissemination to every VA health facility in the country. Both the clinical recommendations and the video communicate to clinical staff the traits, capabilities, tasks, and utility of service dogs for mobility, hearing, and vision impairments. These and other training materials will include professional education credits, so clinical staff will have incentive to participate, and some training opportunities will be required training for a veteran's clinical team when it is necessary to determine if an assistive device is needed. The training provided at local facilities will ensure the veteran's treatment team will be qualified to evaluate between various assistive means, to include understanding the abilities of service dogs, and then be able to prescribe the most appropriate assistive device.

Multiple commenters criticized the rule for disregarding the expertise of service dog organizations. It is true that for a veteran to receive benefits under the rule, a service dog must be prescribed by the veteran's clinical team, and that decision is made without consulting the service dog organization from which a veteran ultimately obtains a service dog. However, the prescription of a service dog is a treatment decision made by the VA clinical team that is treating the veteran for the qualifying impairment, and we believe that consultation with a private organization that has no clinical expertise as to the medical treatment for a specific veteran is inappropriate. Therefore, we make no changes based on these comments. At the same time, service dog organizational expertise and experience are essential to the process whereby a service dog is placed with a veteran. After a clinical decision is made to prescribe a service dog, a service dog organization will use its professional judgment to make independent decisions concerning whether a service dog will actually be placed with the veteran. The ADI-accredited or IGDF-accredited organization conducts its own assessments based on national criteria and its specialized experience in the field, and the veteran must complete the service dog organization's evaluation and training before that organization will match the veteran with a service dog and place that dog in the veteran's home.

VA's role in the service dog organization's assessment and evaluation is purely supportive. For instance, VA will assist the veteran with obtaining medical and psychological

reports and other documentation that the service dog organization may request from VA (if approved for release by the veteran). VA will additionally provide assistance to veterans in locating a service dog organization, if requested. In response to one commenter, however, VA will not formally refer veterans to specific ADI-accredited or IGDF-accredited organizations, or initiate a process whereby a veteran may consent to have VA act as an intermediary between the veteran and the service dog organization. We believe such a referral system would blur the distinct line that should exist between VA's responsibility to determine whether a service dog may be clinically necessary for a veteran, and the service dog actually being placed with the veteran. The clinical practice recommendations and other guidance VA has developed will alert VA staff to commonly available resources that would aid the veteran in locating service dog organizations, and this information could be provided to the veteran (e.g., the Web site to find the nearest ADI-accredited or IGDF-accredited organization). VA will additionally assist the veteran in obtaining medical information the service dog organization may require.

In response to the same commenter, VA will not develop a standard form to be certified or otherwise completed by the service dog organization, for the veteran to submit to VA under § 17.148(c)(1)–(2) to receive benefits. Instead, VA will accept a certificate as required under § 17.148(c)(1)–(2) in all forms as issued to the veteran from the individual service dog organizations. Such certificates must indicate that an adequate training program has been completed to warrant receipt of benefits under the rule. VA's lack of expertise in certifying whether appropriate training has been completed is the precise reason VA has required ADI or IGDF certification for all service dogs acquired on or after the effective date of the final rule.

Some commenters stated that only the service dog organizations themselves should be the designated decision makers under § 17.148, arguing that only these organizations could properly compare service dogs to other assistive devices and determine what is the most ''optimal'' means to assist a veteran. We do not believe a service dog organization would be so qualified, as they do not have the expertise of licensed VA clinicians to clinically assess or treat a specific veteran, nor do they have the clinical responsibility of VA clinicians to evaluate assistive device options other than service dogs. Additionally, as the benefits under the rule are to be administered incident to a veteran's medical treatment, only the veteran's clinical team may be designated decision makers regarding the initial clinical assessment. Therefore, we make no changes based on these comments.

Commenters asserted that having VA clinicians make the determination whether a service dog is optimal discounts the veteran's input into their own treatment options, and instead advocated that the decision should be solely between the veteran and the service dog organization. In keeping with VA's policy of providing patient centered care, VA clinicians do not discount the input of veterans regarding treatment options. As with any other medical care VA provides, the prescription of a service dog for a veteran would be the recommended course of treatment only after the veteran's clinical team considers all relevant factors, to include veteran preference in treatment options. A veteran's preference for a service dog, therefore, would certainly be a factor in a determination to prescribe a service dog. We make no changes based on these comments.

VA Is Not Purchasing or Otherwise Obtaining Service Dogs for Veterans Under the Rule

Several commenters objected to a basic premise in this rule, which is that VA will assist veterans in determining whether a service dog is an appropriate treatment option and will maintain service dogs through the provision of veterinary and other benefits, but VA will not actually purchase or obtain service dogs for veterans. We make no changes based on these comments. As explained in the proposed rulemaking, we reiterate that we interpret the ''may * * * provide'' language in 38 U.S.C. 1714(c) to mean that VA need not actually purchase or acquire dogs for eligible veterans. 76 FR 35162. This is consistent with VA policy, extant prior to the promulgation of this rule, concerning guide dogs for the visually impaired; VA does not purchase or obtain such dogs on behalf of veterans under the similar authority (''may provide'') in 38 U.S.C. 1714(b). As stated previously, we simply lack the facilities and expertise to purchase or obtain, or to train service dogs for placement with veterans, and we will continue to rely on independent organizations that have been recognized as having such expertise. VA has opted instead to offer other benefits to facilitate the provision of service dogs to veterans.

One commenter asserted that VA purchases other ''devices'' for veterans, and further that VA categorizes service dogs as ''devices,'' and therefore that this rulemaking must address how VA plans to purchase service dogs for veterans from service dog organizations. We make no changes based on this comment. The commenter did not specify what type of ''devices'' VA purchases for veterans as a comparison to service dogs, but we assume the intended reference was to prosthetic devices or appliances that may be provided to certain veterans under 38 CFR 17.38 and 17.150. Although we have stated in this rulemaking that we view a service dog as a surrogate for another assistive device, we clarify that with regards to VA procurement policy, we do not treat service dogs in the same manner as prosthetic devices that are purchased for veterans. Unlike prosthetic devices that are provided by VA to veterans at VA expense, the actual placement of a service dog with a veteran is not VA's decision, and ultimately is not a clinical decision—the actual placement is the decision of a service dog organization, subject to that organization's own non-clinical assessment and training standards. VA is unable to provide training and fitting of a service dog for a veteran, as we provide for prosthetic devices that are purchased for veterans, again because VA at this time lacks this expertise.

Notwithstanding VA's lack of expertise in purchasing or obtaining service dogs to provide directly to veterans, several commenters asserted that VA should cover a veteran's out of pocket costs to independently purchase a service dog. We reiterate that the rule is designed to support service dogs only when it is clinically determined that other assistive devices will not adequately enable the veteran to live independently, because a service dog is a long term commitment that requires tremendous dedication and effort on the part of the veteran, as well as potentially significant continuing costs for veterans that will not be paid by VA (e.g., non-prescription food, over-the-counter medications). VA will therefore not directly purchase service dogs for veterans. VA will not potentially incentivize the independent purchase of service dogs by veterans by creating an expectation that the purchase costs will be covered.

Another commenter asserted that VA should establish a ''fee for service'' program to purchase service dogs for veterans, because such remuneration would increase availability of service

dogs as well as decrease potential wait times for veterans to obtain service dogs. We do not agree that the availability of service dogs specifically for veterans is impeded by veterans' inability to cover purchasing costs, because we understand that a majority of service dogs are acquired by veterans with little or no out of pocket cost. Therefore, we make no changes based on this comment. Additionally, we do not believe that a veteran's inability to purchase a service dog would contribute to any potential wait time for that veteran to obtain a service dog. Rather, we believe that the only factors that would contribute to potential wait times for veterans to obtain service dogs would be the supply of trained and available service dogs, which is unaffected by whether such dogs can be purchased or by whom.

VA Will Not Pay for Certain Expenses Under § 17.148(d)(4)

Commenters asserted that VA should pay for certain expenses associated with a service dog that would be excluded under § 17.148(d)(4) as proposed. Specifically, commenters argued that VA should pay for grooming, nail trimming, non-sedated teeth cleaning, nonprescription medications, and nonprescription food and dietary supplements, because commenters asserted that these services are directly related to the dog's ability to provide assistive services, and therefore should be considered covered by VA. See 76 FR 35164 (explaining that the restrictions expressed in § 17.148(d)(4) are present to ''ensure that the financial assistance provided by VA would not be used to provide services that are not directly related to the dogs' ability to provide assistive service.''). Commenters stated that these excluded services are directly related to the dog's ability to provide assistive services because they are either necessary to ensure a service dog's longevity and reliable working service to the veteran, or are necessary to maintain the higher standards of cleanliness service dogs must maintain. We make no changes to the rule based on these comments, but reiterate our general policy as stated in the proposed rule that we regard the service dog as a surrogate for another assistive device, and require that the veteran therefore utilize the service dog responsibly and provide general care and maintenance. As with prosthetic devices prescribed by VA, the veteran is expected to maintain equipment by ensuring it is cared for, cleaned, serviced, and protected from damage. In the case of prosthetic devices, VA repairs broken equipment, and provides annual servicing and replacement parts such as hearing aid batteries or oxygen tank refills, when needed. In the case of a service dog, VA believes this equates to repairing and or replacing harnesses or other hardware, providing annual and emergent veterinary care, providing prescription medications, or paying for other services when prescribed by a veterinarian. In the same way VA would expect a veteran to protect and utilize his or her wheelchair in order to keep it in good working condition, or keep his or her prosthetic limb clean and functioning, VA expects that a veteran will generally maintain the service dog with daily feeding, regular grooming, and by covering any other expenses which are not clinically prescribed by a veterinarian.

Grooming and other excluded services in § 17.148(d)(4) are important for the general health of a service dog as an animal, and may affect a service dog's ability to provide services. However, services excluded in § 17.148(d)(4) are not uniquely required by a service dog to perform the work and specific tasks for which they were trained. Services excluded in § 17.148(d)(4) are general care and maintenance services that all dogs require for general good health and well being, and we therefore do not believe they are directly related to the specific assistance provided by a service dog. For instance, service dogs surely must have their nails maintained at an appropriate length to prevent certain maladies and discomfort associated with overgrowth or damage. However, the exact same need exists for nonservice dogs as well, such that all dogs' general ability to walk and maneuver is affected by maintenance of their nails. Unlike a specialized harness provided by VA, nail grooming is not uniquely required by a service dog to perform the work and specific tasks for which they were trained, and hence is not covered under the rule. We apply this same rationale for other items, such that VA will not pay for standard, nonspecialized leashes and collars, or nonprescription food or medications, or any other basic requirements mandated by State governments for dog ownership generally, such as dog licenses. Again, such standard needs are not unique to service dogs—it is for the overall health and well being of all dogs as domestic animals that they be adequately controlled by their owners, are routinely fed and kept free of pests such as fleas and ticks, etc.

Commenters stated that service dogs are subject to heightened standards of cleanliness by virtue of being permitted access to public areas, which in turn creates a greater need for grooming services. Commenters asserted further that individuals with substantial mobility impairments may not be able to complete necessary grooming to ensure service dogs may gain access to public areas, and specifically stated the inability of these individuals to complete grooming tasks would be exacerbated by the fact that most ADI-certified dogs are large dog breeds with long hair. However, we are not aware of any rules regarding service dog access to public places that hold service dogs to heightened standards of cleanliness that would not otherwise be appropriate for a dog living in a home and assisting a disabled veteran, nor did the commenters offer any specific examples of such heightened standards. Nonetheless, we do not believe that an ADI-accredited or IGDF-accredited service dog organization would place a service dog with an individual who could not demonstrate an ability to provide for the basic maintenance and care of the service dog, to include required grooming sufficient to allow the dog access to a public area. We make no changes based on these comments.

A few commenters noted specifically that many of the services excluded in § 17.148(d)(4) as proposed are discounted for members of the International Association of Assistance Dog Partners (IAADP), and that VA should in turn pay for IAADP memberships for veterans with approved service dogs. We make no changes to the rule based on these comments. The sole cost savings associated with IAADP membership as described by commenters was related to prescription medications, which are covered under § 17.148(d)(1)(ii). Additionally, because the veteran must be generally responsible for expenses related to the nonmedical daily care and maintenance of a service dog, the veteran would also be responsible for membership in any organization that may assist in covering such expenses. One commenter additionally advocated for VA to initiate a service dog support group, and likened the benefits of such a support group to the benefits individuals may receive as IAADP members. For instance, the commenter suggested that such a VA support group should have a membership requirement, and would be a more cost effective way to use VA funds for service dogs as well as promoting socialization and education. Although we do not disagree with the commenter on the potential value of such a support group, we make no changes to this rule based on the same rationale related to IAADP membership as expressed above.

Benefits Will Not Be Provided for More Than One Service Dog at a Time

Commenters asserted that a requirement in § 17.148(d) as proposed, that benefits would only be provided for ''one service dog at any given time'' is too restrictive. Commenters stated that many service dogs continue to live with veteran owners after being replaced by a new service dog, and opined that the veteran should continue to receive benefits to relieve the financial burden of continuing to care for the retired service animal. We make no changes based on these comments. A retired service dog would no longer be providing specific assistance to the veteran to mitigate the effects of a disability, and VA would therefore lack authority to continue to provide benefits to the veteran based on his or her medical need for the service dog. To the extent that keeping a retired service dog could be a financial strain on a veteran, all ADI-accredited and IGDF-accredited organizations offer the option for owners to place retired service dogs in the homes of volunteers.

Commenters also stated that the restriction of benefits to only one service dog at a time does not properly consider the extended training periods often required to obtain replacement service dogs, and will create an undue lapse in service dog benefits for those veterans whose current service dogs will soon be retired. Essentially, commenters asserted that the restriction creates a costly choice for a veteran to either apply benefits under the rule towards obtaining a replacement service dog, or continue to have benefits apply to a current service dog until it is officially retired. We agree that it is important that veterans do not experience a lapse in service dog benefits when obtaining a replacement service dog, and did not intend for the limitation in paragraph (d) to cause such a lapse. Therefore, we have added to paragraph (d)(3) the following note: ''VA will provide payment for travel expenses related to obtaining a replacement service dog, even if the veteran is receiving other benefits under this section for the service dog that the veteran needs to replace.'' To emphasize this clarification, we have added to the introductory text of paragraph (d) a sentence to explain that there is an exception in paragraph (d)(3) to the ''one service dog at any given time'' provision in the rule. This exception will only apply to travel benefits under paragraph (d)(3), because the organization that is training the replacement service dog would be responsible for other benefits under § 17.148(d) as needed by the replacement dog, until the veteran actually acquires the replacement dog from the organization. At the time the veteran acquires the replacement service dog, the veteran would in effect be retiring the former service dog, and would apply all service dog benefits under this section to the replacement dog.

Service Dogs Obtained Before the Effective Date of the Final Rule

Multiple commenters interpreted § 17.148(c)(2) as proposed to compel veterans who obtained non-ADI or non-IGDF certified service dogs before the effective date of the final rule to undergo the certification process with an ADI-accredited or IGDF-accredited organization prior to being eligible for benefits. This is not the intent or function of § 17.148(c)(2), in all cases. The rule clearly states that for veterans to receive benefits for service dogs obtained before the effective date of the rule, veterans may submit proof from a non-ADI or non-IGDF organization that the service dog completed a training program offered by that organization. See § 17.148(c)(2) (explaining that it is only when a veteran may not be able to attain such proof from a non-ADI or non-IGDF organization that ''[a]lternatively, the veteran and dog [could obtain the certification from ADI or IGDF]''). We make no changes based on these comments.

Commenters asserted that for previously obtained dogs, the final rule must establish criteria in § 17.148(c)(2) to allow VA to determine whether the training courses certified by non-ADI or non-IGDF organizations were adequate to produce a well trained dog capable of assisting the veteran. We make no changes based on these comments. As stated in the proposed rule, we do not have the expertise, experience, or resources to develop independent criteria to assess the efficacy of service dog training programs. Additionally, we do not want those veterans with existing service dogs to be subjected to new requirements which could prevent their receipt of benefits. Therefore, we accept a certificate from a non-ADI or non-IGDF organization that existed before the effective date of the final rule as proof that the veteran's service dog has successfully completed an adequate training program, and that a veteran who otherwise meets the criteria in the rule may receive applicable benefits. Essentially, we are ''grandfathering in'' service dogs acquired before the effective date of the final rule by not requiring such dogs to have ADI or IGDF certification.

We further clarify for one commenter that the 1 year limitation in § 17.148(c)(2) to obtain a certificate that the veteran's service dog has successfully completed an adequate training program only applies if the certificate comes from the original non-ADI or non-IGDF organization. The 1 year limitation is not applicable for a veteran who must, because they cannot obtain a certificate from the original non-ADI or non-IGDF organization, undergo new training with an ADI-accredited or IGDF-accredited organization. See § 17.148(c)(2) (explaining that the 1 year limitation applies when a certificate is obtained from a non-ADI organization, or ''[a]lternatively, the veteran and dog [could obtain the certification from ADI or IGDF]''). We make no changes to the rule text based on this comment because the language is clear. In response to commenters' concerns that ADI-accredited organizations will not certify service dogs that were not also initially trained there, VA will ensure through continued workings with ADI-accredited and IGDF-accredited organizations that there exists a mechanism to provide for such certification.

Lastly, one commenter advocated specifically that veterans who currently receive VA benefits for guide dogs should not be required to undergo the clinical determination process in § 17.148(b)(2) to now receive benefits under § 17.148(d). We make no changes based on this comment, as all veterans who would seek to receive benefits under § 17.148(d) must be subject to the same requirements, to ensure equitable administration of benefits. However, we note that for any veteran who is currently receiving guide dog benefits from VA, that veteran has already undergone the same type of clinical evaluation to determine efficacy of the dog, and would have a history of medical documentation supporting the use of the dog as indeed the most optimal device to manage the veteran's impairment. Effectively then, the veterans already receiving guide dog benefits from VA would not be subject to a new clinical evaluation process under § 17.148(b)(2), as this would be duplicative and unnecessary.

Procedures Related to Insurance Coverage and Payments

Section 17.148(d)(1) as proposed would provide an insurance policy to veterans with prescribed service dogs that guarantees coverage of all veterinary treatment considered medically necessary. Commenters urged that § 17.148(d)(1) as proposed should

be revised for multiple reasons, with a majority of commenters stating that certain processes involved in payment for veterinary care should be clarified. Under § 17.148(d)(1)(i), VA ''will be billed for any premiums, copayments, or deductibles associated with the policy'' negotiated and offered by VA to veterans with prescribed service dogs. VA will only pay premiums and other costs as specified in § 17.148(d)(1)(i) for the commercially available policy that VA provides to the veteran, and not for any other policy that a veteran may obtain independently. The insurance company that holds the VA-provided policy will attain appropriate contractor status under Federal acquisition standards by registering with the Central Contractor Registration (CCR) to bill VA for costs specified in § 17.148(d)(1)(i), and will be subject to the same quality standards as other VA contractors.

Multiple commenters stated that the type of insurance coverage that VA would provide in § 17.148(d)(1) as proposed was inadequate, as all commercially available insurance policies for service dogs rely on a reimbursement model whereby veterans would pay the out of pocket cost for veterinary treatment, prior to filing a claim with and being reimbursed by the insurance company. Commenters stated that VA should, instead, establish a system where VA pays for treatment costs, such as providing veterans with prescribed service dogs some type of debit card to be used for veterinary care. The rule clearly states that VA, ''and not the veteran,'' will be billed directly for all costs for which VA is responsible under § 17.148(d)(1)(i). The rule also states that the policy will guarantee coverage for the types of treatment determined by a veterinarian to be medically necessary in § 17.148(d)(1)(ii), but, as proposed, paragraph (d)(1)(ii) did not bar billing a veteran for treatment costs. Our intent has always been to negotiate and procure a contract, to the extent that is commercially feasible, for an insurance policy that will not require the veteran to pay any out of pocket costs for covered veterinary care and treatment costs. VA has researched the commercial market and anticipates that VA will be able to contract for this requirement on VA's terms. In response to these comments and to further ensure that the regulation effectuates our intent, we have revised the language of § 17.148(d)(1)(ii) from the proposed rule so that it bars the billing of veterans for covered costs.

Based on the foregoing, we do not believe that there is a need to clarify any of the payment processes that are authorized by the regulation or to provide in regulation any specific procedures that will be established in accordance with the insurance policy for service dogs, so long as the basic requirements in § 17.148(d)(1) are met concerning not billing veterans. For instance, this rule will not specify that the insurance provider must be registered in the CCR, because it is a requirement under separate Federal Acquisition Regulations that all Federal contractors must be registered in CCR. See 48 CFR 4.1102.

Commenters also criticized that typical insurance policies that would be commercially available would not provide the scope of coverage required to adequately care for a service dog, as the medical needs of a service dog are higher due to the level of physical work a service dog completes on a regular basis. We clarify that the rule intends that VA will select a policy with broad coverage, to ensure that all services which are likely to be considered medically necessary by a veterinarian who meets the requirements of the insurer are in fact covered. VA will consult with ADI, IGDF, and the American Veterinary Medical Association to ensure that the most comprehensive policy, specific to the needs of service dogs, is chosen. Additionally, in response to commenter concerns that such a policy is not likely to be accepted widely across the nation, VA will consider geographic availability when choosing the policy.

Procedures Related to the Reimbursement of Veteran Travel Expenses

Commenters argued that § 17.148(d)(3) as proposed was vague regarding reimbursement and eligibility for travel expenses, and should more specifically indicate the type of travel expenses covered, to include lodging and expenses related to training and retraining/recertification of service dogs. We make no changes to the rule based on these comments. The rule is clear in § 17.148(d)(3) that any veteran who is prescribed a service dog under § 17.148(b) will be eligible to receive payments for travel expenses. We reiterate from the proposed rule that § 17.148(d)(3) is intended to implement 38 U.S.C. 1714(d), ''which allows VA to pay travel expenses 'under the terms and conditions set forth in [38 U.S.C. 111]' for a veteran who is provided a service dog.'' See 76 FR 35164. We believe that the language of section 1714(d) can be read to interpret obtaining a dog as ''examination, treatment, or care'' under section 111, but we would not make payment of section 1714(d) benefits contingent upon the separate eligibility criteria in section 111. This interpretation facilitates administration of section 1714(d) benefits by allowing VA to avoid additional expenses associated with establishing a new means of administering travel benefits outside of section 111 mechanisms.

We clarify that all travel costs associated with obtaining the service dog, to include all necessary initial and follow up training, are covered. Additionally, all types of travel costs which are considered reimbursable in 38 U.S.C. 111 and 38 CFR part 70 are considered reimbursable in this rule, to include approved lodging.

Commenters also indicated that VA should not require a prescription for a service dog before authorizing travel reimbursement related to procurement. We disagree and make no changes based on these comments. We will pay travel benefits only if it is determined by the veteran's clinical team that a service dog is appropriate under § 17.148; otherwise, we would be paying costs related to procuring an assistive device that may not ultimately be approved for the veteran.

Only VA Staff May Provide, Repair, or Replace Hardware Under § 17.148(d)(2)

Commenters asserted that the benefit to provide service dog hardware under § 17.148(d)(2) as proposed would be too restrictive. Commenters stated that veterans should be reimbursed for payments made to non-VA third party vendors to provide, repair, and replace such hardware, instead of the current requirement that the hardware be obtained from a Prosthetic and Sensory Aids Service at the veteran's local VA medical facility. We make no changes to the rule based on these comments. We believe that hardware should only be provided, repaired, and replaced through VA, to ensure that our clinical and safety standards are met. Merely reimbursing third-party providers does not permit VA to oversee hardware provision to ensure that it is ''clinically determined to be required by the dog to perform the tasks necessary to assist the veteran with his or her impairment,'' as required in § 17.148(d)(2). A clinical determination that covered hardware must be task-specific for the type of assistance a service dog provides is essential, or VA would be employing its professional clinical staff to provide and repair common items related to dog ownership generally, such as collars or leashes. The purpose of § 17.148(d)(2) is not to cover all equipment that a dog generally may require, but rather to ensure that the veteran is not burdened in finding, obtaining, or having to repair

or replace certain special hardware that a trained service dog requires to provide specific assistance. We believe that allowing third party vendors would also increase administrative burden for veterans, as this would require the vendor to undergo a separate, extensive, and highly regulated Federal process to identify, select, and utilize third party vendors, which would cause an undue delay for veterans in obtaining necessary hardware.

A Dog Must Maintain Its Ability To Function as a Service Dog

Section 17.148(e) provides that for veterans to continue to receive benefits under the rule, the service dog must continue to function as a service dog, and that VA may terminate benefits if it learns from any source that the dog is medically unable to maintain that role, or a clinical determination is made that the veteran no longer requires the service dog. A few commenters objected to the ''any source'' criterion in § 17.148(e), stating that VA should restrict sources of information to a veteran's medical provider with regards to a veteran's continued clinical need for the service dog, and to the service dog's veterinarian with regards to the service dog's fitness to continue providing assistance. We make no changes to the rule based on these comments. We first clarify that VA will only consider the veteran's clinical team as a source of information to determine whether the veteran continues to require the service dog; this is contemplated in paragraph (e), which states that ''VA makes a clinical determination that the veteran no longer requires the dog.'' With regards to the medical fitness of a service dog, VA must be permitted to receive information from a broad number of sources in a continuous manner while benefits are administered, for the safety of veterans and to ensure that benefits are administered equitably. The ''any source'' criterion as well reduces administrative burden for veterans, in that VA would otherwise need to prescribe a specific and regular means of evaluating whether a service dog has maintained its ability to function as a service dog.

The broad ''any source'' criterion in paragraph (e) does not mean that VA will rely upon information from any source to terminate service dog benefits without considering the source of the information, and first allowing veterans to submit contrary information. The 30 days notice prior to termination of benefits provided for in paragraph (e) allows the veteran ample time to present contrary information, if VA should receive information that a service dog is not able to maintain its function as a service dog.

Commenters additionally stated that VA should exclude any insurance company with which VA contracts to cover veterinary care costs as a source of information concerning the medical fitness of a service dog. The commenters, however, did not provide a rationale for such an exclusion. To the extent that the commenters may be concerned that an insurance company would seek to have service dogs deemed medically unfit to avoid excess expenditures, we do not believe any incentive exists to do so. As we stated in the proposed rule, our understanding is that annual caps on expenditures are a common limitation in insurance policies that cover service dog care, and § 17.148(d)(1)(ii) specifically provides for such caps to be considered in the administration of veterinary care benefits. We reiterate that VA must be permitted to consider information from a broad number of sources, and do not see any inherent reasons that this specific limitation should be implemented. Therefore, we make no changes based on these comments.

Appeals Procedures

In response to commenter concerns that the rule does not detail an appeals process for a veteran whose service dog benefits are to be terminated, or for a veteran who is not prescribed a service dog and cannot obtain service dog benefits, we do not believe VA must prescribe a new appellate mechanism in this rulemaking. All decisions under this rule, whether decisions to prescribe a service dog and initiate service dog benefits, or decisions to terminate such benefits, are clinical determinations and therefore subject to the clinical appeals procedures in VHA Directive 2006–057. It is VHA policy under this appeals process that patients and their representatives have access to a fair and impartial review of disputes regarding clinical determinations or the provision of clinical services that are not resolved at a VHA facility level. This clinical appeals process will be sufficient to resolve conflicts related to the provision or termination of service dog benefits, without prescribing a new appellate mechanism in this rulemaking.

Amendment of Proposed § 17.154 To Include Term ''Veterans''

One commenter requested that we further revise § 17.154 as proposed to delete the reference to ''ex-members of the Armed Services'' and replace it with a reference to ''veterans.'' We agree and have revised the language of § 17.154 from the proposed rule to read: ''VA may furnish mechanical and/or electronic equipment considered necessary as aids to overcoming the handicap of blindness to blind veterans entitled to disability compensation for a service-connected disability.'' The term ''veteran'' has always been used in 38 U.S.C. 1714, and the regulatory term should follow the statute. In other contexts, there may be a difference between an ''ex-member of the Armed Forces'' and a ''veteran'' because the definition of ''veteran'' in title 38 of the United States Code requires discharge or release from service ''under conditions other than dishonorable,'' 38 U.S.C. 101, whereas no such limitation would appear to apply to an ''ex-member of the Armed Forces.'' In the context of 38 CFR 17.154, however, the change does not alter the meaning of the regulation because § 17.154 refers to an ''ex-member'' who is entitled to service-connected disability compensation and who, therefore, must be a veteran (because such compensation is offered only to veterans discharged or released under conditions other than dishonorable).

The Estimated Number of Respondents per Year

The proposed rule estimated that 100 new service dogs would be provided to veterans each year. Multiple commenters objected to this statement, asserting that this number was far too low of an estimate, and further was not a reflection of veteran need for service dogs but rather a reporting of the number of service dogs that ADI could feasibly provide to veterans each year. The estimated burden of 100 is not an estimate of the number of veterans who may need a service dog. Rather, this number is an estimate of the number of new veterans each year that VA expects to present a certificate showing successful completion of training in order to establish a right to obtain benefits under § 17.148(d). This number was based on the number of veterans who sought to receive new guide dog benefits in fiscal year 2010 under § 17.154 (2010), which was 66, plus an additional number of veterans we estimated who would seek to receive new § 17.148 service dog benefits for hearing and mobility impairments. We estimated the number of veterans who would seek new § 17.148 benefits as a one third increase over confirmed guide dogs for which VA provided benefits the previous fiscal year, and based upon a projection for multiple fiscal years, we arrived at 100 new veterans each year seeking benefits under § 17.148. The estimated number of respondents is not, as theorized by commenters, based on

the anticipated supply of service dogs that could be provided annually by ADI-accredited organizations.

Other commenters asserted that the number of estimated respondents at 100 was underreported in the proposed rule for financial reasons, or that VA could only afford to purchase 100 dogs per year for veterans. We reiterate that under the rule, VA is not actually purchasing the service dogs from any ADI-accredited or IGDF-accredited service dog organization, and we have no financial motive to underreport the estimated number of respondents.

The Estimated Total Annual Reporting and Recordkeeping Burden

Multiple commenters asserted that the proposed rule underreported the expected burden time on veterans to complete necessary administrative requirements to receive benefits under the rule. We clarify that the burden time of less than 5 minutes as stated in the proposed rule only contemplates the submission by the veteran of the certification from the service dog organization that indicates certain training requirements have been met, as required by § 17.148(c). The burden time does not reflect any of the time required for VA to conduct its clinical evaluation to determine whether a service dog would optimally benefit a veteran, nor the independent assessments that a service dog organization conducts thereafter to place a service dog with a veteran. Such time is not part of the veteran's burden to respond to our collection by submitting a certificate. We have intentionally kept paperwork to a minimum in obtaining this benefit because veterans in need of service dogs are generally seriously disabled and because veterans applying for these benefits will already be enrolled in the VA health care system.

This Regulatory Action Is Not Significant Under Executive Order 12866, and Would Not Have a Significant Economic Impact on a Substantial Number of Small Entities

One commenter alleged that the rule should be considered significant under Executive Order 12866, because by limiting the source of service animals to ADI-accredited or IGDF-accredited organizations, VA effectively creates a sole-source contract with those agencies that will have a major impact on the service animal industry. We interpret this commenter's statement to mean that because they believe VA will be purchasing guide and service dogs, that such purchasing will adversely affect in a material way the nature of competition with non-ADI and non-IGDF organizations. We reiterate that VA will not be contracting with any ADI or IGDF organization to actually purchase guide or service dogs, and make no changes to the rule based on this comment.

Multiple commenters argued that the rule would have a significant economic impact on a substantial number of small service dog organizations that are either ineligible for membership in the identified accreditation groups because they do not qualify for tax-exempt status (in the case of ADI accreditation), or because they cannot afford the costs and effort that accreditation entails. We assume that commenters believe that VA will be purchasing the service dogs, and therefore that these nonaccredited organizations would be economically disadvantaged unless they comply with the rule's accreditation requirements. As VA will not be actually purchasing service dogs, we do not believe any non-ADI or non-IGDF organization, as small entities, would experience a significant economic impact. This rule does not prevent individuals from acquiring service dogs from any organization, but only establishes criteria that must be met if VA is then going to provide certain benefits related to those service dogs.

We acknowledge that we require all service dogs obtained after the effective date of the rule to be ADI or IGDF certified, and as such veterans may opt to seek the assistance of ADI or IGDF organizations over other nonaccredited organizations in obtaining such dogs. However, there is no indication that nonaccredited organizations rely on veterans as an essential part of their business. In fact, multiple commenters who themselves were nonaccredited organizations, and who objected to the ADI accreditation standard in the rule, reported providing service dogs to veterans free of charge. There is no evidence to suggest that a substantial number of nonaccredited service dog organizations will be detrimentally affected by a financial incentive for veterans to seek to obtain service dogs from accredited service dog organizations. Even if a substantial number of nonaccredited service dog organizations significantly rely on veterans to buy their service dogs, there is also no evidence to suggest that the cost of obtaining ADI or IGDF certification is beyond the reach of a substantial number of non-accredited organizations.

Commenters questioned the reasoning in the proposed rule for our belief that most service dog providers that provide dogs to veterans are already accredited by ADI or IGDF. See 76 FR 35166. Based on multiple commenters who themselves were non-ADI service dog organizations and who did provide service dogs to veterans, we retract the rationale that ''[w]e believe that most service-dog providers that provide dogs to veterans are already accredited in accordance with the final rule'' and also retract the accompanying statement that ''[t]he vast majority of accredited programs do not provide dogs to veterans.'' However, in view of our conclusion that gaining accreditation should not result in a significant financial burden as explained in the proposed rule notice, 76 FR 35166, this does not change our analysis that the rule does not have a significant economic impact on a substantial number of small entities.

VA Will Not Newly Initiate Proposed or Formal Rulemaking Procedures

Multiple commenters stated that VA should abandon this rulemaking, and that it should begin again with a new proposed rule. One commenter further stated that VA should initiate a public hearing, or should initiate formal rulemaking procedures related to the administration of service dog benefits. We decline to pursue either of these actions, as all affected parties were put on proper notice of the intended provisions in the proposed rule, and there were no significant reasons that commenters put forward to require a new regulatory action that were not addressed in this final rule. We believe we have addressed all significant comments and made changes where appropriate, or have reasonably supported why changes were not made.

For all the reasons noted above, VA is adopting the proposed rule as final with changes as noted to § 17.148(b)(2), (d), (d)(1)(ii), and (d)(3) and § 17.154.

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 at § 17.148 contains new collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). On June 16, 2011, in a proposed rule published in

the **Federal Register**, we requested public comments on the new collections of information. We received multiple comments in response to this notice. A majority of the commenters alleged the collection was an illegal restriction of the access rights of individuals with disabilities. The response, as also stated in the preamble to this final rule, is that a certificate showing adequate service dog training is not necessary to gain access to VA facilities, but rather is only necessary to receive benefits under this rule. Some commenters stated that the number of respondents for this collection was underreported, because more than 100 veterans need service dogs each year. The response, as also stated in the preamble to this final rule, is that the estimated burden of 100 is not an estimate of the number of veterans who may need a service dog, but rather is an estimate of the number of new veterans each year that VA expects to present a certificate showing successful completion of training to obtain benefits. Finally, some commenters asserted that the expected burden time for this collection was underreported. The response, as also stated in the preamble to this final rule, is that the burden time of less than 5 minutes only contemplates the submission of the required certificate, and does not reflect any of the time required for VA to conduct its clinical evaluation to determine if a service dog would optimally benefit a veteran, nor the independent assessments that a service dog organization conducts thereafter to place the service dog with the veteran. Therefore, we make no changes to this collection.

The Office of Management and Budget (OMB) has approved the additional collections in part 17 under OMB Control Number 2900–0785. We are adding a parenthetical statement after the authority citations to the section in part 17 for which new collections have been approved so that the control number is displayed for each new collection.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule 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. We do not believe that gaining accreditation should result in a significant financial burden, as the standards for approval by ADI and IGDF are reasonable thresholds that are generally expected and accepted within the industry. The approximate cost to be an accredited organization by IGDF is a one-time fee of $795, with an annual fee of $318 and a per unit fee of $39.45. The approximate cost to be an accredited organization by ADI is $1000 every 5 years with annual fees of approximately $50. Therefore, pursuant to 5 U.S.C. 605(b), this final rule 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 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 final rule have been examined and it has been determined to not 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 an 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 final 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 are 64.009 Veterans Medical Care Benefits, 64.010 Veterans Nursing Home Care, and 64.011 Veterans Dental Care.

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 July 30, 2012, for publication.

List of Subjects in 38 CFR Part 17

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

Dated: August 30, 2012.

Robert C. McFetridge,

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

For the reasons stated in the preamble, VA amends 38 CFR part 17 as follows:

PART 17—MEDICAL

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

Authority: 38 U.S.C. 501, and as noted in specific sections.

■ 2. Add § 17.148 after the undesignated center heading ''PROSTHETIC, SENSORY, AND REHABILITATIVE AIDS'', to read as follows:

§ 17.148 Service dogs.

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

Service dogs are guide or service dogs prescribed for a disabled veteran under this section.

(b) *Clinical requirements.* VA will provide benefits under this section to a veteran with a service dog only if:

(1) The veteran is diagnosed as having a visual, hearing, or substantial mobility impairment; and

(2) The VA clinical team that is treating the veteran for such impairment determines based upon medical judgment that it is optimal for the veteran to manage the impairment and live independently through the assistance of a trained service dog. Note: If other means (such as technological devices or rehabilitative therapy) will provide the same level of independence, then VA will not authorize benefits under this section.

(3) For the purposes of this section, substantial mobility impairment means a spinal cord injury or dysfunction or other chronic impairment that substantially limits mobility. A chronic impairment that substantially limits mobility includes but is not limited to a traumatic brain injury that compromises a veteran's ability to make appropriate decisions based on environmental cues (i.e., traffic lights or dangerous obstacles) or a seizure disorder that causes a veteran to become immobile during and after a seizure event.

(c) *Recognized service dogs.* VA will recognize, for the purpose of paying benefits under this section, the following service dogs:

(1) The dog and veteran must have successfully completed a training program offered by an organization accredited by Assistance Dogs International or the International Guide Dog Federation, or both (for dogs that perform both service- and guide-dog assistance). The veteran must provide to VA a certificate showing successful completion issued by the accredited organization that provided such program.

(2) Dogs obtained before September 5, 2012 will be recognized if a guide or service dog training organization in existence before September 5, 2012 certifies that the veteran and dog, as a team, successfully completed, no later than September 5, 2013, a training program offered by that training organization. The veteran must provide to VA a certificate showing successful completion issued by the organization that provided such program. Alternatively, the veteran and dog will be recognized if they comply with paragraph (c)(1) of this section.

(d) *Authorized benefits.* Except as noted in paragraph (d)(3) of this section, VA will provide to a veteran enrolled under 38 U.S.C. 1705 only the following benefits for one service dog at any given time in accordance with this section:

(1) A commercially available insurance policy, to the extent commercially practicable, that meets the following minimum requirements:

(i) VA, and not the veteran, will be billed for any premiums, copayments, or deductibles associated with the policy; however, the veteran will be responsible for any cost of care that exceeds the maximum amount authorized by the policy for a particular procedure, course of treatment, or policy year. If a dog requires care that may exceed the policy's limit, the insurer will, whenever reasonably possible under the circumstances, provide advance notice to the veteran.

(ii) The policy will guarantee coverage for all treatment (and associated prescription medications), subject to premiums, copayments, deductibles or annual caps, determined to be medically necessary, including euthanasia, by any veterinarian who meets the requirements of the insurer. The veteran will not be billed for these covered costs, and the insurer will directly reimburse the provider.

(iii) The policy will not exclude dogs with preexisting conditions that do not prevent the dog from being a service dog.

(2) Hardware, or repairs or replacements for hardware, that are clinically determined to be required by the dog to perform the tasks necessary to assist the veteran with his or her impairment. To obtain such devices, the veteran must contact the Prosthetic and Sensory Aids Service at his or her local VA medical facility and request the items needed.

(3) Payments for travel expenses associated with obtaining a dog under paragraph (c)(1) of this section. Travel costs will be provided only to a veteran who has been prescribed a service dog by a VA clinical team under paragraph (b) of this section. Payments will be made as if the veteran is an eligible beneficiary under 38 U.S.C. 111 and 38 CFR part 70, without regard to whether the veteran meets the eligibility criteria as set forth in 38 CFR part 70. Note: VA will provide payment for travel expenses related to obtaining a replacement service dog, even if the veteran is receiving other benefits under this section for the service dog that the veteran needs to replace.

(4) The veteran is responsible for procuring and paying for any items or expenses not authorized by this section. This means that VA will not pay for items such as license tags, nonprescription food, grooming, insurance for personal injury, non-sedated dental cleanings, nail trimming, boarding, pet-sitting or dog-walking services, over-the-counter medications, or other goods and services not covered by the policy. The dog is not the property of VA; VA will never assume responsibility for, or take possession of, any service dog.

(e) *Dog must maintain ability to function as a service dog.* To continue to receive benefits under this section, the service dog must maintain its ability to function as a service dog. If at any time VA learns from any source that the dog is medically unable to maintain that role, or VA makes a clinical determination that the veteran no longer requires the dog, VA will provide at least 30 days notice to the veteran before benefits will no longer be authorized.

(Authority: 38 U.S.C. 501, 1714)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0785.)

■ 3. Revise § 17.154 to read as follows:

§ 17.154 Equipment for blind veterans.

VA may furnish mechanical and/or electronic equipment considered necessary as aids to overcoming the handicap of blindness to blind veterans entitled to disability compensation for a service-connected disability.

(Authority: 38 U.S.C. 1714)

[FR Doc. 2012–21784 Filed 9–4–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[EPA–R09–OAR–2011–0955; FRL–9724–2]

Revisions of Five California Clean Air Act Title V Operating Permits Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval of revisions to the Operating Permits (Title V) programs of the Monterey Bay Unified Air Pollution Control District (MBUAPCD), San Luis Obispo County Air Pollution Control District (SLOCAPCD), Santa Barbara County Air Pollution Control District (SBCAPCD), South Coast Air Quality Management District (SCAQMD), and Ventura County Air Pollution Control District (VCAPCD). We proposed these program revisions in the **Federal Register** on March 21, 2012. These revisions require sources with the potential to emit (PTE) of greenhouse gases (GHGs) above the thresholds in EPA's Tailoring Rule, which have not been previously subject

to Title V for other reasons, to obtain a Title V permit. See ''Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule; Final Rule,'' (the Tailoring Rule) (75 FR 31514, June 3, 2010).

DATES: *Effective Date:* This rule is effective on October 5, 2012.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2011–0955 for this action. Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. Some docket materials, however, may be publicly available only at the hard copy location (e.g., voluminous records, maps, copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Roger Kohn, EPA Region IX, (415) 972–3973, *kohn.roger@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

Table of Contents

I. Proposed Action
II. Public Comments and EPA Responses
III. EPA's Final Action
IV. Statutory and Executive Order Reviews

I. Proposed Action

On March 21, 2012 (77 FR 16509), EPA proposed to approve the following rules as part of the five districts' title V operating permit programs.

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
MBUAPCD	218	Title V: Federal Operating Permits	11/17/10	11/7/11
SLOCAPCD	216	Federal Part 70 Operating Permits	3/23/11	8/19/11
SBCAPCD	1301	Part 70 Operating Permits—General Information	1/20/11	4/21/11
SCAQMD	3000	General	11/5/10	11/5/10
	3001	Applicability.		
	3002	Requirements.		
	3003	Applications.		
	3005	Permit Revisions.		
	3006	Public Participation.		
VCAPCD	33	Part 70 Permits—General	4/12/11	8/19/11
	33.1	Part 70 Permits—Definitions.		

We proposed to approve these rules because we determined that they complied with the relevant CAA requirements. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

EPA's proposed action provided a 30-day public comment period. During this period, we did not receive any comments on our proposal.

III. EPA's Final Action

We did not receive any comments that change our assessment that the submitted rules are consistent with Title V of the Clean Air Act and 40 CFR part 70. Therefore EPA is approving these revisions to the five districts' title V operating permits programs.

IV. Statutory and Executive Order Reviews

Today's action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).In addition, this action does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the action is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon dioxide, Carbon dioxide equivalents, Greenhouse gases, Hydrofluorocarbons, Intergovernmental relations, Methane, Nitrous oxide, Perfluorocarbons, Reporting and recordkeeping requirements, Sulfur hexafluoride.

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

Dated: August 16, 2012.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 70, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 70—[AMENDED]

■ 1. The authority citation for part 70 continues to read as follows:

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

■ 2. Appendix A to Part 70 is amended by adding under ''California'' new

paragraphs (r)(5), (z)(5), (aa)(5), (dd)(5), and (gg)(5) to read as follows:

APPENDIX A TO PART 70—APPROVAL STATUS OF STATE AND LOCAL OPERATING PERMITS PROGRAMS

* * * * *

California

* * * * *

(r) * * *

(5) Revisions were submitted on November 7, 2011. Approval became effective on October 5, 2012.

* * * * *

(z) * * *

(5) Revisions were submitted on August 19, 2011. Approval became effective on October 5, 2012.

* * * * *

(aa) * * *

(5) Revisions were submitted on April 21, 2011. Approval became effective on October 5, 2012.

* * * * *

(dd) * * *

(5) Revisions were submitted on November 5, 2010. Approval became effective on October 5, 2012.

* * * * *

(gg) * * *

(5) Revisions were submitted on August 19, 2011. Approval became effective on October 5, 2012.

* * * * *

[FR Doc. 2012–21683 Filed 9–4–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 86

[AMS–FRL–9716–5]

Nonconformance Penalties for On-Highway Heavy-Duty Diesel Engines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to establish nonconformance penalties (NCPs) for manufacturers of heavy heavy-duty diesel engines (HHDDE) in model years 2012 and later for emissions of oxides of nitrogen (NO_X) because we have found the criteria for NCPs and the Clean Air Act have been met. The NO_X standards to which these NCPs apply were established by a rule published on January 18, 2001. In general, NCPs allow a manufacturer of heavy-duty engines (HDEs) whose engines do not conform to applicable emission standards, but do not exceed a designated upper limit, to be issued a certificate of conformity upon payment of a monetary penalty to the United States Government. The upper limit associated with these NCPs is 0.50 grams of NO_X per brake horsepower-hour (g/bhp-hr).

This Final Rule specifies certain parameters that are entered into the preexisting penalty formulas along with the emissions of the engine and the incorporation of other factors to determine the amount a manufacturer must pay. Key parameters that determine the NCP a manufacturer must pay are EPA's estimated cost of compliance for a near worst-case engine and the degree to which the engine exceeds the emission standard (as measured from production engines).

EPA proposed NCPs for medium heavy duty diesel engines. However, EPA is not taking final action with regard to NCPs for these engines at this time because EPA has not completed its review of the data and comments regarding these engines.

DATES: This rule is effective September 5, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID EPA–HQ–OAR–2011–1000. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy in the docket. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the following location: EPA: EPA Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Chuck Moulis, U.S. EPA, National Vehicle and Fuel Emissions Laboratory, 2000 Traverwood, Ann Arbor, MI 48105; Telephone (734) 214–4826; Email *moulis.charles@epa.gov.*

SUPPLEMENTARY INFORMATION:

Regulated Entities

This action could affect you if you produce or import new heavy-duty diesel engines which are intended for use in highway vehicles such as trucks and buses or heavy-duty highway vehicles. The table below gives some examples of entities that may be affected by these regulations. However, because these are only examples, you should carefully examine the regulations in 40 CFR part 86. If you have questions, call the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

Category	NAICS [a] Codes	Examples of potentially regulated entities
Industry	336112 336120	Engine and truck manufacturers.

[a] North American Industry Classification System (NAICS).

Table of Contents

I. Executive Summary
- A. Purpose of This Action
- B. Summary of Today's Action
- C. Impacts of This Action

II. Overview and Background
- A. Overview
- B. Statutory Authority
- C. Background Regarding Nonconformance Penalty Rules
- D. 2007 and 2010 NO_X Standards

III. Previous Interim Final Rule

IV. NCP Eligibility
- A. First Criterion—Whether the MY2010 NO_X Standard Is More Stringent than the Previous NO_X Standard
- B. Second Criterion—Whether Substantial Work Will Be Required To Meet the MY2010 NO_X Standard
- C. Third Criterion—Whether There Is Likely To Be a Technological Laggard
- D. Issues Raised by the D.C. Circuit Court of Appeals

V. Penalty Rates
- A. Upper Limit
- B. Cost Parameter Values
- C. Resulting Penalties
- D. Consideration of Other Methodologies

VI. Economic Impact

VII. Environmental Impact

VIII. Emission Standards for Which We Are Not Establishing NCPs in This Final Rule
- A. Medium Heavy Duty Diesel NO_X Standards
- B. Light Heavy-Duty Diesel NO_X Standards
- C. Heavy-Duty Gasoline Engine Standards
- D. Heavy-duty Diesel Engine NMHC, CO, and PM Standards

E. Heavy-duty CO_2 Standards
IX. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132 (Federalism)
F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)
G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211 (Energy Effects)
I. National Technology Transfer Advancement Act
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
K. Congressional Review Act
X. Statutory Provisions and Legal Authority

I. Executive Summary

A. Purpose of This Action

Section 206(g) of the Clean Air Act (the Act), 42 U.S.C. 7525(g), directs EPA to promulgate regulations permitting manufacturers of heavy-duty engines or heavy-duty vehicles to receive a certificate of conformity for engines or vehicles that exceed an EPA emissions standard if the manufacturer pays a nonconformance penalty (NCP). This action adopts NCPs for MY2012 and later heavy heavy-duty diesel engines (HHDDE) with respect to the NO_X emissions standards applicable to these engines. Engine manufacturers will be able to receive a certificate of conformity based on either demonstrating compliance with the 0.20 g/bhp-hr NO_X emission standard, or paying NCPs under the penalty formula established in this rule. This provides an alternative compliance option in situations where, as here, EPA has determined that the criteria for establishing NCPs have been met.

B. Summary of Today's Action

EPA proposed that the criteria for setting NCPs had been met for the 0.20 g/bhp-hr NO_X emission standard for HHDDEs, and we are setting NCPs for these diesel engines in this final action.[1] The final NCPs for HHDDE are approximately twice the values proposed. This difference is primarily because of new information received during the public comment period related to fuel and diesel exhaust fluid (DEF) prices. The derivation of the final penalties is described in a support document titled ''Nonconformance Penalties for 2012 and later Highway Heavy-Duty Diesel Engines: Technical Support Document'' (Technical Support Document), which is available in the public docket for this rulemaking. Under the final penalty regulations, nonconforming manufacturer with engines at the upper NO_X limit of 0.50 g/bhp-hr would pay a penalty of $3,775 for each model year 2012 engine it produces. Manufacturers would pay a lesser penalty if the NO_X emissions of the engine are lower. For example, the penalty for a 2012 engine with NO_X emissions at 0.30 g/bhp-hr would be $1,259.

C. Impacts of This Action

NCPs have a small environmental impact. We expect relatively few engine families to be certified under these provisions. Any impacts should be short-term in nature because the penalties are structured to increase over time to discourage use in later model years and because the penalty figures are high enough, such that the increase in the maximum penalty in later model years will likely limit the practical availability of NCPs in future years. In addition, Navistar, the only company that has requested certificates based on the use of NCPs, has publicly announced it will introduce new technology engines in 2013 which will meet the 0.20 g/hp-hr NO_X standard without the need for NCPs.

NCPs generally also have minimal adverse economic impacts. Their use is optional, and manufacturers have historically chosen to use NCPs only when they are otherwise unable to comply with emissions standards. Manufacturers that choose to make use of the NCPs will incur those costs, which are based on the cost of complying with the emission standards.

II. Overview and Background

A. Overview

Section 206(g) of the Clean Air Act (the Act), 42 U.S.C. 7525(g), directs EPA to promulgate regulations permitting manufacturers of heavy-duty engines (HDEs) or heavy-duty vehicles (HDVs) to receive a certificate of conformity for HDEs or HDVs that exceed a Federal emissions standard if the manufacturer pays a nonconformance penalty (NCP). Congress adopted section 206(g) in the Clean Air Act Amendments of 1977 as a response to a concern about manufacturers unable to comply with technology-forcing emissions standards for heavy-duty engines in the lead-time provided for the emissions standards. NCPs were intended to remedy this concern, while ensuring that conforming manufacturers would not suffer a competitive disadvantage compared to nonconforming manufacturers.

The first NCP rule, sometimes referred to as the ''generic'' NCP rule, established three basic criteria for determining the emission standards for which nonconformance penalties would be established in any given model year. 50 FR 35374 (August 30, 1985). The first criterion is that the emission standard in question is a new emission standard or that the standard is an existing standard and becomes more difficult to meet. This can occur in two ways, either by the emission standard itself becoming more stringent, or due to its interaction with another emission standard that has become more stringent. Second, EPA must find that substantial work is required in order to meet the emission standard. Third, EPA must find that it is likely that a manufacturer will be unable to comply by the end of the lead time provided for technological reasons (referred to in earlier rules as a ''technological laggard''). The first NCP rule also established the formula for determining the amount of an NCP. In subsequent NCP rules, EPA made determinations about which emissions standards met the criteria for establishing NCPs, and specified the values for various parameters that are used in the formula to calculate the dollar value of a manufacturer's NCP. The regulations addressing these provisions are in Subpart L of 40 CFR part 86.

EPA proposed that these criteria had been met for the 0.20 g/bhp-hr NO_X emission standard for heavy heavy-duty diesel engines. 77 FR 4736 (January 31, 2012).[2] Although we did not identify the technological laggard in the NPRM, we have since identified Navistar as the manufacturer that needs NCPs. We proposed to establish NCPs because Navistar was unable to achieve the 0.20 g/bhp-hr NO_X standard and did not have sufficient emission credits to cover the 2012 model year. At the time of the proposal, Navistar was attempting to meet the NO_X emission standard with a technology that is different than the approach used by other engine manufacturers. However, Navistar recently announced that it would switch its approach to use the same general technology as the other enginemanufacturers—a catalytic approach called selective catalytic reduction (SCR). As described in Section IV. C., we have determined that

[1] The proposed rule was published at 77 FR 4736 (January 31, 2012).

[2] EPA simultaneously published an Interim Final Rule establishing interim NCPs for heavy heavy-duty engines (77 FR 4678, January 31, 2012).

Navistar will be unable to apply this technology to all of its engine families sold in the U.S. to achieve 0.20 g/hp-hr NO_X for at least several months, and will need NCPs until it completes its transition to the new technology.

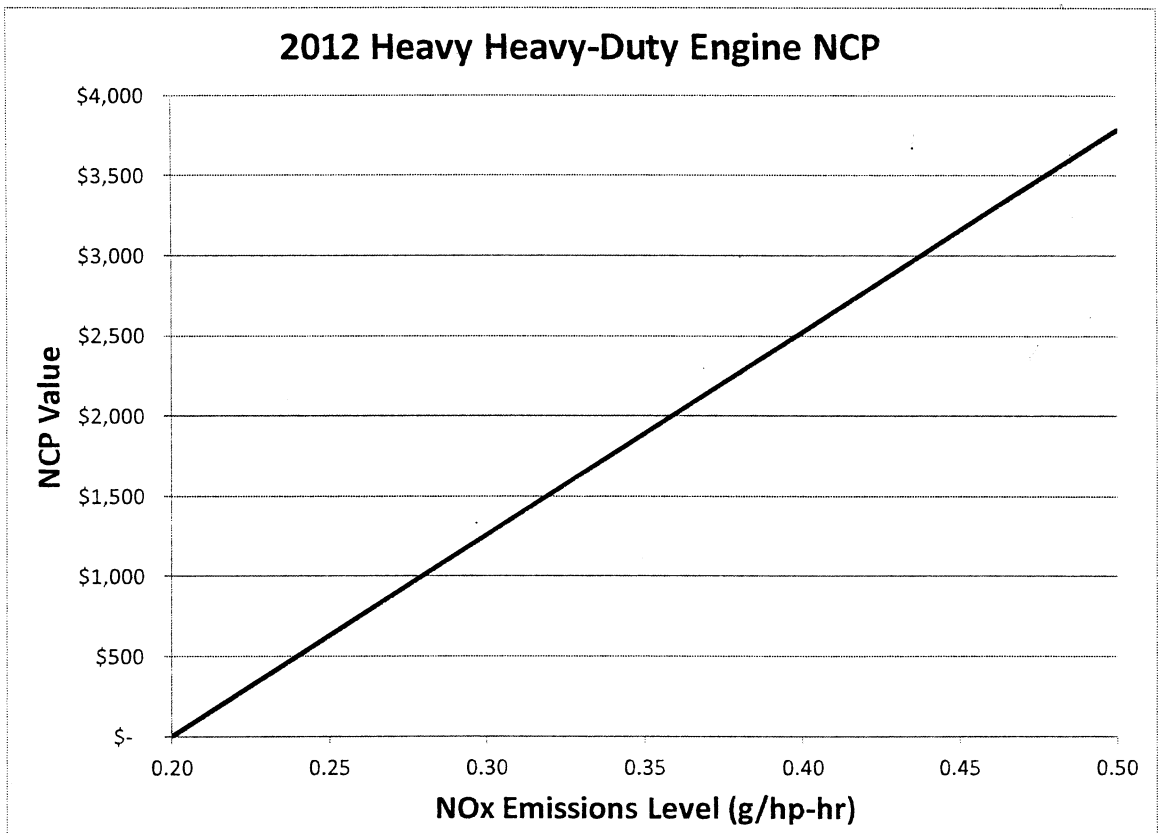
We proposed to base the calculation of the NCPs on the existing regulatory framework, revising only the upper limit and the cost parameters. We also proposed to set the upper limit at 0.50 g/bhp-hr, which means that no manufacturer paying NCPs would be allowed to certify engines with NO_X emissions above this limit. The proposed penalty for HHDDEs at that limit was $1,919 for model year 2012. Consistent with the provisions of the existing regulations, this value reflected our best estimate of the near-worst case cost difference between an engine with NO_X emissions at the upper limit and a compliant engine. The regulations contain provisions to increase the penalties each year for later model years.

The NCPs being finalized for HHDDE are approximately twice the values proposed. This difference is primarily because of new information received during the public comment period related to fuel and diesel exhaust fluid (DEF) prices. The derivation of the final penalties is described in a support document titled ''Nonconformance Penalties for 2012 and later Highway Heavy-Duty Diesel Engines: Technical Support Document'' (Technical Support Document), which is available in the public docket for this rulemaking.

It is important to note that the NCP parameters being finalized were developed using the same basic methodology described in the NPRM. As in all NCP rules, the final NCPs are based on the estimated difference in compliance costs for engines at the upper limit and engines at the standard. Thus, engines with emissions at the upper limit can be considered to be baseline engines for the analysis. These baseline engines also represent the engines against which complying engines could compete in the marketplace.

As shown in Figure 1, a nonconforming manufacturer with engines at the upper NO_X limit of 0.50 g/bhp-hr would pay a penalty of $3,775 for each model year 2012 engine it produces. For later model years, this maximum penalty will increase by several hundred dollars per year as specified in 40 CFR 86.1113–87. While the exact rate of increase will depend on the number of engines for which NCPs are used, the penalty for engines at the upper limit could be more than $5,000 by 2015. Manufacturers would pay a lesser penalty if the NO_X emissions of the nonconforming engine are lower. For example, the penalty for a 2012 engine with NO_X emissions at 0.30 g/bhp-hr would be $1,259.

Figure 1 – Penalty level as a function of compliance level



We received numerous comments on our proposal to establish NCPs. Our detailed analysis of these comments is contained in the Response to Comments document for this rulemaking. The major comments are summarized briefly below.

- Several commenters questioned whether the regulatory criteria for establishing NCPs had been met. These comments are addressed in Section IV.
- Several commenters addressed the level of the penalty, mostly claiming that the penalty needed to be higher to meet the statutory requirement to remove the competitive disadvantage for

complying manufacturers. These comments are addressed in Section V.

• The few comments we received on the upper limit supported setting it at 0.50 g/bhp-hr. These comments are addressed in Section V. A.

• Comments on the methodology used to calculate costs addressed both our proposed methodology and alternative methodologies. Comments on our proposed methodology are discussed in Section V. B. and comments on alternative methodologies are discussed in Section V. D.

NCPs have a small environmental impact. We expect relatively few engine families to be certified under these provisions. Any impacts should be short-term in nature because the increase in the maximum penalty in later model years will likely limit the practical availability of NCPs in future years. The structure of the penalties, by increasing over time, discourages use in later model years; and because the penalty figures are high enough, such that use in later model years is unlikely to be a viable option for any manufacturer.

NCPs generally also have minimal adverse economic impacts. Their use is optional, and manufacturers have historically chosen to use NCPs only when they are otherwise unable to comply with emissions standards. Manufacturers that choose to make use of the NCPs will incur those costs, which are based on the cost of complying with the emission standards.

Section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C. chapter 5, generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. APA section 553(d) excepts from this provision any action that grants or recognizes an exemption or relieves a restriction. Since today's action can be considered to relieve a restriction that would otherwise prevent a manufacturer from certifying, EPA is making this action effective immediately upon publication. This Final Rule does not set new requirements, but rather creates an optional path by which a manufacturer unable to meet the NO_X standard may obtain a certificate of conformity that they could not otherwise obtain without this Final Rule. Thus, the NCPs promulgated in this Final Rule will apply for all engines introduced into commerce on or after September 5, 2012.

B. Statutory Authority

Section 206(g) of the Act, 42 U.S.C. 7525(g), directs EPA to promulgate regulations permitting manufacturers of heavy-duty engines (HDEs) or heavy-duty vehicles (HDVs) to receive a certificate of conformity for HDEs or HDVs that exceed a Federal emissions standard, but do not exceed an upper limit associated with that standard, if the manufacturer pays a nonconformance penalty (NCP) . Congress adopted section 206(g) in the Clean Air Act Amendments of 1977 as a response to a concern with requiring technology-forcing emissions standards for heavy-duty engines. The concern was if strict technology-forcing standards were promulgated, then some manufacturers might be unable to comply in the lead-time provided for the emissions standards and would be forced out of the marketplace. NCPs were intended to remedy this concern. The nonconforming manufacturers would have a temporary alternative that would permit them to receive a certificate of conformity by payment of a penalty, allowing the engines or vehicles to be introduced into commerce and sold. At the same time, conforming manufacturers would not suffer compared to nonconforming manufacturers, because the NCPs would remove the competitive disadvantage to them. NCPs would be based, in part, on money saved by the nonconforming manufacturer. Providing this relief facilitated EPA's authority to set technology forcing standards. Without this relief, EPA may have needed to be more cautious in setting standards, given the possibility that a lagging manufacturer might not be able to meet the standards in the lead-time provided.

Under section 206(g)(1), NCPs may be offered for HDVs or HDEs. The penalty may vary by pollutant and by class or category of vehicle or engine. No NCP-based certificate may be issued if the engine or vehicle exceeds the degree of reduction determined by the Administrator to be practicable. This emission level is identified in the regulations as the upper limit. Section 206(g)(3) requires that NCPs:

• Account for the degree of emission nonconformity;

• Increase periodically to provide incentive for nonconforming manufacturers to achieve the emission standards; and

• Remove the competitive disadvantage to conforming manufacturers.

Section 206(g) authorizes EPA to require testing of production vehicles or engines in order to determine the emission level upon which the penalty is based. If the emission level of a vehicle or engine exceeds an upper limit of nonconformity established by EPA through regulation, the vehicle or engine would not qualify for an NCP under section 206(g) and no certificate of conformity could be issued to the manufacturer. If the emission level is below the upper limit but above the standard, that emission level becomes the ''compliance level,'' which is also the benchmark for warranty and recall liability. The manufacturer who elects to pay the NCP is liable for vehicles or engines that exceed the compliance level in use. The manufacturer does not have in-use warranty or recall liability for emissions levels above the standard but below the compliance level.

C. Background Regarding Nonconformance Penalty Rules

Since the promulgation of the first NCP rule in 1985, subsequent NCP rules generally have been described as continuing ''phases'' of the initial NCP rule. The first NCP rule (Phase I), sometimes referred to as the ''generic'' NCP rule, established three basic criteria for determining the eligibility of emission standards for nonconformance penalties in any given model year. 50 FR 35374 (August 30, 1985). When adopted in 1985, EPA intended to use the criteria of 40 CFR 86.1103–87 in determining whether to establish NCPs. They were included in the regulations to clarify that EPA's obligation under the generic rule to establish NCPs only applied where these criteria were met. As described in Section V. of this Final Rule, we have determined that these criteria have been met.[3]

The first criterion is that the emission standard in question is a new emission standard or that the standard is an existing standard and becomes more difficult to meet. This can occur in two ways, either by the emission standard itself becoming more stringent, or due to its interaction with another emission standard that has become more stringent. Under the second criterion, EPA must find that substantial work is required in order to meet the emission standard. As described in § 86.1103–87(b), EPA considers ''substantial work'' to mean the application of technology not previously used in that vehicle or engine class/subclass, or a significant modification of existing technology, in order to bring that vehicle/engine into compliance. EPA does not consider minor modifications or calibration changes to be classified as substantial work. EPA considers that substantial work is required if such work is needed to bring emissions from the level of the

[3] We note that EPA may revise the criteria at any time through notice and comment rulemaking. Thus, these criteria do not constrain EPA from adopting NCPs in other circumstances, as long as the statutory criteria of section 206(g) are met.

previous standard to the level of the new or revised standard, even if at the time the NCP rulemaking is taking place, some manufacturers have already completed that work. Third, EPA must find that a manufacturer is likely to be noncomplying for technological reasons (referred to in earlier rules as a ''technological laggard''). Prior NCP rules have considered such a technological laggard to be a manufacturer who cannot meet a particular emission standard due to technological (not economic) difficulties and who, in the absence of NCPs, might be forced from the marketplace.

The criteria and methodologies established in the 1985 NCP rule have since been used to determine eligibility and to establish NCPs for a number of heavy-duty emission standards. Phases II, III, IV, V, and VI published in the period from 1985 to 2002, established NCPs that, in combination, cover the full range of heavy-duty; from heavy light-duty trucks (6,000–8,500 pounds gross vehicle weight) to the largest diesel truck and urban bus engines. NCPs have been established for hydrocarbons (HC), carbon monoxide (CO), nitrogen oxides (NO_X), and particulate matter (PM). The most recent NCP rule (67 FR 51464, August 8, 2002) established NCPs for the 2004 and later model year NO_X standard for heavy-duty diesel engines (HDDEs). The NCP rulemaking phases are summarized in greater detail in the Technical Support Document for this rulemaking.

D. 2007 and 2010 NO_X Standards

The 0.20 g/bhp-hr NO_X standard that applies for current and future heavy-duty engines was adopted January 18, 2001 (66 FR 5001), and first applied in the 2007 model year. However, because of phase-in provisions adopted in that rule and use of emission credits generated by manufacturers for early compliance, manufacturers have been able to continue to produce engines with NO_X emissions greater than 0.20 g/bhp-hr. Most engines during the phase-in had NO_X emissions near 1.2 g/bhp-hr. The phase-in provisions ended after model year 2009 so that the 0.20 g/bhp-hr NO_X standard was fully phased-in for model year 2010. Equally important, the cap applicable to Family Emission Limits (FELs)[4] for credit-using engine families was lowered to 0.50 g/bhp-hr beginning in model year 2010. Because of these changes that occurred in model year 2010, the 0.20 g/bhp-hr NO_X emission standard is often referred to as the 2010 NO_X emission standard, even though it applied to engines as early as model year 2007.

III. Previous Interim Final Rule

On January 31, 2012, EPA simultaneously published an Interim Final Rule establishing interim NCPs for heavy heavy-duty engines and a parallel Notice of Proposed Rulemaking (NPRM). The NCPs in this Final Rule will supersede the NCPs that were promulgated in the Interim Final Rule as of September 5, 2012.

Several engine manufacturers petitioned EPA to rescind that Interim Final Rule. These petitions and EPA's responses denying them have been placed into the Docket for this rule.

These engine manufacturers also filed judicial challenges to the Interim Final Rule. *Mack Trucks, et al.* v. *EPA,* No. 12–1077 (DC Cir). They challenged EPA's decision to establish NCPs in an interim final rule without going through notice and comment. They also challenged our finding that the regulatory criteria had been met to promulgate NCPs for the 2010 NO_X standard, as well as our conclusion that the interim NCP levels removed the competitive disadvantage for complying manufacturers. On June 12, 2012, the Court of Appeals for the DC Circuit issued an opinion holding that EPA violated the procedural requirements for rulemaking because EPA did not have good cause to issue the rule without providing notice and opportunity for comment. *Id.,* 2012 U.S. App. LEXIS 11851 (June 12, 2012). The Court did not rule on the merits of EPA's findings about the regulatory criteria or the level of the NCP. Nevertheless, it stated in dicta its concerns about these issues, which are discussed below in Sections IV. (NCP Eligibility) and V. (Penalty Rates).

IV. NCP Eligibility

Section II. C. of this Final Rule notes that EPA regulations provide for three criteria to be met in order to determine that an NCP should be established in any given model year. As is described below, these three criteria address different aspects of the appropriateness of NCPs, and it is important to consider each criterion separately in its own proper context. In general, the first two criteria address whether the standard in question created the possibility that a technological laggards could develop, while the third criterion addresses the likelihood that there will be a technological laggard. For the 2010 NO_X standard, we find that these criteria have been met for heavy heavy-duty diesel engines, and it is therefore appropriate to establish NCPs for this standard for the current model year and later.

A. First Criterion—Whether the MY2010 and Later NO_X Standard Is More Stringent Than the Previous NO_X Standard

The first criterion requires that the emission standard in question must be more stringent than the previous standard. This is the case with the 2010 NO_X standard. The previous emission standard for this category is a combined NMHC + NO_X standard of 2.4 g/bhp-hr, or optionally a 2.5 g/bhp-hr NMHC + NO_X with a limit of 0.5 g/bhp-hr NMHC.[5] The 2010 (*i.e.,* current) standards are 0.20 g/bhp-hr for NO_X and 0.14 g/bhp-hr for NMHC.

Some commenters argued that this standard should no longer be considered a new standard because it went into full effect two model years ago. We did not promulgate NCPs for the 2010 and 2011 model years because we had no basis for concluding it was likely that any manufacturer would qualify as a technological laggard, as all manufacturers met the standard either directly or through application of credits. However, the fact that we did not promulgate NCPs for the first year a standard went into effect does not preclude us from promulgating NCPs for such standard at a later time, when it is determined the regulatory criteria have been met. While it is not a path we have generally taken, nothing in the statute or in our regulations, which refer to new or revised standards, precludes EPA from promulgating NCPs after the first year a new or revised standard goes into effect. See 50 FR 35374, 35376 (August 30, 1985), and 50 FR 9204, 9206 (March 6, 1985).

The first criterion, as with the other two criteria, reflects the key concepts underlying the NCP program—NCPs are designed to address situations where technological laggards are likely to develop in response to the adoption of technology forcing emission standards for this sector under CAA section 202(a)(3)(A). One purpose of section 206(g) is to avoid, at least temporarily, the problem of technological laggards being driven out of the market because of their inability to meet technology forcing emission standards in the lead-time provided. 50 FR 9204, 9205 (March

[4] FELs are emission levels specified by the manufacturer that serve as the applicable emission standard for engines participating in the emission averaging program. The FEL cap is the highest FEL to which a manufacturer may certify an engine using emission credits.

[5] NMHC stands for non-methane hydrocarbons, which is a measure of total hydrocarbons with the methane emissions subtracted out. For typical on-highway diesel fueled heavy-duty engines, methane emissions are on the order of 10 percent of the total hydrocarbon emissions.

6, 1985), 50 FR 35375 (August 30, 1985) (''The possibility of a technological laggard is a key concept in the NCP availability scheme.''). The first criterion is directly linked to this—''This condition creates the possibility for a technological laggard to exist.'' 50 FR 9204, 9206 (March 6,1985).

Given this purpose, the appropriate way to consider whether the new or revised standard is more stringent is to consider it from the point of adoption of the standard, by comparing it to the prior standard. It is at the point that EPA has adopted a standard that may force technology changes, and it is the difference in stringency between the old and the new or revised standard, that raises the possibility of a technological laggard. The passage of time after adoption of the standard does not change the analysis of whether the new or revised standard is or is not more stringent than the previous standard. 50 FR 9204, 9206 (March 6, 1985). Even if EPA considers NCPs some model years after adoption of the standard the comparison under the first criterion is still between the new or revised standard and the prior standard, and their relative stringency.

The first criterion establishes one circumstance that must occur to establish NCPs under the generic rule: a new or revised standard must be more stringent than the previous standard for the pollutant, or an existing standard must become more difficult to achieve. The passage of time by itself, from MY2010 to MY2012, does not change the fact that the MY2010 NO_X standard was and continues to be more stringent than the standard applicable to model years before 2010, and this increase in stringency created the possibility for a technological laggard to exist. The first criterion is thus more in the nature of a static or historic fact, a threshold determination typically made based on the facts in existence at the time of adoption of the new or revised standard, a comparison of the stringency of the previous and the new or revised standard.

Based on this, EPA rejects commenters' arguments. Even though the determination on the first criterion is not being made until some model years after adoption of the 2010 standard, the 2010 NO_X standard has always been a new or revised standard compared to the prior standard, and the 2010 standard was and continues to be more stringent than the preexisting NO_X standard. The passage of time does not change the fact that adoption of a more stringent standard for MY2010 created the possibility for a technological laggard to exist. The 2010 standard is certainly a new or revised standard and certainly is more stringent than the previous standard for NO_X. The fact that we are now in MY2012 does not change this conclusion.

B. Second Criterion—Whether Substantial Work Will Be Required To Meet the MY2010 NO_X Standard

Under the second criterion, substantial work must be required to meet the standard. When we first established the 2010 NO_X standard, we considered it to be a technology-forcing standard and subsequent history has shown that substantial work has been required to meet this emission standard. More importantly, all heavy heavy-duty diesel engines currently certified to the 0.20 g/bhp-hr standard without using credits are using new aftertreatment systems (that were generally not used in 2009) to meet this standard.[6] Indeed, even Navistar substantially redesigned its emission control system in its attempt to achieve lower emissions without NO_X aftertreatment. This work clearly meets the definition of substantial work, as it involves the use of either: New catalytic controls and related technology not previously used in these engines, or the significant modification of existing EGR and related technology. None of the complying manufacturers dispute that they have done substantial work to achieve the 0.20 g/bhp-hr NO_X standard. In fact, they emphasized in their comments how much work they have done to meet the standard.

The second criterion builds on the first criterion, as it involves an evaluation of the nature and degree of the technological challenge of the new or revised standard. If the new or revised standard increases the stringency to such a degree that it cannot be met by simple modifications to existing technology (*i.e.,* that substantial work will be required to comply), then this criterion is satisfied. Like the first criterion, the second criterion reflects the key concern with the issue of a technological laggard—''When manufacturers must perform substantial work, it is possible that at least one will be unsuccessful and will become a laggard.'' 50 FR 9204, 9206 (March 6,1985). Like the first criterion, it is a determination of circumstances that establish a threshold or baseline for setting NCPs under the generic rule. It identifies circumstances that mean there is *a possibility* that a laggard may exist.

Given this purpose, the appropriate way to consider the second criterion is to evaluate all of the work that must be accomplished to move from compliance with the previous standard to compliance with the new or revised standard. The possibility of a technological laggard is created by this entire amount of work that must be done, not any one subset or increment of the work. Thus, if EPA evaluates this criterion at some point after adoption of the new or revised standard, EPA still considers all of the work to go from the previous to the new or revised standard, and not just the work remaining as of the date the determinations are made about compliance with the criteria under the generic NCP rule.

While commenters did not dispute that substantial work was required to meet the 2010 standard, some commenters claim *it is no longer true* that substantial work is required because some manufacturers have met the standard. Some commented that these determinations must be based on the factual circumstances at the time of the NCP rulemaking and not the time the revised standard was issued. We disagree with these claims for two reasons.

First, this criterion is to be evaluated based on the total amount of work needed to go from meeting the previous standard to meeting the current standard, regardless of the timing of such changes. Indeed, the commenters' approach would seem to be directly contrary to the purpose of the statute. The NCP program is designed to allow technological laggards to be able to certify engines even if other manufacturers have met the standard. There is a clear expectation that some manufacturers might be technological laggards. 50 FR 9204, 9206 (March 6,1985) (''When manufacturers must perform substantial work, it is possible that at least one will be unsuccessful and will become a laggard.'') Where there is a technological laggard, it is the typical situation that other manufacturers have already complied or will comply on time. The fact that some manufacturers have surpassed the technological hurdles and achieved compliance with the new or revised standard does not in any way show that there is or cannot be a technological laggard who at least temporarily has not surpassed the technological hurdles. Refusing to establish NCPs solely

[6] For this Final Rule, EPA describes those manufacturers that have achieved the 0.20 g/hp-hr emission standard as ''conforming'', ''compliant'' or ''complying'' manufacturers, and those that have not as the ''nonconforming'', ''noncompliant'' or ''noncomplying'' manufacturers. However, it is important to clarify that manufacturers certifying above the 0.20 g/hp-hr NO_X emission standard using emission credits are in compliance with regulations as long as they have enough emission credits to offset their total NO_X emissions above the standard.

because some manufacturers comply at the time NCPs are established would frustrate Congress' purpose by preventing establishment of NCPs when there is a technological laggard who temporarily can not comply with the standards and cannot certify engines without the NCP program.

Thus, EPA bases the determination of substantial work on the total amount of work to go from compliance with the prior standard to compliance with the new standard, even if at the time of the NCP rulemaking some manufacturers have already completed some or all of such work. Under this criterion, the important question is whether manufacturers who were using technology that met the previous standard would need to conduct significant work to develop new technology or to build upon/change the old technology to meet the revised standard. Questions about work that still needs to be done *at the point EPA begins an NCP rulemaking* are relevant only in the context of the third criterion, whether there is likely to be a technological laggard. To avoid this confusion for future NCPs, we are clarifying in the regulatory text that this criterion is to be evaluated based on the need for new or modified technology or design to meet the new or revised standard regardless of the timing for such changes.

Second, even under the current circumstances, we find that Navistar has needed to do substantial work to meet the standard. This is the case whether one considers the total amount of work to go from the previous standard to the MY2010 NO_X standard, or whether one only considers the amount of work to go from the current status of its technology to compliance with the MY2010 standard. See the discussion below concerning the work conducted by Navistar to date and expected in the future.

We informed engine manufacturers in 2010 that we believed the first two criteria had been met.[7] We note that the commenters now questioning whether these criteria have been met did not dispute our earlier view that we could have set NCPs at that time had we determined that a technological laggard was likely to develop. At that point, EPA was clear that the reason we were not establishing NCPs at that time was because we had not determined that a technological laggard was likely to develop.

C. Third Criterion—Whether There Is Likely To Be a Technological Laggard

Under the third criterion, EPA considers all of the circumstances to determine whether there is likely to be a technological laggard. In the 1985 generic rule EPA indicated that:

> Third, EPA must find that there is likely to be a technological laggard. Even when a standard becomes more stringent (or there is an adverse effect on a previously attainable standard), and even when manufacturers must perform substantial work, all manufacturers may still be able to meet the more stringent standard. For instance, compliance with a standard may involve merely the transference of technology from a similar application. Thus, EPA must make a determination whether the circumstances will likely give rise to a laggard.50 FR 9204, 9206 (March 6, 1985).

One of the concepts underlying a technological laggard is that a manufacturer faced with a new or revised standard, especially one that is technology forcing, will direct substantial resources and effort to develop and employ technology aimed at achieving compliance with the more stringent standard. Whether the manufacturer develops and employs the same or different technology than other manufacturers, there is a possibility that such a manufacturer will be temporarily unable to achieve the emissions standard in the lead time provided based on technological reasons. Instead of refusing to certify the manufacturer's engines, and driving them out of the market, the NCP program is specifically designed to provide a temporary path for certification until the remaining technological issues are resolved and the manufacturer achieves the standard. 50 FR 9204 (March 6,1985). The third criterion is designed to implement this concept, based on EPA's evaluation of all of the circumstances.

In this case, all of the circumstances indicate that there is more than a likelihood that there is an engine manufacturer that has not yet achieved the MY2010 NO_X standard for technological reasons—we have determined that Navistar is in fact such a manufacturer. Unlike the rest of the industry, Navistar attempted to comply without SCR to reduce NO_X emissions.[8] However, to date Navistar has not succeeded in reaching the 0.20 g/bhp-hr emission level. At this time, the only engine families Navistar has certified since the MY2010 standard took effect have used advanced EGR technology, and have been certified based on either banked emission credits or on Navistar's payment of the interim NCPs. Navistar does not have sufficient credits to cover its entire model year 2012 production without NCPs. Navistar has acknowledged in its public comments on this rule that it is effectively a technological laggard. On July 6, 2012, Navistar announced that it has begun the process of redesigning its trucks to use SCR engines in addition to their in-cylinder emission control technology. Navistar expects the SCR engines to be available beginning in early 2013. We have determined that Navistar will need access to NCPs to lawfully produce engines during this multi-month transition process.

Several commenters noted that Navistar cannot be a technological laggard as it has applied for certification of an engine family using this technology, seeking a certificate for a 0.20 g/bhp-hr engine that complies without the use of credits. However, Navistar has withdrawn that application based on EPA concerns that the engine design (with its current hardware) does not meet the 0.20 g/bhp-hr NO_X standard.

While Navistar has announced that it will switch to SCR-based emission controls, we have determined that the work needed for Navistar to redesign all of its U.S. engines and vehicles for its announced alternate compliance path based on SCR cannot be completed immediately. Thus, Navistar will need NCPs during this transition period. These limitations are technological rather than economic in nature. Among the steps Navistar must complete, it must:

- Select an SCR system design
- Make arrangements with component suppliers
- Validate components
- Recalibrate its engine to work with the SCR system
- Redesign it trucks to fit the SCR hardware
- Complete its emission testing and durability testing for certification
- Obtain EPA approval for the new engine-SCR system

We do not have a precise estimate of how long this will take for Navistar's entire U.S. production of heavy heavy-duty diesel engines and associated vehicles. However, based on our experience and knowledge of this industry, this type of technology introduction is not finished in a one or two month period. Navistar has acknowledged as much in their July 6, 2012 announcement, which stated they will begin making the new technology products available in early 2013.

[7] "Nonconformance Penalties for Heavy-Duty Diesel Engines in 2010 Model Year", Letter from Karl J. Simon, Director, EPA Compliance and Innovative Strategies Division, February 22, 2010.

[8] This technology is based on internal engine controls and advanced exhaust gas recirculation technology.

Several commenters argued Navistar voluntarily chose a different technology path than other manufacturers, and could have complied in the lead time provided if it had developed and employed SCR technology from the beginning. Since Navistar chose what the commenters consider to be the wrong technology path, they argue it is a laggard based on its own business decision and not technological limitations. They stated that NCPs should not be established under these circumstances. We generally would agree with commenters' assertions that Navistar presumably could have chosen the same SCR technology path as other manufacturers some time ago, and presumably could have already achieved compliance with the MY2010 standard in the same timeframe they did. If that had occurred, there would be no basis for establishing NCPs. However, we disagree with commenters' conclusions that NCPs should not be established based on this difference in choice of technology pathway.

Navistar made a decision to attempt to meet the emission standard using a different technology path, without SCR. As with most of EPA's mobile source emissions standards, the MY2010 emission standard is a performance standard, and does not specify what technology must be used or require that all manufacturers use the same technology. Commenters' approach would penalize a manufacturer who attempts to innovate and develop a technology pathway different from its competitors. This would effectively discourage technological innovation by requiring all manufacturers to use the same technology once one manufacturer has met the standard using that technology. Otherwise they would risk being driven from the market as no NCPs would be established. Such an interpretation would undercut the purpose of technology forcing standards—to adopt standards where manufacturers may have to develop advanced technology or technology that is at the cutting edge of emissions control. This interpretation would suppress technological innovation out of fear that a wrong technological choice will lead to having to leave a market without the temporary benefit of NCPs. This approach would also ignore the premise of promulgating NCPs, which is that they are appropriate when one or more manufacturers have not met the standard, while one or more others have. Whether the laggard is not able to achieve compliance because of a technological hurdle in developing the same or different technology as their competitors, the result is the same—they risk being removed from the market based on technological issues, if NCPs are not established. EPA does not see a valid basis for drawing such a distinction between technology pathways in deciding whether there is likely to be a technological laggard.

As discussed later, in Section V. on the penalty rate, the provision of NCPs is only a temporary solution for the noncomplying technological laggard. The first-year penalty rate is designed to remove the economic disadvantage for the complying manufacturers, preventing harm to the competitors. The NCP rate also increases over time, such that in a short period of time the noncomplying manufacturer needs to achieve compliance or the increasing penalty rate will in effect drive it from the market. Since the NCP protects a complying manufacturer from a competitive disadvantage irrespective of the technology path chosen by its competitor, it is appropriate that EPA not draw a distinction based on whether the technological laggard chose the same or a different technology path than the complying manufacturers. This helps to preserve the nature of EPA's standards as technology forcing performance standards that promote technological innovation across this sector of industry.

Having made its decision to pursue a non-SCR technology to meet the standards, Navistar has not been able to produce engines that have been certified to meet the 0.020 standard without credits. The evidence is clear that Navistar chose to develop a different technological solution than other manufacturers, and that technological issues concerning this solution have delayed Navistar's ability to meet the standard. It is for this technological reason that Navistar cannot meet the standard, not for economic reasons.

D. Issues Raised by the DC Circuit Court of Appeals

As noted above, in *Mack Trucks, et al.* v. *EPA,* No. 12–1077 (DC Cir), the court included comments in its opinion, *in dicta,* concerning the appropriateness of NCPs under the circumstances presented in the Interim Final Rule. The court stated that:

> We do recognize the pending final rule means our vacatur of the IFR on these procedural grounds will be of limited practical impact. Before the ink is dry on that final rule, we offer two observations about the parameters of this rulemaking. First, NCPs are meant to be a temporary bridge to compliance for manufacturers that have ''made every effort to comply.'' United States v. Caterpillar, Inc., 227 F. Supp. 2d 73, 88 (D.D.C. 2002). As EPA itself has explained, NCPs are not designed to bail out manufacturers that voluntarily choose, for whatever reason, not to adopt an existing, compliant technology. See 77 Fed. Reg. 4,736, 4,739 (Jan. 31, 2012) (''NCPs have always been intended for manufacturers that cannot meet an emission standard for technological reasons rather than manufacturers choosing not to comply.''); 50 Fed. Reg. 35,402, 35,403 (Aug. 30, 1985) (stating that NCPs are inappropriate ''if many manufacturers' vehicles/engines were already meeting the revised standard or could do so with relatively minor calibration changes or modifications''). Based solely on what EPA has offered in the IFR, it at least appears to us that NCPs are likely inappropriate in this case.[9]

The court noted that NCPs are intended to be a temporary bridge to compliance for manufacturers who have ''made every effort to comply'' and are not designed for manufacturers that voluntarily choose, for whatever reason, not to adopt an existing, compliant technology. EPA agrees with these general concepts, but they do not apply in this case. The court's comments concern the issue of whether substantial work is needed to achieve compliance with the MY2010 NO_X standard, and whether Navistar is properly considered likely to be a technological laggard in achieving compliance with this standard in light of the technology pathway it chose. Based on all of the circumstances before EPA, it is reasonable to determine that Navistar has made every effort to comply, for the technology pathway it chose. The need for NCPs is based on the failure to achieve the emissions standards using this technology. This failure is based on technological reasons, and not other reasons.

The court's statement that NCPs were intended for manufacturers that ''made every effort to comply'' (*United States* v. *Caterpillar, Inc.,* 227 F. Supp. 2d 73, 88 (D.D.C. 2002)) was made in a different context and does not apply here. This comment was in response to a suggestion from Caterpillar in that earlier case that the consent decree at issue should have been interpreted in a certain way (or modified) as EPA failed to issue an NCP rule with enough lead time. Caterpillar argued that it was harmed by this delay because the purpose of the NCPs was to allow a manufacturer to weigh the costs of compliance against the costs of paying NCPs. The court rejected this view, as it would allow ''engine manufacturers * * * to calibrate the intensity of their compliance efforts to the NCP for each new standard, allowing them to opt for

[9] *Id.,* slip op. at 15.

noncompliance when compliance becomes more expensive than the NCP. This kind of second-guessing, however, was clearly not Congress' intent in providing for NCPs.'' 227 F.Supp. at 88. The court noted that ''[i]nstead, NCPs were intended to give a manufacturer that has made every effort to comply, but has been unable to achieve compliance, a chance to continue to participate in the market. Thus, NCPs serve their purpose even if promulgated after a company has made its engine design decisions, since those decisions should be based on whether compliance can be achieved, not on whether compliance is less expensive than paying NCPs.'' *Id.* at 88–89.

In that context, it is clear that the court's prior statement addressed the claim that a manufacturer should be able to base their engine design decisions on the availability of NCPs, weighing which costs more and deciding based on this whether to pursue a technology pathway to compliance or pay NCPs. The court made clear that providing this kind of economic choice on compliance is not the purpose of an NCP. The court specifically noted that NCPs are appropriate in a case where the failure to achieve compliance is based on technological concerns encountered along the path to achieving compliance—that is, in circumstances like those in this current rulemaking.

The court's statement was not related to whether, *evaluating in retrospect at the point an NCP is established,* a manufacturer had made every effort to comply prior to adoption of the NCPs. Navistar chose to pursue an engine emissions control design that is non-SCR based several years before NCPs were proposed. NCPs would be used by Navistar while it addresses the technology-based hurdles it now faces in switching to SCR controls. It faces these technology hurdles now as a result of the technology pathway it chose years before the NCP was adopted. The NCPs would not be used, as Caterpillar asked the court to allow in the earlier case, to decide what technology path to follow and how hard to pursue it based on the economics of the cost of NCPs. In this case, Navistar made considerable efforts to develop and employ the non-SCR technology. Its choice of technological pathway to compliance was not based on weighing the costs of compliance with the cost of NCPs. The court's concerns in *Caterpillar* are not applicable to the facts in this NCP rulemaking.

The court also quoted from the generic 1985 rulemaking, noting that NCPs would not be appropriate if ''many manufacturers were already meeting the standard, or could do so with relatively minor calibration changes or modifications.'' This language from the 1985 rulemaking refers to the second criterion, whether substantial work is required to achieve compliance with the more stringent new or revised standard. As discussed above, this is based on all of the work that must be done to move from the previous standard to the more stringent new or revised standard. This criterion is to be evaluated based on actual work needed to go from meeting the previous standard to meeting the current standard, regardless of the timing of such changes. Based on this, the amount of work remaining to be done when the NCP rulemaking occurs is not relevant to the second criterion. Likewise, whether some manufacturers have already achieved compliance at the time of the NCP rulemaking is also not relevant to determining whether the second criterion has been met. As noted above, it is not unexpected that at the time of this NCP rulemaking that ''many manufacturers' vehicles/engines were already meeting the revised standard or could do so with relatively minor calibration changes or modifications.'' However, rejecting NCPs solely because some manufacturers have achieved or are on a path to achieve compliance, while one or more other manufacturers are not in the same position, would prevent lagging manufacturers from certifying in exactly those circumstances Congress contemplated providing for NCPs—some manufacturers are able to achieve compliance in the lead time provided, but for technological reasons others are not. NCPs are designed to address just this situation, to temporarily avoid driving these manufactories out of the market. 50 FR 35374 (August 30,1985).

Clearly, in this case, substantial work was required to meet the 0.20 g/bhp-hr standard. Every manufacturer has included (or will soon include) for the first time NO_X aftertreatment (selective catalytic reduction), on their engines to meet the standard. Prior to deciding to change its technology approach, Navistar also greatly modified its exhaust gas recirculation (EGR) system to reduce NO_X emissions and would likely have needed to do significantly more work to further reduce its NO_X emissions to meet the standard. These are substantial changes to the emission control systems of these engines. While several manufacturers are currently using SCR systems, they were not doing so until they were required to meet the 2010 NO_X standard. Therefore, it is clear that substantial work was needed to go from the previous standard to achieve compliance with the 2010 NO_X standard, and the second criterion is satisfied.

The court also noted that NCPs are not intended in a situation where the failure to achieve compliance is not related to technological reasons, but to a manufacturer's choosing to not employ an available complying technology. As discussed above, EPA agrees that the basis for establishing NCPs must be a technological based laggard. The reasons for not achieving the emissions standard in the lead time provided must be based on a technological failure in developing and employing the chosen technology pathway. The court refers to a statement made by EPA when discussing the relationship between NCPs for the 2010 NO_X standard and credits for the CO_2 emissions standards adopted for heavy-duty engines and trucks.[10] 77 FR 4739 (January 31, 2012). EPA stated it was not providing NCPs for the new CO_2 emissions standard as it was not in a position to determine that a technological laggard was likely to develop for that CO_2 standard. In that context, EPA also determined that an engine that was certified to the 2010 NO_X standard using NCPs should not be able to generate credits at the same time under the CO_2 emissions standards. EPA recognized that there was an interplay between NO_X control and CO_2 control, such that higher levels of NO_X could lead to lower levels of CO_2 emissions. Under those circumstances, providing credits for the CO_2 program could provide an incentive for a manufacturer to increase NO_X emissions but still certify an engine using NCPs, where they could otherwise achieve the NO_X standard without NCPs. That manufacturer could then generate credits under the CO_2 program for the decrease in CO_2 emissions resulting from the increase in NO_X emissions. Thus, the manufacturer would be choosing to not comply with a standard for which it was technologically capable of complying, and would be doing so to generate emission credits that would provide it some advantage in the future. This would not be consistent with either the purpose of the CO_2 credit program (to provide an incentive for manufacturers to take technological and other efforts to over comply with the CO_2 standard) or the purpose of the NCP program (to provide relief to

[10] EPA stated ''NCPs have always been intended for manufacturers that cannot meet an emission standard for technological reasons rather than manufacturers choosing not to comply.''

manufacturers that fail to achieve the standard on time for technological reasons, not for other reasons such as the economic benefit of generating CO_2 credits by voluntarily increasing emissions of NO_X).

EPA's observation in the proposal confirmed that the basic purpose of NCPs is to provide relief where there is a laggard for technological reasons, not other reasons. The concerns raised regarding CO_2 credits and NO_X NCPs are not related to our finding that Navistar is a technological laggard. No one argues that Navistar has failed to achieve a technological solution because of a decision to generate credits or reap economic benefits elsewhere. Instead Navistar's failure to achieve the standard as of this date is based on technological and not other reasons.

This is similar to the circumstances in 2002 when Caterpillar developed its ''ACERT'' technology rather than use cooled EGR technology, which it had been developing until 2001. It needed to use NCPs because of delays in developing ACERT. In that case, Caterpillar did not dispute that cooled-EGR would achieve the necessary emission reductions; rather it chose to attempt to meet the standard using what it believed to be a superior technology.

The court also noted its concern with the level of the penalty in the Interim Final Rule, and whether it adequately removed the economic disadvantage to conforming manufacturers. That issue is addressed in Section V. below.

V. Penalty Rates

This rulemaking is the most recent in a series of NCP rulemakings. These are referred to as Phases and are referenced below.[11] The discussions of penalty rates and related reports and analyses in those rulemakings are incorporated by reference. This section briefly reviews the penalty rate formula originally promulgated in the Phase I rule (currently found at 40 CFR 86.1113–87) and discusses how EPA arrived at the penalty rates in this Final Rule.

The penalty rates being established in this rule rely on the existing NCP regulatory structure. Only a few changes are being made to the regulations. As proposed, we are setting of the upper limit at 0.50 g/hp-hr and are clarifying in § 86.1104–91 that EPA may set the upper limit at: (1) a level below the previous standard if we determine that the lower level is achievable by all engines, or (2) a level above the previous standard if we determine that the standard is not achievable by all engines. We also proposed cost parameters to reflect the compliance costs for the 2010 standards and are finalizing these cost parameters, after revising them based on comments. Finally, in response to comments, we are clarifying that the second NCP criterion is to be evaluated without regard to the specific timing of the NCP rule.

We received many comments supporting higher or lower penalties for a variety of reasons. However, the most important criteria in evaluating the penalties are how they conform to the statutory requirements and how they conform to the regulatory requirements. With respect to the statutory requirements for the penalties in the first year, we note that the purpose of adopting NCPs is to allow a noncompliant manufacturer to continue selling its engines, provided it pays the penalty. However, section 206(g) of the Clean Air Act directs EPA to set the NCPs at a level that will ''remove any competitive disadvantage'' to complying manufacturers. Contrary, to what some commenters suggested, this first year penalty level is not intended to punish the noncomplying manufacturer beyond the level needed to remove any competitive disadvantage for complying manufacturers.

EPA has also set regulatory requirements for penalty levels. Most significantly, the regulations require that penalties be based on total incremental costs of compliance relative to engines at the upper limit, which we have done. In the first NCP rule, it was determined that compliance cost differences between engines at the upper limit and engines at the standard would be appropriate measures of the competitive disadvantage for complying manufacturers.[12] We believe that the final NCPs being established conform to both the regulatory requirements and the statutory requirements.

The NCP rates being adopted in this FRM are specified for model year 2012. As required by section 206(g) of the Act, the existing regulations include a formula that increases (or ''escalates'') the penalty rates with each new model year. The purpose of the escalator is to provide an incentive for manufacturers who use NCPs for more than one model year to achieve compliance quickly rather than continuing to use NCPs for multiple model years.

As proposed, we will apply this annual adjustment formula to the NCPs by setting the 2012 model year as year number one. This is consistent with the existing regulatory text that states that year one is the first year that NCPs are available (see 40 CFR 1113–87(a)(4)). Traditionally, when NCPs are adopted, they are available the first model year the new or revised emission standard applies and there is no question about which model year should be year one for purposes of the annual escalator. However, this is less straightforward for this NCP rule. First, the 0.20 g/bhp-hr first applied beginning in the 2007 model year, as part of a phase-in, but did not take full effect until MY2010. In addition, we are adopting NCPs more than two model years later. While we received comments supporting setting 2010 as the base year, we continue to believe the 2012 model year is the correct year for the first year of the escalator calculation. As discussed further in the Response to Comments document, we are not revising the regulatory text that specifies that year one is the first year that NCPs are available. Using the first year of NCP availability as the first year for the escalator calculation, the initial NCPs (*i.e.,* NCPs during the first model year of availability) remove the disadvantage for the complying manufacturers, as Congress intended. Under this approach, the escalator would apply staring in MY2013, the earliest that any manufacturers could be using NCPs for more than one model year. This ties the initiation of the escalator, and the start of the economic incentive it provides, to the first year in which circumstances that call for such an incentive can exist—the second year of availability. MY2013 is the first year any manufacturer could use this NCP for multiple years. Adding an extra penalty equivalent to two years of escalation is contrary to the intent for this escalation. No manufacturer had access to NCPs prior to 2012, and requiring an escalator based on the two previous years of the standard would treat a manufacturer who uses NCPs in either 2012 or 2013 as if they had already used NCPs for several more years than the actual usage. The additional escalator and related additional incentive is more than is needed to meet the objective of the escalator provision, and therefore is consistent with the purpose of the escalator provision.

We are specifying the NCP formula using the normal NCP parameters: COC_{50}, COC_{90}, MC_{50}, F, and UL. The

[11] The previous NCP rules include: the Phase VI rulemaking (67 FR 51464, August 8, 2002), Phase IV rulemaking (58 FR 68532, December 28, 1993), Phase III rulemaking (55 FR 46622, November 5, 1990), the Phase II rulemaking (50 FR 53454, December 31, 1985) as well as the Phase I rulemaking (50 FR 35374, August 30, 1985).

[12] While we have followed the regulatory formula for determining penalties for this rule, it should be noted that if we were to find that conforming to the regulatory requirements would not conform to the statutory requirements, we would need to revise the regulatory requirements through rulemaking.

NCP formula is the same as that promulgated in the Phase I rule. As was done in previous NCP rules, we consider incremental manufacturer costs and incremental owner costs (for complying engines relative to the upper limit), but do not consider certification costs because both complying and noncomplying manufacturers must incur certification costs. COC_{50} is an estimate of the industry-wide average incremental cost per engine (references to engines are intended to include vehicles as well) associated with meeting the standard for which an NCP is established, compared with meeting the upper limit. COC_{90} is an estimate of the 90th percentile incremental cost per engine associated with meeting the standard for which an NCP is established, compared with meeting the associated upper limit. Conceptually, COC_{50} represents costs for a typical or average manufacturer, while COC_{90} represents costs for the manufacturers with the highest compliance costs.

MC_{50} is an estimate of the industry-wide average marginal cost of compliance per unit of reduced pollutant associated with the least cost effective emission control technology installed to meet the new standard. MC_{50} is measured in dollars per g/bhp-hr for heavy-duty engines. F is a factor used to derive MC_{90}, the 90th percentile marginal cost of compliance with the NCP standard for engines in the NCP category. MC_{90} defines the slope of the penalty rate curve near the standard and is equal to MC_{50} multiplied by F. UL is the upper limit above which no engine may be certified.

The derivation of the cost parameters is described in a support document titled ''Technical Support Document: Nonconformance Penalties for 2012 and later Highway Heavy-Duty Diesel Engines'' (Technical Support Document), which is available in the public docket for this rulemaking. All costs are presented in 2011 dollars. The Technical Support Document also includes alternative cost analyses that were considered. These alternative analyses are discussed in Section V.D of this preamble.

A. Upper Limit

The upper limit (UL) is the emission level established by regulation above which NCPs are not available. A heavy duty engine cannot use NCPs to be certified for a level above the upper limit. CAA section 206(g)(2) refers to the upper limit as a percentage above the emission standard, set by regulation, that corresponds to an emission level EPA determines to be ''practicable.'' The upper limit is an important aspect of the NCP regulations not only because it establishes an emission level above which no engine may be certified using NCPs, but it is also a critical component of the cost analysis used to develop the penalty rates. The regulations specify that the relevant costs for determining the COC_{50} and the COC_{90} factors are the difference between an engine at the upper limit and one that meets the applicable standards (see 40 CFR 86.1113–87).

The regulatory approach adopted under the prior NCP rules sets the upper limit at the prior emission standard when a prior emission standard exists and is then changed to become more stringent. EPA concluded that this upper limit should be reasonably achievable by all manufacturers with engines or vehicles in the relevant class. It should be within reach of all manufacturers of HDEs or HDVs that are currently allowed so that they can continue to sell their engines and vehicles while finishing their development of fully complying engines. A manufacturer of a previously certified engine or vehicle should not be forced to immediately remove an HDE or HDV from the market when an emission standard becomes more stringent. The prior emissions standard generally meets these goals because manufactures have already certified their vehicles to that standard.

In the NPRM, we proposed to revise the regulations in § 86.1104–91 to clarify that EPA may set the upper limit at a level below the previous standard if we determine that the lower level is achievable by all engines or vehicles in the relevant subclass. That provision of the regulations was not opposed by any commenters and is included in this final rule. We are also finalizing the upper limit at 0.50 g/bhp-hr, which was widely supported by commenters. For this rule, all manufacturers are currently certifying all of their engines at or below the 0.50 g/bhp-hr FEL cap, providing clear evidence that this level can be met by all manufacturers. The reason EPA has rejected past suggestions that the upper limit should be more stringent than the prior emission standard does not apply here, as there is no difficulty in this case in identifying a limit that could be met by all manufacturers. See 50 FR 35377 (August 30, 1985). Thus, setting the upper limit for this NCP rule at 0.50 g/bhp-hr NO_X conforms to the purpose of the upper limit in setting NCPs.

As proposed, we are also specifying that EPA could set the upper limit at a level above the previous standard in unusual circumstances, such as where a new standard for a different pollutant or other requirement effectively increases the stringency of the standard for which NCPs would apply. This occurred for heavy heavy-duty engines with the 2004 standards. While this change would not apply for this current NCP rulemaking, we proposed to add this clarification to make the regulations consistent with past practices.

B. Cost Parameter Values

The regulations being adopted specify that the values in Table 1 be used in the NCP formula for the 2012 and later model year NO_X standard of 0.20 g/bhp-hr for heavy heavy-duty diesel engines. The basis is summarized here. The complete derivation of these parameters and a discussion of other approaches that were considered are described in the Technical Support Document for this rulemaking.

TABLE 1—NCP CALCULATION PARAMETERS

Parameter	*Heavy heavy-duty diesel engines*
COC_{50}	*3,219*
COC_{90}	*$3,775*
MC_{50}	*$10,729 per g/bhp-hr*
F	*1.173*
UL	*0.50 g/bhp-hr*

Some commenters argued that EPA should not deviate from prior precedents for calculating costs. However, EPA has not used the same methodology in calculating costs in each of the previous NCP rules. In each of our six previous NCP rulemakings, we estimated costs using a methodology appropriate for the specific circumstances that applied at the time. None were approached in exactly the same way. In each case we considered key factors such as differences in calibration, hardware, and operating costs, but there have been some NCP calculations where other potential individual cost or cost saving elements have been included or excluded for various reasons. In determining how to calculate costs of compliance, EPA considers not only what data are available, but also the extent to which each cost element may affect the competitive balance of the market.

The NCP parameters being finalized were developed using the same basic methodology described in the NPRM. As in all NCP rules, the final NCPs are based on the estimated difference in compliance costs for engines at the upper limit and engines at the standard. Thus, engines with emissions at the upper limit can be considered to be baseline engines for the analysis. These baseline engines also represent the

engines against which complying engines could compete in the marketplace. In this analysis, the most important baseline engine is the engine used as the baseline for calculating the nominally worst case compliance costs (COC_{90}). As is described later, because the penalty curve being finalized in this NCP rule is a straight line, the value of COC_{50} does not affect the penalty curve.

The cost parameters being finalized are higher than the values proposed. These changes reflect new information received during the public comment period, most notably new updated information about fuel and DEF prices that was not available at the time we completed the cost analysis for the proposal. EPA also received comments suggesting that the effectiveness of the heavy heavy-duty NCPs in meeting the statutory requirement to remove competitive disadvantage for complying manufacturer needs to be evaluated relative to engines that could be developed in the near term (such as a reoptimized SCR engine). In response to these comments and the new information received, EPA is revising the COC_{90} baseline engine because we believe that the revised baseline engine better represents an optimized engine than the baseline engine used for the proposal. These changes are discussed in more detail below.

The Clean Air Act's requirements to ''remove any competitive disadvantage'' to complying manufacturers effectively requires EPA to consider not only existing engines with NO_X emissions over the standard, but also engines that could reasonably be developed during the period in which NCPs are available. Thus, the NCPs must be high enough to protect complying manufacturers from a competitive disadvantage relative both to SCR engines that are optimized to emit NO_X at a level of 0.50 g/bhp-hr and to engines without SCR that emit at that level. We considered several methodologies for estimating the incremental compliance costs between the upper limit and the standard and selected the approach that best removes the potential competitive disadvantage for complying manufacturers. See Section V. D. for additional discussion of these alternate approaches.

It is important to note that while we received comments stating that the level of our proposed NCP was not high enough to remove the competitive advantage Navistar has selling non-SCR engines, none of the commenters provided evidence that this was the case (such as evidence of increased market share or increased profits for Navistar). None of the commenters provided any method by which the value of Navistar's actual competitive advantage could be calculated. Nevertheless, we have determined based on the information available to us that Navistar's competitive advantage is not greater than the competitive advantage based on compliance costs that we calculated relative to the reoptimized SCR baseline engine we have used as the basis of our COC_{90} costs.

(1) General Methodology

Our approach to estimating compliance costs differs slightly from that used in recent NCP rules, where EPA based the NCPs directly on the actual compliance cost increases associated with meeting the standard for complying manufacturers (borne by the complying manufacturers and the operators who purchase their compliant engines), whether provided by the manufacturers or estimated by EPA. This was appropriate in those prior rules because each of the manufacturers had actually produced engines at the upper limit (which was usually the previous emission standard) and had reengineered those engines to meet the new or revised standard, so the costs associated with that change were straightforward to calculate. We determined that the manufacturers' input accurately reflected the manufacturers' actual costs because the costs were derived directly from actual in-production engine information. In the case of this NCP rule, however, compliant manufacturers have generally not designed and optimized their in-production engines for the U.S. market at 0.50 g/bhp-hr NO_X (the upper limit) and then reengineered their engines to meet the 0.20 g/bhp-hr standard.[13] Thus, a compliance cost estimate based directly on actual experience for the full range of in-production engines was not available for this NCP rule.

Instead of averaging actual cost increases relative to the upper limit (because none were available), the NCP penalty formulas for this rule are based primarily on EPA's estimate of the cost difference between a hypothetical engine emitting at the upper limit (the ''baseline engine'') and one emitting at the standard (the ''compliant engine''). We received compliance cost information from several engine manufacturers, both before the proposal and during the comment period, and used that information to inform our own analysis of compliance costs, as described in the Technical Support Document.

It is worth noting that each of the engine manufacturers that provided cost information before the proposal considered baseline engines with different technology packages. However in their comments on the proposal, complying manufacturers based their compliance costs on either a baseline engine equipped with similar hardware as EPA's revised baseline engine, or based on a pre-2010 non-SCR engine with NO_X emissions near 1.2 g/bhp-hr. See Section V. D. of this notice for a discussion of why using the 1.2 g/bhp-hr baseline engine is not appropriate.

As noted earlier, with NCPs available, a complying manufacturer could compete against not only EGR-equipped engines, but also against SCR-equipped engines that could be reoptimized to emit at 0.50 g/hr-hr. Since engine manufacturers are not currently producing SCR-equipped heavy heavy-duty engines at the upper limit, such engines must be considered based on our best estimate of how such an engine would be manufactured. Based on our review of the various hypothetical baseline engine designs, we proposed to use as a baseline engine our best estimate of an optimized SCR engine, because we believed it would be the most competitive 0.50 g/bhp-hr engine. Information available at that time projected little difference when comparing fuel and DEF prices, so for the proposal we assumed the baseline engine would have been optimized to use less DEF compared to 0.20 g/bhp-hr engines but had the same fuel consumption rates.[14] We did not believe there would be a significant difference in costs using a baseline engine optimized for better fuel consumption, because we projected that fuel savings would have been offset by increased DEF costs. As is described in the Technical Support Document, for the proposal we also believed estimating costs by this approach was the least speculative method to determine compliance costs, and we did not believe there were competing designs that were substantially more competitive based on the compliance cost inputs we used.

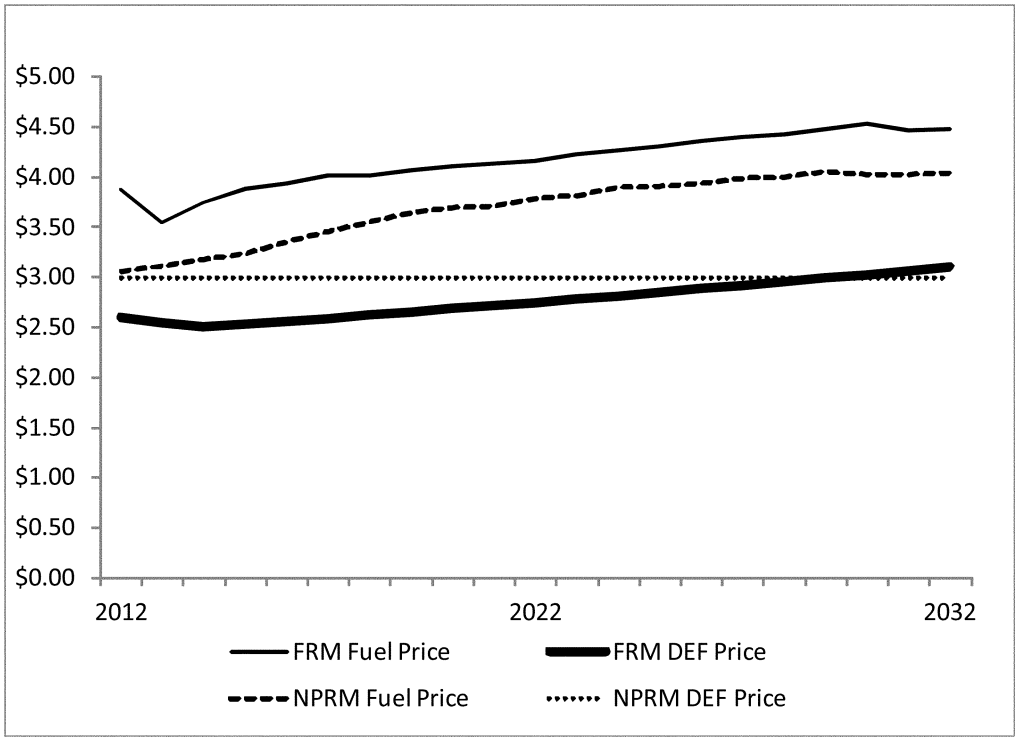
[13] Note that Cummins is using emission credits to certify one medium heavy-duty engine family with a NO_X FEL at 0.50 g/hp-hr. While costs associated with this medium heavy-duty engine cannot be used directly for heavy heavy-duty engines, as described in the Final TSD, related confidential cost information provided by Cummins was used to significantly inform our cost analysis.

[14] The proposal was based on the Energy Information Administration's 2011 fuel price projections and the retail price of DEF in October 2011; this Final Rule is based on the Energy Information Administration's 2012 fuel price projections and the DEF price projection from Integer Research. See Chapter 3 of the Technical Support Document for additional detail.

Based on new information and comments we received, we are revising our baseline engine for the heavy heavy-duty service class. Specifically, as is described below, we are revising the COC_{90} baseline engine to be more optimized for low fuel consumption at 0.50 g/bhp-hr NO_X than was assumed for the proposal. For the proposal, we estimated that reducing NO_X emissions from 0.50 g/bhp-hr to 0.20 g/bhp-hr would require an increase in DEF consumption but would not change fuel consumption because we projected that there would be little price difference between DEF and fuel. However, we now have new information indicating that fuel prices will likely be at least one dollar per gallon higher than DEF prices for the foreseeable future. We agree with commenters that engine manufacturers designing engines for 0.50 g/bhp-hr NO_X would have responded (and could still respond) to this price difference by optimizing their existing 0.20 g/bhp-hr SCR engine designs to have slightly higher engine-out NO_X, which would reduce fuel consumption, and reduce the excess NO_X by increasing DEF consumption. Thus compared to this revised baseline engine, a compliant engine would have higher fuel consumption but lower DEF consumption.

We are now projecting that DEF prices will be at least one dollar less per gallon than diesel fuel prices for the foreseeable future (as shown in Figure 2), and the appropriate baseline engine is one that would have been designed to take advantage of this price difference. We have updated our fuel price projections using the Energy Information Administration's (EIA) Annual Energy Outlook 2012 (AEO2012) to project fuel prices through 2035. EIA is now projecting diesel fuel prices will be about fifty cents more per gallon than was projected in 2011. We have also revised our projection of DEF prices based on information from Integer Research provide by commenters. While we proposed using a constant DEF price through 2042 (because we did not have any projections for future DEF prices at the time we developed the proposal), we are now projecting that DEF prices will fall for the next few years, and then increase as the price of natural gas increases (using AEO2012 projections).[15]

Figure 2 Proposed and Final Fuel and DEF Price Projections



The current baseline engine is similar, but not identical, to what we proposed with respect to hardware. As proposed, the baseline engine technology package would employ the same basic emission controls used to meet the 2007 NO_X and PM emission standards (*e.g.* cooled exhaust gas recirculation (EGR), optimized turbo-charging, optimized fuel injection, diesel particulate filters), plus liquid urea based selective catalytic reduction (SCR) NO_X emissions control technology with an appropriately sized tank for the liquid urea (also known as diesel emission fluid or ''DEF''). However, we now believe the baseline engine could have used less expensive hardware than we proposed. We continue to believe that manufacturers could reduce the size of the SCR catalyst if they were allowed to meet a higher NO_X emission limit. In addition, we now believe that they could also reduce the precious metal loading of the diesel oxidation catalyst (DOC), and lower the cost of the turbocharger. Thus, the hardware component of the compliance costs has gone up from what we proposed (*i.e.,* the cost of the hardware on the baseline engine has gone down). Further details are provided in this rule's Technical Support Document.

(a) Calculated Values

The most significant of the NCP parameters is the 90th percentile costs

[15] Natural gas is used in the production of urea, a primary component of DEF.

of compliance, COC_{90}, which defines the penalty for engines emitting at the upper limit. The value of COC_{50} is important only when EPA estimates that marginal compliance costs change as the compliance level approaches the standard. In such cases, COC_{50} defines that point on the curve at which the slope changes. However, for this NCP rule we believe that because of the narrow emission range between the upper limit and the standard (0.20 to 0.50 g/bhp-hr), it is appropriate to assume that marginal compliance costs are constant. Thus, we are not summarizing our derivation of COC_{50} in this preamble since its value does not affect the penalty amounts. See the Technical Support Document for a discussion of COC_{50}.

We estimated COC_{90} by assuming the baseline engine would have been an SCR equipped engine with tailpipe NO_X emissions at 0.50 g/bhp-hr and that it would have looked very similar to an engine with tailpipe NO_X emissions at 0.20 g/bhp-hr. However, as noted above, the higher NO_X emissions of the baseline engine would allow the use of less expensive hardware and would be calibrated to minimize the combined consumption of fuel and DEF. As described in more detail in the Technical Support Document, we estimated reasonable 90th percentile (or worst case) costs associated with bringing such a baseline engine into full compliance with the 0.20 g/bhp-hr NO_X emission standard.[16] We note that the average costs associated with SCR may well be lower than the 90th percentile costs presented here.

We estimate that the SCR hardware used by a complying manufacturer (*i.e.,* an SCR system that would achieve 0.20 g/bhp-hr NO_X) cost the manufacturer $5,522 per engine for the 90th percentile engine compared to an engine emitting at 1.2 g/bhp-hr. We estimate that the baseline hardware (*i.e.,* an engine and SCR system that would achieve 0.50 but not 0.20 g/bhp-hr NO_X) for the 90th percentile engine would have cost the manufacturers only $4,441 (including R&D, warranty, and other overhead costs) after hardware savings associated with the DOC and turbocharger are deducted. Therefore, the manufacturers would have to spend $1,081 more in hardware, R&D, warranty and other overhead costs to produce a 0.20 g/bhp-hr engine than it would have cost to produce a 0.50 g/bhp-hr engine. We calculated the difference in operating costs the same way.

These COC_{90} costs are summarized in the Table 2. The values in the tables are the costs that would be incurred by a manufacturer or operator for a model year 2012 0.20 g/bhp-hr engine relative to a 0.50 g/bhp-hr baseline engine. All operating costs are presented as net present value (NPV) relative to 2012 using a 7 percent discount rate.[17] For example, we estimate that the NPV of the lifetime fuel cost of a 0.20 g/bhp-hr engine would be $8,833 higher than the fuel cost for a baseline engine, but the NPV of DEF costs would be $6,191 lower.

TABLE 2—COC_{90} DOLLAR-PER-ENGINE † COSTS

[2011 dollars]

	FRM COC_{90}	NPRM COC_{90}
Lifetime Fuel Costs	$8,833	$0
Lifetime DEF Costs (Savings)	(6,191)	1,374
Hardware Costs	927	474
Research and Development Cost	19	9
Warranty and Other Manufacturer Costs	135	62
Operator Repair Costs	52	0
Total Cost	3,775	1,919

† Although penalties are accessed per engine, costs include vehicle costs.

We estimated the marginal costs of compliance as being equal to the total incremental costs of compliance divided by 0.30 g/bhp-hr (the difference between the upper limit and the standard). This assumes that the cost to reduce emissions from 0.30 g/bhp-hr to 0.20 g/bhp-hr is not significantly different from the cost to reduce emissions from 0.50 g/bhp-hr to 0.40 g/bhp-hr. This results in a penalty curve that is a straight line, which in turn makes our estimate of the average cost of compliance irrelevant to the calculation of the penalty. In other words, the COC_{50} point lies directly between zero cost at 0.20 g/bhp-hr and COC_{90} at the Upper Limit of 0.50 g/bhp-hr NO_X. The penalty paid for engines at any compliance level between the standard and the upper limit would be equal to EPA's estimate of the highest marginal cost paid by a complying manufacturer for the same emission range.

C. Resulting Penalties

The calculation parameters listed in Table 1are used to calculate the penalty rate. These parameters are used in the penalty rate formulas which are defined in the existing NCP regulations (See 40 CFR 86.1113(a)(1) and (2)). Using the parameters in Table 1, and the equations in the existing NCP regulations, we have plotted penalty rates versus compliance levels in Figure 1 above. This penalty curve is for the first year of use of the NCPs (*i.e.,* the annual adjustment factors specified in the existing NCP regulations have been set equal to one). The maximum first year penalty is equal to COC_{90}, which is $3,775.

The Clean Air Act NCP provisions require that the penalty be set at such a level that it removes competitive disadvantage for a complying manufacturer. For the reasons described in the Technical Support Document, we believe that the NCPs being established in this rulemaking fulfills this requirement.

D. Consideration of Other Methodologies

We received comments suggesting how we should revise our estimated costs, if we continued to use the proposed methodology. Where appropriate, we incorporated these concepts into our final cost

[16] The Act requires that we remove competitive disadvantage for complying manufacturers. We recognize that there is uncertainty in our estimates. To ensure that we protect the complying manufacturer our overall approach is somewhat conservative. See the Technical Support Document for additional discussion of how we addressed uncertainty in our estimates.

[17] Penalties are calculated based on costs for a model year 2012 engine. The regulations include separate provisions to increase penalties for later model years.

methodology. We also received comments arguing that we should change our methodology. However, as described in the Technical Support Document, we determined that the other methodologies were not appropriate.

Our primary methodology estimates the difference in lifetime compliance costs between a compliant 0.20 g/bhp-hr engine and a 0.50 g/bhp-hr engine that we believe would have the greatest competitive advantage over the compliant engine. As noted earlier, we believe that an SCR engine optimized for 0.50 g/bhp-hr would have the greatest competitive advantage over compliant engines. Two of the other approaches we considered would have involved using non-SCR engines as the baseline engines, as suggested by some commenters. However, as described below, we determined that these approaches would not sufficiently remove the potential competitive advantage of an optimized SCR engine.

In the first approach we considered using a 0.50 g/bhp-hr EGR engine (such as the engines Navistar is currently selling) as the baseline engine. This option was supported by one manufacturer during preproposal discussion, but was not supported in any comments on the NPRM. Nevertheless, we evaluated this approach to ensure that our methodology is the most appropriate one. Specifically, we estimated the hardware and operating costs associated with adding SCR to a non-SCR engine to meet the 0.20 g/bhp-hr standard. As is described in the Technical Support Document, we estimated that there would be significant hardware costs to add SCR plus significant operating costs for DEF consumption. However, these would be mostly offset by the fuel savings associated with SCR engines, plus hardware savings from down-sizing the EGR system. The combined effect would be to make the costs of going from the EGR engine to the compliant engine lower than the costs of going from the baseline SCR engine to the compliant engine. Put another way, this means that the cost savings of changing from a compliant engine to an EGR-only engine are smaller than the cost savings of changing from a compliant engine to the baseline SCR engine, indicating that an EGR engine at 0.50 g/bhp-hr would have a smaller competitive advantage than the baseline engine we used to develop the final NCPs. Moreover, this means that NCPs based on this approach would not remove the competitive disadvantage to complying manufacturers, where manufacturers of optimized SCR engines could pay the lower NCP and still have a competitive advantage over compliant engines.

In the second approach, we considered setting an upper limit at 1.2 g/bhp-hr and including the full cost of SCR as the compliance cost. As was true for the previous approach, we estimated that most of the hardware and DEF costs would be offset by the fuel savings, making the NCP at 0.50 g/bhp-hr lower than our estimate of the competitive advantage for SCR engines optimized for 0.50 g/bhp-hr. This means that setting the upper limit at 1.2 and calculating costs in this way would not remove the competitive disadvantage for complying manufacturers compared to a manufacturer who optimized its SCR engine for 0.50 g/bhp-hr NO_X. Note that while we evaluated this approach with respect to costs and competitive disadvantage, we think that there are other reasons why it would not be appropriate to set the upper limit at 1.2 g/bhp-hr. In particular, the upper limit may not be set at a level that is higher than the level that EPA determines is practicable, which would be no higher than 0.50 g/bhp-hr.

Finally, we considered other scenarios in which the baseline engine would have been an SCR engine that was fundamentally redesigned to have NO_X emissions at 0.50 g/bhp-hr (rather than reoptimizing an existing design). For example, some manufacturers have suggested that it would be possible to redesign engines to meet 0.50 g/bhp-hr without cooled EGR. This could result in significant savings for hardware and warranty costs. We determined that, while it may well be technologically possible to redesign current SCR engines to meet 0.50 g/bhp-hr NO_X with significantly lower hardware costs, there is no business scenario in which such savings would justify paying an NCP. Fundamentally redesigning an engine would take a minimum of two years and involve substantial capital costs. So a manufacturer that began redesigning its engines today could not expect to have the new engine ready for production before model year 2015. At that point, the annual adjustments to the NCPs would have increased the penalty substantially. Moreover, using NCPs in model year 2015 and later would result in a rapidly increasing penalty due to the annual adjustment factors, so a manufacturer would need to recover all of its investments within one or two model years. However, this would require the manufacturer to raise its prices so much that it would make its engines uncompetitive in the marketplace.

VI. Economic Impact

Because the use of NCPs is optional, manufacturers have the flexibility and will likely choose whether or not to use NCPs based on their ability to comply with emissions standards. If no manufacturer elects to use NCPs, these manufacturers and the users of their products will not incur any additional costs related to NCPs. NCPs remedy the potential problem of having a manufacturer forced out of the marketplace due to that manufacturer's inability to conform to new, strict emission standards in a timely manner. Without NCPs, a manufacturer which has difficulty certifying HDEs in conformance with emission standards or whose engines fail a Selective Enforcement Audit (SEA) has only two alternatives: fix the nonconforming engines, perhaps at a prohibitive cost, or prevent their introduction into commerce. The availability of NCPs provides manufacturers with a third alternative: continue production and introduce into commerce upon payment of a penalty an engine that exceeds the standard until an emission conformance technique is developed. Therefore, NCPs represent a regulatory mechanism that allows affected manufacturers to have increased flexibility. A decision to use NCPs may be a manufacturer's only way to continue to introduce its products into commerce.

VII. Environmental Impact

When evaluating the environmental impact of this rule, one must keep in mind that, under the Act, NCPs are a consequence of enacting new, more stringent emissions requirements for heavy duty engines. Emission standards are set at a level that most, but not necessarily all, manufacturers can achieve by the model year in which the standard becomes effective. Following International Harvester v. Ruckelshaus, 478 F. 2d 615 (DC Cir. 1973), Congress realized the dilemma that technology-forcing standards could potentially cause, and allowed manufacturers of heavy-duty engines to certify nonconforming vehicles/engines upon the payment of an NCP, under certain terms and conditions. This mechanism was intended to allow manufacturer(s) who cannot meet technology-forcing standards immediately to continue to manufacture nonconforming engines while they tackle the technological problems associated with meeting new emission standard(s). Thus, as part of the statutory structure to force technological improvements without driving manufacturers or individual engine models out of the market, NCPs

provide a flexibility that fosters long-term emissions improvement through the setting of lower emission standards at an earlier date than could otherwise be feasible. Because NCPs are designed to increase with time, manufacturers using NCPs are likely to reduce emission levels to meet the standard as quickly as possible, which minimizes the environmental impact.

As is always the case with NCPs, the potential exists for there to be more extensive use of NCPs beyond what is projected at this time, where we project use by one manufacturers for a limited number of model years. For example, depending upon the penalty rate and other factors, some otherwise fully compliant manufacturers could elect to pay the NCP in order to reconfigure their 0.20 g/bhp-hr NO_X compliant engines to emit up to 0.50 g/bhp-hr so that they can re-optimize engine hardware and vehicle operating costs. This potential action is not without R&D and other financial costs to the manufacturer and thus is not a decision which would be taken lightly. Furthermore, we believe that any such impacts would be short-term and self-limiting in nature because the NCP annual adjustment factor, established via prior NCP rules, increases the levels of the penalties over time and based on the extent of the use of NCPs by all manufacturers. In other words the NCP program is structured such that the incentives to produce engines that meet the standard increase year-by-year and increase upon NCP use. The practical impact of this adjustment factor is that the NCPs will rapidly become an undesirable option for all manufacturers that may elect to use them. However, while we expect their use to be limited, we have no way of predicting at this time exactly how many engines will make use of the NCPs. Navistar has indicated that it will use NCPs until sometime in 2013, when it begins introducing vehicles with SCR technology that meet the 0.20 g/hp-hr standard. Because of these uncertainties we are unable to accurately quantify the potential impact the NCPs might have on emission inventories, although, as stated above, any impacts are expected to be short-term and self-limiting in nature.

VIII. Emission Standards for Which We Are Not Establishing NCPs in This Final Rule

This section identifies the emission standards for which we are not establishing NCPs in this Final Rule.

A. Medium Heavy Duty Diesel NO_X Standards

EPA proposed to find that the criteria for providing NCPs had been met for medium heavy duty diesel engines, and we proposed NCPs for these engines. However, EPA is not taking final action with regard to NCPs for these engines at this time because EPA has not completed its review of the comments and the technical data regarding establishing NCPs for these engines. A full discussion of compliance costs for medium heavy-duty engines is contained in Appendix C of the TSD for this rule. Parties may provide comments regarding these estimates by submitting comments to the docket for this rule.

B. Light Heavy-Duty Diesel NO_X Standards

EPA believes that the first two NCP criteria have been met for the 2010 NO_X standard for light heavy-duty diesel engines. However, we have not determined that there is likely to be a technological laggard. We are unaware of any manufacturer that will be unable to either achieve 0.20 g/bhp-hr for the 2012 and 2013 model year or will not have sufficient NO_X emission credits to continue certifying light heavy-duty engines for the foreseeable future.

C. Heavy-Duty Gasoline Engine Standards

In a final rule published on January 18, 2001 (66 FR 5001), EPA established more stringent emission standards for all heavy-duty gasoline (or ''Otto-cycle'') vehicles and engines. These standards took two forms: a chassis-based set of standards for complete vehicles under 14,000 pounds GVWR (the chassis-based program), and an engine-based set of standards for all other Otto-cycle heavy-duty engines (the engine-based program). Each of the two programs has an associated averaging, banking, and trading (ABT) program. The new standards generally took effect starting with the 2008 model year, and since all manufacturers are in compliance with them, the criteria for establishing NCPs has not been met and we are not establishing NCPs for gasoline engines or vehicles.

D. Heavy-duty Diesel Engine NMHC, CO, and PM Standards

EPA adopted new NMHC and PM for model year 2007 and later heavy-duty engines in the same rule that set the 2010 NO_X emission standard (66 FR 5001, January 18, 2001). The CO standard was not changed. We are not establishing NCPs for any of these other standards because all manufacturers are already fully compliant with them.

E. Heavy-duty CO_2 Standards

In a final rule published on September 15, 2011 (76 FR 57106), EPA established new CO_2 emission standards for all heavy-duty vehicles and engines. We are not considering NCPs for any of these standards at this time because we currently do not have a basis to conclude that a technological laggard is likely to develop.

As proposed, we are adding a new regulatory provision related to these CO_2 emission standards. The provision prohibits generating emission credits for CO_2 or any other pollutant from engines paying NCPs for NO_X. Given the general tradeoff between CO_2 and NO_X emissions, we were concerned that a manufacturer capable of meeting the 0.20 g/bhp-hr NO_X emission standard could choose to pay an NCP in order to generate CO_2 credits by recalibrating its engines for higher NO_X emissions and lower CO_2. There are two reasons this would be inappropriate. It would not be consistent with either the purpose of the CO_2 credit program (to provide an incentive for manufacturers to take technological and other efforts to over comply with the CO_2 standard) and would not be consistent with the purpose of the NCP program (to provide relief to manufacturers that fail to achieve the standard on time for technological reasons, not for other reasons such as the economic benefit of generating CO_2 credits by voluntarily increasing emissions of NO_X).

IX. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action'' because it raises novel legal and policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. It only updates the penalty amounts to correspond to the current emission standards. However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations 40 CFR part 86,

subpart L under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0132. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

(1) Overview

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of these rules on small entities, small entity is defined as: (1) a small business as defined by SBA regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

(2) Summary of Potentially Affected Small Entities

After considering the economic impacts of this rule on small entities, I certify that this action will not have a significant impact on a substantial number of small entities.

When these emission standards were established, the final rulemaking (66 FR 5001, January 18, 2001) noted that we were not aware of ''any manufacturers of heavy-duty engines that meet SBA's definition of a small business.'' Based on an updated assessment, EPA has identified a total of about 14 manufacturers that produce diesel cycle heavy-duty motor vehicle engines. Of these, none of these are small businesses that are producing engines with NO_X emissions above 0.20 g/bhp-hr. Based on this, we are certifying that this rule will not have a significant economic impact on a substantial number of small entities.

(3) Conclusions

I therefore certify that this Final Rule will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

This 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. The agency has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for the private sector in any one year. Because the use of NCPs is optional, manufacturers have the flexibility and will likely choose whether or not to use NCPs based on their ability to comply with emissions standards. The availability of NCPs provides manufacturers with a third alternative: to continue production and introduce into commerce upon payment of a penalty an engine that exceeds the standard until an emission conformance technique is developed. Therefore, NCPs represent a regulatory mechanism that allows affected manufacturers to have increased flexibility. Thus, this action is not subject to the requirements of sections 202 or 205 of the UMRA. This action is also not subject to the requirements of section 203 of the UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. These rules will apply to manufacturers of on-highway engines and not to state or local governments. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This Final Rule does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rule will be implemented at the Federal level and impose compliance costs only on engine manufacturers who elect to use the NCP regulatory flexibility to comply with emissions standards. Tribal governments would be affected only to the extent they purchase and use engines and vehicles to which an NCP has been applied. Thus, Executive Order 13175 does not apply to this rule.

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

Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211 (Energy Effects)

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. We have concluded that any energy impacts of this rule will be small because:

- The NCPs will be used for a limited duration.
- This rule will affect a small number of heavy duty vehicles relative to the total in-use fleet.
- The per-vehicle impact of this rule will be small.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs the agencies to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials, specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the EPA decides not to use available and applicable voluntary consensus standards.

This rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. The overall environmental impacts of this action are expected to be small and of limited duration. Moreover, there is no reason to believe that trucks using NCP engines will be more likely to operate near any minority or low-income populations than other trucks.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**.

Nonconformance Penalties for On-highway Heavy-Duty Diesel Engines

Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective September 5, 2012.

X. Statutory Provisions and Legal Authority

Statutory authority for the vehicle controls in these rules is found in CAA sections 202 and 206(g), of the CAA, 42 U.S.C. 7521 and 7525(g).

List of Subjects in 40 CFR Part 86

Administrative practice and procedure, Confidential business information, Motor vehicle pollution, Reporting and recordkeeping requirements.

Dated: August 30, 2012.

Lisa P. Jackson,

Administrator.

For the reasons set forth in the preamble, the Environmental Protection Agency is amending 40 CFR chapter I of the Code of Federal Regulations as follows:

PART 86—CONTROL OF EMISSIONS FROM NEW AND IN–USE HIGHWAY VEHICLES AND ENGINES

■ 1. The authority citation for part 86 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart L—[Amended]

■ 2. Section 86.1103–87 is revised to read as follows:

§ 86.1103–87 Criteria for availability of nonconformance penalties.

(a) EPA shall establish for each subclass of heavy-duty engines and heavy-duty vehicles (other than motorcycles), an NCP for a motor vehicle pollutant, when any new or revised emission standard is more stringent than the previous standard for the pollutant, or when an existing standard for that pollutant becomes more difficult to achieve because of a new or revised standard, provided that EPA finds:

(1) That for such subclass of engines or vehicles, substantial work is required to meet the standard for which the NCP is offered, and

(2) That there is likely to be a technological laggard.

(b) Substantial work, as used in paragraph (a)(1) of this section, means the application of technology that was not generally used in an engine or vehicle class or subclass to meet standards prior to the implementation of the new or revised standard, or the significant modification of existing technology or design parameters, needed to bring the vehicle or engine into compliance with either the more stringent new or revised standard or an existing standard which becomes more difficult to achieve because of a new or revised standard. Substantial work is determined by the total amount of work required to meet the standard for which the NCP is offered, compared to the previous standard, irrespective of when EPA establishes the NCP.

■ 3. Section 86.1104–91 is revised to read as follows:

§ 86.1104–91 Determination of upper limits.

EPA shall set a separate upper limit for each phase of NCPs and for each service class.

(a) Except as provided in paragraphs (b), (c), and (d) of this section, the upper limit shall be set as follows:

(1) The upper limit applicable to a pollutant emission standard for a subclass of heavy-duty engines or heavy-duty vehicles for which an NCP is established in accordance with § 86.1103–87, shall be the previous pollutant emission standard for that subclass.

(2) If a manufacturer participates in any of the emissions averaging, trading, or banking programs, and carries over certification of an engine family from the prior model year, the upper limit for that engine family shall be the family emission limit of the prior model year, unless the family emission limit is less than the upper limit determined in paragraph (a) of this section.

(b) If no previous standard existed for the pollutant under paragraph (a) of this section, the upper limit will be developed by EPA during rulemaking.

(c) EPA may set the upper limit during rulemaking at a level below the level specified in paragraph (a) of this section if we determine that a lower level is achievable by all engines or vehicles in that subclass.

(d) EPA may set the upper limit at a level above the level specified in paragraph (a) of this section if we determine that the such level will not be achievable by all engines or vehicles in that subclass.

■ 4. Section 86.1105–87 is amended by revising paragraph (e) and adding paragraph (j) to read as follows:

§ 86.1105–87 Emission standards for which nonconformance penalties are available.

* * * * *

(e) The values of COC_{50}, COC_{90}, and MC_{50} in paragraphs (a) and (b) of this section are expressed in December 1984 dollars. The values of COC_{50}, COC_{90}, and MC_{50} in paragraphs (c) and (d) of this section are expressed in December 1989 dollars. The values of COC_{50}, COC_{90}, and MC_{50} in paragraph (f) of this section are expressed in December 1991 dollars. The values of COC_{50}, COC_{90}, and MC_{50} in paragraphs (g) and (h) of this section are expressed in December 1994 dollars. The values of COC_{50}, COC_{90}, and MC_{50} in paragraph (i) of this section are expressed in December 2001 dollars. The values of COC_{50}, COC_{90}, and MC_{50} in paragraph (j) of this section are expressed in December 2011 dollars. These values shall be adjusted for inflation to dollars as of January of the calendar year preceding the model year in which the NCP is first available by using the change in the overall Consumer Price Index, and rounded to the nearest whole dollar in accordance with ASTM E29–67 (reapproved 1980), Standard Recommended Practice for Indicating Which Places of Figures Are To Be Considered Significant in Specified Limiting Values. This method was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This document is available from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, and is also available for inspection as part of Docket A–91–06, located at the U.S. EPA, Air and Radiation Docket and Information Center, 1301 Constitution Ave. NW., Room 3334, EPA West Building, Washington, DC 20004, (202) 202–1744 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*. This incorporation by reference was approved by the Director of the Federal Register on January 13, 1992. These materials are incorporated as they exist on the date of the approval and a notice of any change in these materials will be published in the **Federal Register**.

* * * * *

(j) Effective in the 2012 and later model years, NCPs will be available for the following emission standard:

(1) Diesel heavy-duty engine oxides of nitrogen standard of 0.20 grams per brake horsepower-hour in § 86.007–11(a)(1)(i).

(i) [Reserved].

(ii) For heavy heavy-duty diesel engines:

(A) The following values shall be used to calculate an NCP in accordance with § 86.1113–87(a):

(*1*) COC_{50}: $3,219.

(*2*) COC_{90}: $3,775.

(*3*) MC_{50}: $10,729 per gram per brake horsepower-hour NO_X.

(*4*) F: 1.173.

(*5*) UL: 0.50 grams per brake horsepower-hour NO_X.

(B) The following factor shall be used to calculate the engineering and development component of the NCP for the standard set forth in § 86.007–11(a)(1)(i) in accordance with § 86.1113–87(h): 0.005.

(2) Manufacturers may not generate emission credits for any pollutant from engines for which the manufacturer pays an NCP for the NO_X standard identified in paragraph (j)(1) of this section.

(3) The penalty shall be adjusted annually as specified in § 86.1113–87 with 2012 as the first year. Note that this means AAF_{2012} is equal to 1.

■ 5. Section 86.1113–87 is amended by revising paragraph (g)(1) to read as follows:

§ 86.1113–87 Calculation and payment of penalty.

* * * * *

(g)(1) Except as provided in paragraph (g)(2) of this section, the nonconformance penalty or penalties assessed under this subpart must be paid as follows:

(i) By the quarterly due dates, *i.e.,* within 30 days of the end of each calendar quarter (March 31, June 30, September 30 and December 31), or according to such other payment schedule as the Administrator may approve pursuant to a manufacturer's request, for all nonconforming engines or vehicles produced by a manufacturer in accordance with paragraph (b) of this section and distributed into commerce for that quarter.

(ii) The penalty shall be payable to U.S. Environmental Protection Agency, NCP Fund, Motor Vehicle and Engine Compliance Program, P.O. Box 979032St. Louis, MO 63197–9000. Note on the check and supporting information that this is an NCP payment.

* * * * *

[FR Doc. 2012–21967 Filed 9–4–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2002–0302; FRL–9359–9]

Dichlorvos (DDVP); Order Denying NRDC's Objections on Remand

AGENCY: Environmental Protection Agency (EPA)

ACTION: Final Order.

SUMMARY: In this order, EPA denies an objection to a prior order denying a petition requesting that EPA revoke all pesticide tolerances for dichlorvos under section 408(d) of the Federal Food, Drug, and Cosmetic Act. The objection was filed on February 1, 2008, by the Natural Resources Defense Council (NRDC). The original petition was also filed by NRDC. Previously, in July 2008, EPA denied this same objection but the United States Court of Appeals for the Second Circuit vacated that decision, in part, and remanded the matter to EPA. This order is being issued in response to the court's remand.

DATES: This order is effective September 5, 2012.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2002–0302, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Melanie Biscoe, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7106; email address: *biscoe.melanie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

In this document EPA denies an objection by the Natural Resources Defense Council (NRDC) concerning

EPA's denial of NRDC's petition to revoke pesticide tolerances. This action may also be of interest to agricultural producers, food manufacturers, or pesticide manufacturers. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (North American Industrial Classification System (NAICS) code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

II. Introduction

A. What action is the agency taking?

In this order, EPA is issuing a revised denial of an objection to an earlier EPA order, (72 FR 68662, December 5, 2007), denying a petition to revoke all tolerances established for the pesticide dichlorvos (DDVP) under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. Both the objection as well as the petition was filed with EPA by NRDC. (Refs. 1 and 2). EPA had previously denied this objection, (73 FR 42683, July 23, 2008), but that order was vacated, in part, by the United States Court of Appeals for the Second Circuit. (*NRDC* v. *US EPA,* 658 F.3d 200 (2d Cir. 2011)).

NRDC's petition, filed on June 2, 2006, pursuant to FFDCA section 408(d)(1), asserted numerous grounds as to why the dichlorvos tolerances allegedly fail to meet the FFDCA's safety standard. This petition was filed as EPA was completing its reassessment of the safety of the dichlorvos tolerances pursuant to FFDCA section 408(q). (Ref. 3). In response to the petition, EPA undertook an extensive review of its dichlorvos safety evaluation in the tolerance reassessment decision. Based on this extensive review, EPA concluded that dichlorvos met the FFDCA safety standard and, therefore, denied the petition. (72 FR 68695). NRDC then filed objections with EPA to the petition denial order and requested a hearing on its objections. The objections narrowed NRDC's claims to two main assertions—that, in assessing the risk to dichlorvos, EPA unlawfully reduced the statutory tenfold (10X) additional safety factor for the protection of infants and children and EPA unlawfully relied on a human toxicity study (the Gledhill study). After carefully reviewing the objections and hearing requests, EPA determined that NRDC's hearing requests did not satisfy the regulatory requirements for such requests and that its substantive objections were without merit. (73 FR 42709–42711). NRDC sought review of EPA's decision in the United States Court of Appeal for the Second Circuit. As noted, the Second Circuit court vacated a portion of EPA's order finding that ''[b]ecause EPA failed to explain why it did not use a 10X children's safety factor for dichlorvos risk assessments that relied on the Gledhill study, EPA acted in an arbitrary and capricious manner.'' (658 F.3d at 218). Specifically, the court vacated ''those portions of EPA's July 23, 2008 order assessing the risk of dichlorvos based on the Gledhill study * * *'' (Id.). The court remanded the matter to EPA. (Id. at 219).

On remand, EPA has carefully examined the court's opinion and has reconsidered that portion of its prior decision that relied on the Gledhill study in assessing dichlorvos risk. Because the court found this portion of EPA's order to be arbitrary and capricious due to its absence of an adequate explanation on the additional safety factor for the protection of infants and children, EPA focused on a reexamination of what additional safety factor for the protection of infants and children should be applied for the assessments based on the Gledhill study. EPA concludes, like it did in the July 23, 2008 order, that a threefold (3X) additional safety factor will protect the safety of infants and children. Accordingly, EPA again denies NRDC's objections as to those portions of the July 23, 2008 order that were vacated. Although EPA reaches the same conclusion on remand on the additional safety factor for the protection of infants and children, EPA has provided a revised, more extensive explanation for its position. Because this revised explanation addresses the court's reason for finding portions of the July 23, 2008 order to be arbitrary and capricious, EPA has not otherwise reopened or reconsidered that prior order.

B. What is the agency's authority for taking this action?

NRDC petitioned to revoke the dichlorvos tolerances pursuant to the petition procedures in FFDCA section 408(d)(1). (21 U.S.C. 346a(d)(1)). Under section 408(d), EPA may respond to such a petition by either issuing a final or proposed rule modifying or revoking the tolerances or issuing an order denying the petition. (21 U.S.C. 346a(d)(4)). Here, EPA responded by issuing an order under section 408(d)(4)(iii) denying the petition. (72 FR 68622, December 5, 2007).

Orders issued under section 408(d)(4)(iii) are subject to a statutorily-created administrative review process. (21 U.S.C. 346a(g)(2)). Any person may file objections to a section 408(d)(4)(iii) order with EPA and request a hearing on those objections. (Id.). EPA is required by section 408(g)(2)(C) to issue a final order resolving the objections to the section 408(d)(4)(iii) order. (21 U.S.C. 346a(g)(2)(C)). NRDC filed objections to EPA's denial of its dichlorvos petition and EPA issued a section 408(g)(2)(C) order denying NRDC's objections. (73 FR 42683, July 23, 2008). EPA's order denying NRDC's objections was vacated, in part, and remanded to EPA. This revised order on remand is also being issued under section 408(g)(2)(C).

III. Statutory and Regulatory Background

In this Unit, EPA provides background on the relevant statutes and regulations governing the matter on remand as well as a much-abbreviated discussion on pertinent Agency risk assessment policies. A full discussion of EPA's approach to pesticide risk assessment is included in EPA's prior order on NRDC's objections. (73 FR 42685–42688). Because the court's decision focused on the explanation offered by EPA for its use of safety factors, this Unit includes an expanded discussion on use of safety or uncertainty factors, including the additional safety factor required by the FQPA for the protection of infants and children. Further, because Benchmark Dose Methods analysis is discussed for the first time in this revised order, a short section explaining that concept is included.

A. FFDCA/FIFRA and Applicable Regulations

1. *In general.* EPA establishes maximum residue limits, or ''tolerances,'' for pesticide residues in food and feed commodities under

section 408 of the FFDCA. (21 U.S.C. 346a). Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is ''adulterated'' under section 402 of the FFDCA and may not be legally moved in interstate commerce. (21 U.S.C. 331, 342). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). Section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA), which added the provisions discussed below establishing a detailed safety standard for pesticides, additional protections for infants and children, and the endocrine disrupting substances screening program. (Pub. L. 104–170, 110 Stat. 1489 (1996)).

EPA also regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), (7 U.S.C. 136 et seq). While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution, (7 U.S.C. 136a(a)), and establishes a registration regime for regulating the use of pesticides. FIFRA regulates pesticide use in conjunction with its registration scheme by requiring EPA review and approval of pesticide labels and specifying that use of a pesticide inconsistent with its label is a violation of Federal law. (7 U.S.C. 136j(a)(2)(G)).

2. *Safety standard for pesticide tolerances.* A pesticide tolerance may be promulgated or left in effect by EPA only if the tolerance is ''safe.'' (21 U.S.C. 346a(b)(2)(A)(i)). This standard applies when responding both to petitions to establish and petitions to revoke tolerances. ''Safe'' is defined by the statute to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' (21 U.S.C. 346a(b)(2)(A)(ii)).

Risks to infants and children are given special consideration. Providing additional protection to infants and children was a particular focus of the FQPA. Section 408(b)(2)(C) requires EPA to make a specific determination regarding the safety of tolerances to infants and children and to consider, among other things, information ''concerning the special susceptibility of infants and children to the pesticide chemical residues * * *.'' (21 U.S.C. 346a(b)(2)(C)(i)(II) and (ii)(II)). This provision also creates a presumptive additional safety factor for the protection of infants and children. Specifically, it directs that ''[i]n the case of threshold effects, * * * an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.'' (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to ''use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.'' (Id.). For convenience's sake, the legal requirements regarding the additional safety margin for infants and children in section 408(b)(2)(C) are referred to throughout this Order as the ''FQPA safety factor for the protection of infants and children'' or simply the ''FQPA safety factor.''

3. *Procedures for establishing, amending, or revoking tolerances.* Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in the FFDCA. Generally, a tolerance rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (See 21 U.S.C. 346a(d)(1)). EPA publishes in the **Federal Register** a notice of the petition filing and requests public comment. (21 U.S.C. 346a(d)(3)). After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing, amending, or revoking the tolerance, issue a proposed rule to do the same, or deny the petition. (21 U.S.C. 346a(d)(4)).

Once EPA takes final action on the petition by establishing, amending, or revoking the tolerance or denying the petition, any party may file objections with EPA to EPA's decision on the petition and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)). Objections and hearing requests must be filed within 60 days. (Id.). The statute provides that EPA shall ''hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections.'' (21 U.S.C. 346a(g)(2)(B)). EPA regulations make clear that hearings will only be granted where it is shown that there is ''a genuine and substantial issue of fact,'' the requestor has identified evidence that ''would, if established, resolve one or more of such issues in favor of the requestor,'' and the issue is ''determinative'' with regard to the relief requested. (40 CFR 178.32(b)). Further, a party may not raise issues in objections unless they were part of the petition and an objecting party must state objections to the EPA decision and not just repeat the allegations in its petition. *Corn Growers* v. *EPA,* 613 F.2d 266 (D.C. Cir. 2010), cert. denied, 131 S. Ct. 2931 (2011). EPA's final order on the objections is subject to judicial review. (21 U.S.C. 346a(h)(1)).

B. EPA Risk Assessment for Tolerances—Policy and Practice

1. *The safety determination—risk assessment.* To assess risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps: (1) Identification of the toxicological hazards posed by a pesticide; (2) determination of the ''level of concern'' with respect to human exposure to the pesticide; (3) estimation of human exposure to the pesticide; and (4) characterization of risk posed to humans by the pesticide based on comparison of human exposure to the level of concern.

Toxicological hazards posed by a pesticide are identified through use of testing in laboratory animals or humans. Generally, EPA will use the lowest ''no observed adverse affect level'' (NOAEL) or ''lowest observed adverse effect level'' (LOAEL) from the available studies or a calculated value called a Benchmark Dose as a starting point (called ''the Point of Departure'') in estimating the ''level of concern'' for human exposure to the pesticide. Points of Departure and levels of concern will be identified for all exposure routes to the pesticide (oral, dermal, and inhalation) and durations of exposure (acute, short-term, intermediate-term, and chronic). Another critical aspect of the ''level of concern'' determination involves the use of safety or uncertainty factors to compensate for the limitations of toxicology testing. Safety and uncertainty factors are discussed in detail in Unit III.B.2. below. Having identified a pesticide's hazards, the Point(s) of Departure, and level(s) of concern, EPA then estimates exposure to the pesticide taking into account the various routes of exposure, how exposures vary over time, and the differences in exposure to different subpopulations. Finally, EPA combines information on hazard, level of concern, and exposure to produce a characterization of the risk posed by the pesticide. Risks are calculated for all of the various routes and durations of exposure scenarios associated with a pesticide. These risk assessment

scenarios may be calculated separately for different age-based population groups (e.g., non-nursing infants) or applied to all population groups, including infants and children, depending on information on the potential for exposure and data on differential sensitivity. A more comprehensive discussion of this risk assessment process is presented in EPA's previous order denying objections. (73 FR 42685–42689).

Before turning to a detailed discussion of safety and uncertainty factors, EPA's risk characterization process is briefly summarized because it is frequently referred to in this order. For pesticides that pose a risk over a certain threshold of exposure, EPA's characterization of risk is presented in one of two ways: Either using the Reference Dose (RfD) approach or the Margin of Exposure (MOE) approach. Importantly, these different approaches do not render substantively different results. Both approaches use the same data—the Point of Departure, the applicable safety/uncertainty factors, and human exposure to the pesticide; they just express the characterization of risk in a different metric. Under the RfD approach, EPA directly extrapolates a dose from an animal or human study to an overall safe dose for humans. An RfD is calculated by dividing all applicable safety/uncertainty factors into the level of exposure from animal or human studies determined appropriate for assessing risk (i.e., the ''Point of Departure''). Estimated human exposure to the pesticide is then compared to the RfD to determine if it is excessive. Under the Margin of Exposure (MOE) approach, EPA does not calculate a safe dose in humans but rather focuses on the margin of exposure between a dose from an animal or human study and human exposure to the pesticide. A MOE is calculated by dividing human exposure to the pesticide into the Point of Departure. To determine whether that MOE is considered sufficiently protective of humans, EPA compares it to the product of all applicable safety/uncertainty factors, referred to as the target MOE. MOEs that are less than the target MOE indicate a risk of concern. At bottom, both approaches extrapolate a safe measure of human exposure from animal or human studies using a mixture of uncertainty/safety factors.

2. *Safety and uncertainty factors.*

i. *History.* It has long been a standard risk assessment practice to use numerical factors in conjunction with experimental toxicity data in assessing risk to humans from exposure to chemical substances. (Ref. 4). These numerical factors are designed to provide an additional margin of safety so that risks to the populations covered by an assessment are not understated. The practice was first developed by the Food and Drug Administration (FDA) in the middle part of the last century. (Ref. 5). An influential 1954 paper by two FDA scientists called for a hundredfold margin of safety when extrapolating from long-term animal experiments to calculate safe doses in humans. (Ref. 6). The paper justified this safety factor on the basis of, among other things, potential differences in sensitivity between humans and laboratory animals as well as potential variations in sensitivity within humans. Accordingly, the paper recognized that a smaller factor would be appropriate where adequate human data are available. An explicit recommendation for a factor ''as low as 10'' was made by the Joint Food and Agricultural Organization/World Health Organization (FAO/WHO) Meeting on Pesticide Residues in 1965 for circumstances where human data was relied upon. (Ref. 7 at 12). Eventually, it became common regulatory practice to treat the hundredfold margin of safety as comprised of two tenfold factors: The first addressing the potential difference in sensitivity between humans and experimental animals (*i.e.,* interspecies sensitivity) and the second addressing variation within the human population (*i.e.,* intraspecies sensitivity). The rationale for these two factors is concisely summarized in a recent publication from the International Programme on Chemical Safety:

> The interspecies uncertainty factor can be considered to convert the NOAEL/NOAEC [No observed adverse effect concentration] for animals (derived from a small group of relatively homogeneous test animals) into the NOAEL/NOAEC anticipated for an average representative healthy human. The uncertainty factor for human variability converts the NOAEL/NOAEC for the average human into a NOAEL/NOAEC for susceptible humans. Although adverse effect data in humans can be used directly without the need for an interspecies factor, the paucity of such data means that the vast majority of risk assessments are based on studies in experimental animals.

(Ref. 8 at 15).

EPA, as well as other Federal and international regulatory bodies, also will, where appropriate, apply additional numerical factors to take into account chemical-specific considerations affecting the risk assessment. (Ref. 9) Use of these additional factors is further explained in Unit III.B.2.v., vi, and vii.

ii. *Terminology.* Different terminology has been used to label numerical factors used in calculating safe doses of chemical substances. As noted, they were first referred to as ''safety'' factors. The terminology has evolved over the decades, however, such that what was once generally called a safety factor has come to be generally referred to as an uncertainty factor. (Ref. 10 at A–3). The rationale for the change was that, although the use of such factors does promote safety, there was a concern that the use of the term ''safety'' implied that these factors provided absolute safety. (Ref. 11). The FQPA reintroduced the term ''safety'' factors with its reference to a ''margin of safety.'' 21 U.S.C. 346a(b)(2)(C). Subsequent to the passage of FQPA, EPA's Office of Pesticide Programs (OPP) has used the terms safety factor and uncertainty factor interchangeably. Both terms have been criticized by the National Academy of Sciences (NAS). The NAS explained that the terms safety and uncertainty imply that factors ''are simply added on for safety or because of a lack of knowledge or confidence in the process.'' (Ref. 12 at 132). To the contrary, according to the NAS, these factors are scientifically-based and used ''to adjust for differences in individual human sensitivities, for humans' generally greater sensitivity than test animals' on a milligram-per-kilogram basis, for the fact that chemicals typically induce harm at lower doses with longer exposures, and so on.'' (Id.).

iii. *Scientific basis for inter- and intraspecies factors.* Only limited scientific data, involving differing sensitivity of humans and animals, are cited in the 1954 article in justification of the recommendation for a hundredfold safety factor. Subsequent investigations of both animal and human toxicity data, however, have provided general support for the protectiveness of the tenfold factors for interspecies and intraspecies sensitivity differences if an adequate toxicity database is available. (Refs. 9, 13, 14, and 15). The interspecies factor has been investigated through comparisons of toxicity testing in laboratory animals and humans. (Refs. 15 and 16). The protectiveness of the human intraspecies factor has been assessed through examining sub-population differences both among various human age groups (the young, adults, and elderly) as revealed in pharmaceutical trials and between juvenile and adult laboratory animals identified in toxicity testing. (Ref. 13 at 211 (''For substances other than pharmaceuticals, age-related differences in toxicity have been primarily investigated in rodent studies.''); Ref. 17 at 462–463

(describing pharmaceutical trials involving humans and comparative studies in juvenile and adult laboratory animals)). For example, the NAS, in its report ''Pesticides in the Diets of Infants and Children,'' looked to both human data and animal data in evaluating the potential for increased sensitivity in infants and children to pesticides. (Ref. 18 at 344–345).

iv. *Adjustment of inter- and intraspecies factors.* In addition to evaluating the protectiveness of the intra- and interspecies uncertainty factors, scientists have also examined both generic biological as well as chemical-specific factors that may affect intra- and interspecies variability with the aim of deriving more accurate uncertainty factor values than the default tenfold values.

One reason humans are considered to be potentially more sensitive to toxic agents than laboratory animals is that otherwise equivalent external doses of such agents for humans and animals on a milligram-per-kilogram of body weight basis may result in a greater internal dose for humans. This is due to species differences in general metabolic processes—commonly referred to as toxicokinetics—and ''is thought to be related to species differences in exchange surfaces and distribution networks that constrain concentration and flux of metabolic reactants.'' (Ref. 19 at 4–35; see Ref. 15 at 228).

In addition to toxicokinetic effects on internal dose, differences between humans and laboratory animals are also driven by toxicodynamic factors. Toxicodynamics refers to the manner in which the target tissue and body respond to the toxic agent. Thus, interspecies differences are a factor of both differences in the internal dose received by humans and animals and differences in how humans and animals react to the internal dose received. Similarly, sensitivity differences between juveniles and adults, whether humans or animals, are also considered to be tied to toxicokinetic and toxicodynamic factors. Accordingly, both the inter- and intraspecies uncertainty factors are considered to have toxicokinetic and toxicodynamic components. EPA typically has considered both the tenfold (10X) inter- and intraspecies factors to be roughly equally divided on a logarithmic basis (i.e., $10^{0.5}$ or roughly a 3X factor) between toxicokinetics and toxicodynamics. (Ref. 19 at 4–29; *see also* Ref. 19 at 4–40 (explaining why two 3X factors [technically, 3.16X] would be equivalent to a 10X factor)). Other organizations have recommended that, while toxicokinetics and toxicodynamics play an equal role in intra-human variability, toxicokinetics has a greater effect on interspecies differences and thus recommend that the tenfold interspecies factor be divided into a fourfold factor for toxicokinetics and 2.5-fold factor for toxicodynamics. (Ref. 8 at 17; *see* Ref. 14).

Of the toxicokinetic and toxicodynamic differences between humans and animals and among various human subgroups, the most is known about the toxicokinetic differences between humans and animals. For inhalation exposures, EPA has used toxicokinetic information on humans and animals to create generic dosimetric adjustment factors that replace that portion of the interspecies factor tied to toxicokinetic differences. (Refs. 19 at 4–29; 20). Where such dosimetric adjustment factor is used, the interspecies factor is reduced to 3X.

EPA guidance entitled ''A Review of the Reference Dose and Reference Concentration Processes'' (''RfD Guidance'') also urges that data be developed to support substitution of chemical-specific adjustment factors (sometimes referred to as data-derived factors) for the default 10X uncertainty factors for inter- and intraspecies variability. (Ref. 19 at xviii –xix, 4–47). This guidance recognizes that chemical-specific data from both humans and animals has been relied upon by EPA to adjust the human intraspecies uncertainty factor citing an article by Dourson et al. That article collects instances in which EPA has adjusted uncertainty factors on a chemical-specific basis. (Ref. 9). For example, Dourson et al. point to a 1996 EPA assessment of Aroclor that reduced the human intraspecies factor to 3X given that the Point of Departure came from a sensitive animal population—there, infant rhesus monkeys. In discussing the Dourson et al. article, the RfD Guidance notes that:

> In those cases where developmental effects were the most sensitive endpoint (0 RfCs, 6 RfDs), reduction of the intraspecies [uncertainty factor] from 10 to 3 was based on data derived either from human data showing which age groups or time periods were most susceptible (e.g., methyl mercury exposure to the developing fetus) or from an animal study with support from strong human or other data (e.g., Aroclor 1016 in utero exposure in monkeys, strontium-induced rachitic bones in young rats).

(Ref. 19 at 4–43). The RfD Guidance endorsed a view similar to that expressed in an agency-wide paper prepared in development of EPA's Children's Safety Factor Policy. That paper also noted that there were circumstances where data from human studies or from animal studies might support reduction of the human intraspecies uncertainty factor: ''The Toxicology Working Group recommends that reduction of the intraspecies uncertainty factor from a default of 10 be considered only if data are complete and the age group or window of vulnerability during development has been clearly delineated, preferably based on human data or on animal data with supporting human data.'' (Ref. 21 at 28). On the other hand, the RfD guidance also recognized that a 10X intraspecies factor ''may sometimes be too small because of factors that can influence large differences in susceptibility, such as genetic polymorphisms.'' (Ref. 19 at 4–44).

In sum, the 10X inter- and intraspecies factors are default values. Although there is substantial scientific support for these default values, chemical-specific human and animal data may be relied upon in reducing, confirming, or increasing these default values.

v. *Additional Safety/Uncertainty Factors.* In addition to the inter- and intraspecies factors, risk assessors from EPA as well as other Federal and international regulatory agencies also apply ''additional'' or ''modifying'' safety/uncertainty factors based on specific circumstances related to the toxicity data, particularly with regard to deficiencies in that data. Like the inter- and intra-species factors, these additional factors help to ensure that risks to populations covered by an assessment are not understated. Additional factors are applied to address: (1) An absence of critical toxicity data; (2) the failure of a study to identify a NOAEL; (3) the necessity of using sub-chronic data to choose a Point of Departure for estimating chronic risk; and (4) results in a study that suggest the inter- or intraspecies factors may not be sufficient (sometimes referred to as a ''modifying factor''). (Ref. 10 at 9). Generally, a safety factor value of 10X or 3X (which is considered to be one-half of 10X on the logarithmic scale) is used to address these concerns.

The protectiveness of these default values has also been the subject of scientific examination. Studies have been done on the variations in the levels of NOAELs in the databases for various pesticides. They confirm the need for an additional factor when core data are lacking. (Ref. 22). Examination of the completeness of the animal database remains important even when human data are used as the Point of Departure for calculating the RfD. The latest EPA guidance on RfDs emphasizes that in

these circumstances ''[i]nformation on life stages and organ systems may come from either animal or human studies.'' (Ref. 19 at 4–45). The guidance notes that ''the lack of a two-generation animal reproduction study might be considered a deficiency even if the reference value is based on human data.'' (Id.). Similarly, research has been conducted on existing databases to determine the adequacy of uncertainty factors used to address reliance on a LOAEL instead of a NOAEL, or subchronic data to estimate chronic risk. (Refs. 9 and 15).

Selection of particular values for these additional uncertainty values depends on what is known from the full body of information about the chemical, including both data from testing with animals and humans, about the chemical. For example, as EPA's RfD Guidance advises: ''the size of the database factor to be applied will depend on other information in the database and on how much impact the missing data may have on determining the toxicity of a chemical and, consequently, the POD [Point of Departure].'' (Ref. 19 at 4–45). With regard to an additional factor for extrapolation of a NOAEL from a LOAEL, Dourson et al. report that ''[a]nalysis of several data bases suggest that a factor of 10 or lower is adequate and that use of data does support a lower factor with certain chemicals.'' (Ref. 9 at 112). The critical consideration, according to Dourson et al., is the severity of the effect at the LOAEL: ''The data indicate that when faced with a LOAEL and not a NOAEL, the choice of uncertainty factor should generally depend on the severity of the effect at the LOAEL.'' (Id.). Specifically, Dourson et al. note that ''[l]ess severe effects would not require a large factor, because, presumably, the LOAEL is closer to the unknown NOAEL.'' (Id.).

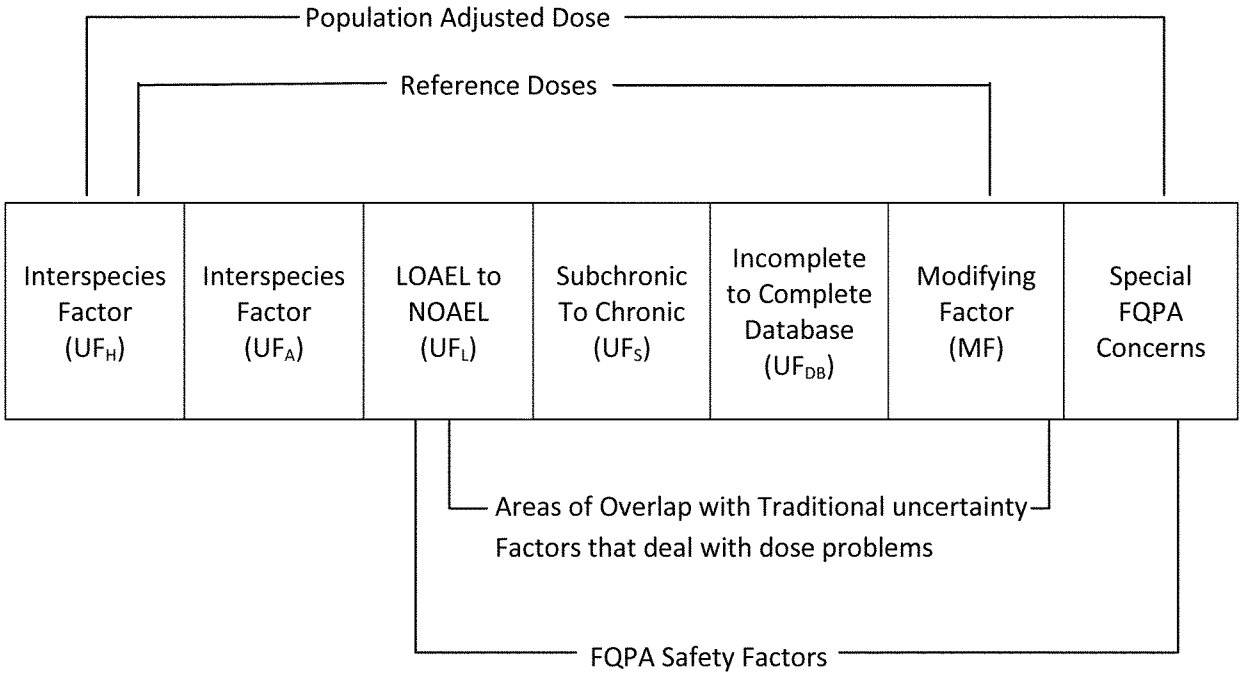
vi. *FQPA safety factor—integration with traditional uncertainty factors.* EPA's safety/uncertainty factor practice with regard to pesticides was altered to a degree by the Food Quality Protection Act (FQPA). (Ref. 10). That Act established a presumptive additional ''safety'' factor of 10X to protect infants and children. The additional factor was designed to account for the completeness of the toxicity and exposure databases and the potential for pre- and post-natal toxicity. EPA has interpreted this legislation as both a ''codification and expansion'' of prior EPA practice with regard to additional safety/uncertainty factors. (Ref. 10 at A–3—A–5). It codified EPA's prior practice by requiring the additional presumptive factor to address toxicity data completeness issues (i.e., absence of a particular study, lack of a NOAEL in a completed study, or absence of chronic data). These traditional additional uncertainty factors became FQPA safety factors for the protection of infants and children. This accords greater protection to infants and children because for FQPA safety factors, unlike pre-FQPA additional factors, there is a presumption, which can only be overcome by reliable data, that they will be applied. At the same time, EPA concluded that Congress had not intended EPA to double-up on safety factors by, for example, applying an additional uncertainty factor due to missing data, and applying an FQPA additional safety factor as well to address the same missing data. (Ref. 10 at A–4). Congress expanded EPA's prior practice by providing that the additional FQPA safety factor for the protection of infants and children was designed to address not just toxicity data deficiencies but exposure data deficiencies as well and by its emphasis on protecting against potential pre- and post-natal toxicity. In theory, EPA could have, prior to the enactment of the FQPA, used an ''additional'' or ''modifying'' factor to address health risks to children not otherwise protected by the interspecies, intraspecies, or data deficiency safety factors, but use of such a factor was not common. The FQPA also modified the status quo by making the additional safety factor for infants and children presumptive in nature.

The narrowly-focused and highly-prescriptive nature of the FQPA safety factor provision has required careful integration with pesticide risk assessment approaches under other statutes and, more generally, with Agency risk assessment practices. As noted above, the FQPA, with regard to the assessment of risks to infants and children, essentially codified EPA's prior risk assessment practice as to additional uncertainty factors and it expanded the use of additional uncertainty factors into new areas. The FQPA, however, did not speak to use of traditional (non-additional) uncertainty factors (i.e., the inter- and intraspecies factors). Thus, the end result was that some uncertainty factors for FFDCA pesticides remained unaffected by the new statutory requirements (the inter- and intraspecies factors), some uncertainty factors became FQPA safety factors (additional uncertainty factors that addressed toxicity data deficiencies), and some safety factors that either had previously never existed or were at least extremely rare were created as a statutory phenomenon (a factor to address exposure data base deficiencies and a factor to address potential pre- and post-natal toxicity). This selective inter-weaving of statutory requirements with Agency science policy made FFDCA risk assessments for pesticides unique compared to general Agency risk assessment practice.

Pesticide risk, however, is not regulated under a single statute. Risks to workers or the environment from pesticide use are regulated by EPA under FIFRA, not the FFDCA. Further, EPA may address risks posed by pesticide contamination of the environment under several other statutes, including the Safe Drinking Water Act, 42 U.S.C. 300f et seq., the Resource Conservation and Recovery Act, 42 U.S.C. 6901 et seq., and the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601 et seq. Prior to enactment of the FQPA's specific provisions on pesticide risk assessment, a pesticide risk assessment performed by EPA's Office of Pesticide Programs under the aegis of FFDCA section 408 could generally be easily translated for use by the Office of Pesticide Programs under FIFRA, or by the other media offices within EPA for use under other statutes. However, once pesticide risk assessment under the FQPA became not simply a matter of good scientific practice but was channeled by explicit statutory requirements, it became incumbent upon the Office of Pesticide Programs to prepare its FFDCA pesticide risk assessments in a manner that clearly delineated what aspects of the assessment were driven solely by science and what aspects primarily by FQPA statutory requirements. Specifically, the Office of Pesticide Programs had to be transparent with regard to whether it was relying on FQPA safety factors based on unique FQPA requirements (exposure database deficiencies and potential pre- and post-natal toxicity) or FQPA safety factors that are essentially a codification of prior general EPA ''additional'' safety/uncertainty factor practice.

EPA addressed these transparency issues at length in its 2002 policy statement on the FQPA safety factor. To clarify how the FQPA safety factor provision left a portion of prior safety/uncertainty practice unchanged, codified another portion, and also expanded the use of safety factors, EPA explained the overlap between the FQPA safety factor and additional safety factors in depth and included the following figure to graphically illustrate the issue:

Figure 1. Relationship between Rfd Derivation and the PAD Calculation



Special FQPA Concerns:

- Residual Concerns with respect to exposure data
- Residual Concern for pre- and postnatal toxicity

(Ref.10, Figure 3)

With regard to providing transparency on the FQPA safety factor decisions, EPA took two steps. First, it adopted a new term, the ''special'' FQPA safety factor, for children safety factors that were based solely on the new FQPA requirements. Second, it adopted the approach of calculating two different safe doses for a pesticide: one that excluded any ''special'' FQPA safety factors and one that included them. The former was referred to, in line with standard EPA policy, as a Reference Dose (RfD), and the latter as a Population Adjusted Dose (PAD). Introducing the new terminology on FQPA safety factors into long-established safety factor practice has proved challenging. EPA staff on occasion drafted documents that (1) claimed no FQPA safety factor was needed but applied an additional uncertainty factor to address the completeness of the toxicity data base or reliance on a LOAEL; or (2) treated the ''special'' FQPA safety factor as the only type of FQPA safety factor. However, as EPA's policy made clear, EPA interpreted FFDCA section 408(b)(2)(C) as codifying prior practice as to additional uncertainty factors such that these factors became FQPA factors. The mislabeling of uncertainty factors did not substantively change risk assessment outcomes but it did raise the confusion level on an already complex topic. Eventually, EPA determined that the term ''special'' FQPA safety factor caused more problems than it solved and abandoned it. However, EPA has retained the approach of continuing to calculate both a safe dose with, and without, what was once referred to as ''special'' FQPA safety factors.

vii. *FQPA safety factor—decision-making guidance.* In 2002, EPA issued detailed policy guidance for Agency risk assessors on decision-making under the FQPA safety factor provision. The purpose of this guidance was concisely set forth by EPA: ''[T]his guidance explains how OPP intends to 'take intoaccount * * * potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children'' as directed by FFDCA section 408(b)(2)(C)(i).' '' (Ref. 10 at ii). Although the guidance is structured around these statutory considerations, EPA also emphasizes throughout that the FQPA safety factor decision is a weight-of-the-evidence decision that must consider all available data. Thus, the policy specifies that ''[b]efore any decisions are made on the appropriate FQPA safety factor applied to ensure the safety of infants and children from the use of a particular pesticide, all of the relevant submitted data for the pesticide should be assembled and reviewed by Agency scientists.'' (Id. at 8).

This emphasis on the broadness of the inquiry is repeated in the discussion of the statutory consideration related to the completeness of the toxicity database. According to EPA, this consideration should not be narrowly focused on EPA's existing database requirements. Rather, ''the 'completeness' inquiry should be a broad one that takes into account all data deficiencies.'' (Ref. 10 at 23). At the same time, the guidance stresses that ''a determination of the possible need for and size of the database uncertainty factor will necessarily involve an assessment that

considers the overall weight-of-evidence to evaluate the significance of the data deficiency.'' (Id. at 26).

With regard to potential pre- and post-natal toxicity, the policy emphasizes that evaluation of this consideration cannot be divorced from the existing process for choosing levels of concern (i.e., RfDs, PADs, and target MOEs). Thus, EPA instructs risk assessors to evaluate the concern with data showing pre- and post-natal toxicity by considering, among other things, ''the degree to which protection for infants and children is provided by the standard approach for deriving RfDs through the application of traditional uncertainty factors.'' (Id. at 29). The guidance stresses that ''[i]n particular, the risk assessor should consider the protection accorded infants and children by the intraspecies uncertainty factor.'' (Id.). EPA notes that the scientific literature as well as the National Academy of Sciences has concluded that the intraspecies factor is generally adequate to protect infants and children; however, the policy points out that certain chemicals may display greater than 10X age-related variability. For this reason, EPA reiterates that ''[t]he adequacy of the standard intraspecies factor to address the potential for greater sensitivity or susceptibility of children should be considered in the context of evidence on potential pre- and post-natal toxicity as discussed below.'' (Id.; *see also* Id. at 51–52). The policy paper went on to provide numerous examples of weight-of-the-evidence considerations relevant to evaluation of human and animal data on pre- and post-natal toxicity. (Id. at 30–33).

The discussion on the completeness of the exposure database focuses on whether the various approaches EPA uses to assess exposure are likely to understate it. Risk assessors are to evaluate whether their assessments ''have addressed all significant exposure routes'' and whether ''there may be uncertainty about whether OPP's approach to estimating exposure for a particular use pattern, pathway, or aggregate exposure is sufficiently health protective.'' (Id. at 48).

3. *Benchmark dose approach.* As indicated above, EPA has traditionally used a NOAEL or LOAEL as a Point of Departure in estimating an exposure level of concern for a pesticide or other substance. Increasingly, however, EPA uses a more sophisticated modeling tool known as the Benchmark Dose approach as an alternative to using NOAELs or LOAELs for Point of Departure selection. (Refs. 23). A benchmark dose, or BMD, is a point estimate along a dose-response curve that corresponds to a specific response level. For example, a BMD^{10} represents a 10% change from the background level (the background level is typically derived from the control group). In addition to a BMD, a confidence limit may also be calculated. Confidence limits express the uncertainty in a BMD that may be due to sampling and/or experimental error. The lower confidence limit on the BMD is termed the benchmark dose limit (BMDL). Use of a BMD or BMDL for deriving the Point of Departure allows more precise estimates of the Point of Departure, resulting in tighter confidence intervals. Use of the BMDL also helps ensure with high confidence (e.g., 95% confidence) that the selected percentage of change from background is not exceeded. Numerous scientific peer review panels over the last decade have supported the Agency's application of the BMD approach as a scientifically supportable method for deriving Point of Departures in human health risk assessment, and as an improvement over the historically applied approach of using NOAELs or LOAELs. (Refs. 24, 25, and 26). The NOAEL/LOAEL approach can look at the dose response at only the few doses used in a study, and is therefore limited by the characteristics of the study design, such as dose selection, dose spacing, and sample size. (Ref. 23 at 3–5). With the BMD approach, all the dose response data are used to derive a dose response curve. For all of these reasons, BMD analysis is preferred by EPA to the NOAEL/LOAEL approach of selecting a Point of Departure from studies when the available data are amenable to BMD modeling consistent with the biological processes relevant to the study in question.

IV. Dichlorvos

Dichlorvos is a chlorinated organophosphate pesticide that inhibits plasma, red blood cell (RBC), and brain cholinesterase in a variety of species. (Ref. 3 at 122–123). Cholinesterase inhibition is a disruption of the normal process in the body by which the nervous system chemically communicates with muscles and glands. Although cholinesterase inhibition in the nervous system is not itself regarded as a direct adverse effect, it is ''generally accepted as a key component of the mechanism of toxicity leading to adverse cholinergic effects.'' (Ref. 27 at 25; see 73 FR 42688–42689). Inhibition of blood cholinesterase ''is not an adverse effect, but may indicate a potential for adverse effects on the nervous system'' and thus serves as a ''surrogate'' for cholinesterase inhibition in the nervous system (Ref. 27 at 28). Subchronic and chronic oral dichlorvos exposures to rats and dogs as well as chronic inhalation dichlorvos exposure to rats resulted in significant decreases in plasma, RBC, and/or brain cholinesterase activity. Repeated, oral subchronic dichlorvos exposures in male humans were associated with statistically and biologically significant decreases in RBC cholinesterase inhibition. These cholinesterase effects occurred at dose levels below levels at which any other adverse effect was seen. Generally, there was no evidence of increased sensitivity to young animals following exposure to dichlorvos. No evidence of increased sensitivity to young animals was seen following *in utero* dichlorvos exposure to rat and rabbit fetuses as well as pre/post natal dichlorvos exposure to rats in developmental, reproduction, and comparative cholinesterase studies. The only evidence of sensitivity in the young was seen in one parameter, auditory startle amplitude, in a developmental neurotoxicity study; however, the effects in the rat pups in that study were at levels well above levels that result in RBC cholinesterase inhibition.

Because inhibition of cholinesterase activity was identified as the most sensitive effect, it was selected as the toxicity endpoint for assessment of risks for all acute and chronic dietary exposures, as well as short-, intermediate-, and long-term (chronic) dermal, inhalation, and incidental oral residential exposures. For each risk assessment scenario, EPA selected a Point of Departure based on either an animal or human study taking into account the duration of the study and the route of exposure used in the study. (Ref. 3 at 130–135). These Points of Departure were used in calculating RfD/PADs and acceptable MOEs. Due to the lack of sensitivity differences between adults and juveniles, the resulting RfD/PADs and acceptable MOEs were designated as applicable to all population subgroups, including infants and children. Animal studies were used in choosing levels of concern for evaluating risk from acute and chronic dietary exposure; acute dermal exposure; and acute and chronic inhalation exposure. A human study (the Gledhill study) was used in evaluating risk from short-term incidental oral exposure; short-, intermediate-, and long-term dermal exposure; and short- and intermediate-term inhalation exposure. All of the studies from which a Point of Departure was selected were conducted in adults

(adult humans or adult animals). (See Table 1).

Safety factor determinations used in determining the level of concern for each risk assessment scenario differed based on whether EPA relied on one of several different animal studies or a human study for the Point of Departure for that scenario. For levels of concerns derived from a Point of Departure from an animal study, EPA generally applied a 100X safety factor (10X for interspecies variability and 10X for intraspecies variability). Based on a weight-of-the-evidence evaluation, EPA removed the 10X FQPA safety factor for risk assessments based on an animal study. (See Table 1). EPA's weight-of-the-evidence evaluation concluded that (1) the toxicity database was complete; (2) most of the data indicated no increased sensitivity in the young and the only evidence of increased sensitivity occurred at levels well above the Points of Departure used for establishing the levels of concern; and (3) its estimate of human exposure to dichlorvos was not understated.

For levels of concerns derived from a Point of Departure from the human study, EPA applied a 10X safety factor for intraspecies variability and a 3X FQPA safety factor. (72 FR 68694–68695). No interspecies factor was applied because EPA was not extrapolating a level of concern in humans from a dose in an animal study. The weight-of-the-evidence balance for the FQPA safety factor was slightly different for risk assessments relying on the Gledhill human study for the Point of Departure. In addition to all of the considerations pertaining to the assessments with an animal-derived Point of Departure, the Gledhill-based risk assessments introduced another factor to consider—namely, that the Gledhill study raised a data completeness issue due to the fact that it only identified a LOAEL. This latter factor convinced EPA to retain a portion of the FQPA safety factor when relying on the human study for the Point of Departure. EPA concluded, however, that reliable data supported reduction of the 10X factor to 3X because the effect seen at the LOAEL in that study was so marginal (16 percent RBC cholinesterase inhibition) that a lower dose would have been unlikely to detect any adverse effect. (72 FR 68694–68695; see Table 1).

TABLE 1—SUMMARY OF RISK ASSESSMENT SCENARIOS, POPULATION GROUPS, AND UNCERTAINTY/SAFETY FACTORS FOR DICHLORVOS

Scenario	Study from which point of departure taken	Age and species of study subjects	Population groups covered by risk assessment	Uncertainty/safety factors
Acute Dietary	Rat acute oral cholinesterase study.	Adult rats	All population groups, including infants and children.	Interspecies—10X; Intraspecies—10X; FQPA—1X.
Chronic Dietary	1-year dog study	Adult dogs	All population groups, including infants and children.	Interspecies—10X; Intraspecies—10X; FQPA—1X.
Short-term Incidental Oral.	Human 21-day oral study.	Adult humans	All population groups, including infants and children.	Interspecies—1X; Intraspecies—10X; FQPA—3X.
Acute Dermal and Acute Incidental Oral.	Rat acute oral cholinesterase study.	Adult rats	All population groups, including infants and children.	Interspecies—10X; Intraspecies—10X; FQPA—1X.
Short-, Intermediate- and Long-term Dermal.	Human 21-day oral study.	Adult humans	All population groups, including infants and children.	Interspecies—1X; Intraspecies—10X; FQPA—3X.
Acute Inhalation	Rat acute oral cholinesterase study.	Adult rats	All population groups, including infants and children.	Interspecies—10X; Intraspecies—10X; FQPA—1X.
Short- and Intermediate-term Inhalation.	Human 21-day oral study.	Adult humans	All population groups, including infants and children.	Interspecies—1X; Intraspecies—10X; FQPA—3X.
Long-term Inhalation	2-year rat inhalation study.	Adult rats	All population groups, including infants and children.	Interspecies—10X; Intraspecies—3X; FQPA—1X.

V. NRDC's Petition to Revoke Dichlorvos Tolerances and the Administrative Proceedings on the Petition

A. NRDC's Petition and EPA's Denial of the Petition

On June 2, 2006, the NRDC filed a petition with EPA which, among other things, requested that EPA conclude the dichlorvos tolerance reassessment process by August 3, 2006, with a finding that the dichlorvos tolerances do not meet the FFDCA safety standard and issue a final rule by August 3, 2006, revoking all dichlorvos tolerances. NRDC's petition contained dozens of claims as to why dichlorvos' FFDCA tolerances should be revoked. After carefully considering all of NRDC's claims, the public comment received on the petition, and a revised risk assessment EPA conducted in response to the petition, EPA issued an order pursuant to FFDCA section 408(d)(4)(iii) denying the request to revoke dichlorvos' FFDCA tolerances. (72 FR 68662, December 5, 2007).

B. NRDC's Objections and EPA's Denial of the Objections

On February 1, 2008, NRDC filed, pursuant to FFDCA section 408(g)(2), objections to EPA's denial of its tolerance revocation petition and requested a hearing on those objections. NRDC's objections and requests for hearing included two main claims: (1) That EPA has unlawfully failed to retain the full 10X safety factor for the protection of infants and children; and (2) that it was unlawful for EPA to rely on a toxicity study for dichlorvos (the Gledhill study) that was conducted with humans. Because NRDC did not seek judicial review on EPA's substantive conclusions on the latter issue but only challenged EPA's denial of a hearing on the issue, and because the Second Circuit court on review did not reach the hearing issue, the Gledhill study is

further discussed only to the extent it bears on the FQPA safety factor decision.

NRDC cited several grounds for its assertion that EPA unlawfully lowered the 10X children's safety factor. However, only two of its arguments were later raised in NRDC's judicial challenge to EPA's decision. First, NRDC claimed that EPA lacked adequate data on dichlorvos' potential effects on the endocrine system because EPA had not received data on endocrine effects through the Endocrine Disruptor Screening Program. Second, NRDC argued that EPA's choice of a 3X additional safety factor was based on generic data and ''not [ ] on any data specific to DDVP.'' (Ref. 1 at 5).

EPA denied both of NRDC's reasons for its objection to the choice of a 3X FQPA factor. EPA rejected NRDC's endocrine data argument on both legal and factual grounds. EPA concluded that the statute gave it broad discretion to determine what data are needed in making a determination on the FQPA safety factor and that nothing in section 408(p), creating the Endocrine Disruptor Screening Program, overrode that broad discretion. As a factual matter, EPA found that it had adequate data on endocrine effects from the existing dichlorvos database. (73 FR 42697–42698).

EPA also rejected NRDC's claim that it relied on wholly generic data, rather than dichlorvos-specific data, in choosing a 3X FQPA factor. NRDC's argument here was that EPA chose 3X because EPA considers 3X to be a half-value of a 10X factor rather than on data pertaining to dichlorvos. In response, EPA noted that its petition denial order had comprehensively restated its basis for its FQPA safety factor decision, and that restatement focused in great detail on the toxicology data for dichlorvos, particularly, the data on the sensitivity of the young. (73 FR 42695). EPA further pointed out that although the statutory considerations underlying the FQPA safety factor generally supported removal of the 10X additional factor, the reason EPA chose to retain a 3X FQPA safety factor for some assessments was directly tied to a deficiency in a dichlorvos study (the Gledhill study) that is critical to those assessments. (Id.). Thus, there was no basis for NRDC's claim that EPA had not relied on dichlorvos-specific data in making its FQPA safety factor decision.

VI. Judicial Review of EPA's Denial Order

A. NRDC's Petition for Judicial Review and the Matters Presented on Review

NRDC petitioned the Second Circuit court for review of EPA's denial of certain of its objections and hearing requests. As to its hearing requests, NRDC argued that EPA improperly denied its request for a hearing on statistical and informed consent issues presented by the Gledhill study. As to its objections, NRDC asserted (1) that, as a legal matter, EPA was required to retain the 10X FQPA factor if it did not have data from the Endocrine Disruptor Screening Program; and (2) that EPA's choice of a 3X FQPA factor was arbitrary and capricious because EPA had relied upon ''generic assertions that unlawfully fail to take into account any dichlorvos-specific information for infants and children.'' (Ref. 28 at 37). NRDC supported the latter argument in the following fashion. First, it argued that EPA chose 3X solely because it was half of 10X. Second, NRDC asserted that EPA's consideration of the Gledhill study did not constitute ''dichlorvos-specific information for infants and children'' because the Gledhill study was conducted with adults. Third, NRDC dismissed EPA's reliance on dichlorvos developmental studies in animals on the ground that a prior case had held that EPA had not, in that particular case, offered an adequate explanation of how the data on developing animals supported the FQPA factor chosen.

In response, EPA explained that NRDC's focus on EPA's discussion of why 3X is considered half of 10X ignored the central part of EPA's analysis: An assessment of whether the dichlorvos data showed 3X would be safe. EPA responded to the claim of a failure to consider ''dichlorvos-specific information for infants and children'' by noting that the Gledhill study had not been considered in isolation in the decision on the FQPA safety factor but in the context of ''the animal data showing no difference in adult-young sensitivity'' because it was ''that very data that shows why the Gledhill study is appropriate for the entire population * * *'' (Ref. 29 at 63). Further, EPA noted that NRDC's argument that EPA reliance on animal sensitivity data does not justify a choice of 3X contradicted the core of NRDC's claim—that EPA had not considered ''dichlorvos-specific information for infants and children.'' (Id. at 62).

B. The Second Circuit Court's Decision on Review

On review, the Second Circuit court addressed three issues: (1) Was EPA legally compelled to retain the 10X FQPA safety factor in the absence of obtaining data from the Endocrine Disruptor Screening Program; (2) did EPA adequately explain its decision on the FQPA safety factor; and (3) was NRDC entitled to an evidentiary hearing with regard to its claims regarding the alleged statistical and informed consent deficiencies in the Gledhill study.

1. *Endocrine data.* The court held that EPA was not statutorily required to retain the 10X FQPA factor in circumstances where it has not obtained the data required under the Endocrine Disruptor Screening Program. (658 F.3d at 219). The court found ''no indication in the statute or legislative history that Congress * * * intended the children's safety factor to be mandatory in assessing the risks of all pesticides until EPA completed the estrogen disruptor screening program * * *'' (Id.). According to the court, ''Congress allowed EPA to determine, based on all available data, whether there was 'reliable data' supporting a reduced or waived children's safety factor * * *'' (Id.).

2. *FQPA safety factor.* Contrary to the narrow FQPA safety factor issue presented to EPA in NRDC's objections—did EPA's decision on the FQPA safety factor rely on ''a generic assertion [instead of being] based on any data specific to DDVP''?—the court framed the issue on the FQPA factor more broadly: ''NRDC now seeks review of that EPA order, arguing in part that EPA failed to explain why, when assessing the safety of dichlorvos for certain exposure scenarios, EPA did not apply an additional tenfold children's safety factor, to account for potential pre- and post-natal toxicity and completeness of data with respect to exposure and toxicity to infants and children.'' (Id. at 201).

The court found that, for risk assessments relying on the Gledhill study in deriving the Point of Departure, EPA had provided essentially no explanation with regard to the FQPA safety factor. The court noted that EPA had retained an additional 3X safety factor for these risk assessments but the court concluded that it was EPA's express position that this factor was not based on any evaluation of the risks to infants and children but rather was intended to address the lack of NOAEL in the Gledhill study only. According to the court, ''[i]n EPA's IRED and two published orders, EPA consistently

reiterated this position and declined to claim that the 3X factor was based on any evaluation of the risk to infants and children.'' (Id. at 216). Further, the court concluded that, unlike the risk assessments that were not based on the Gledhill study, EPA did not rely on the developmental animal studies showing no differential sensitivity between adult and juvenile animals. According to the court, ''EPA explicitly stated that it did not rely on any animal studies.'' (Id. at 217). The court thought this abnegation of reliance of animal studies was confirmed by EPA's decision not to apply an interspecies factor to the Gledhill-based assessments. (Id.). Although the court noted that EPA called the 3X factor a FQPA factor, the court found that label to be insufficient absent an explanation ''[i]n []either its IRED []or its two orders [of] how the 3X factor was designed 'to take into account potential pre- and post-natal toxicity and completeness of the data with respect to infants and children.' '' (Id.). The court held that EPA's reasoning concerning the marginal effects seen at the LOAEL in the Gledhill study did not constitute a sufficient explanation because EPA did not relate that reasoning ''to 'potential pre- and post-natal toxicity and completeness of the data with respect to infants and children.' '' (Id.). Finally, the court questioned EPA's analysis that the effects at the LOAEL were marginal suggesting that EPA had not done a proper statistical analysis. (Id. at 218).

Accordingly, the court concluded that, as to risk assessments that used the Gledhill study to derive the Point of Departure, EPA's order was arbitrary and capricious due to EPA's failure to provide an adequate explanation with regard to its decision on the FQPA safety factor. (Id.). Given this conclusion, the court vacated the aspect of EPA's order pertaining to risk assessments based on the Gledhill study and remanded the matter to EPA. (Id. at 220).

3. *Evidentiary hearing.* With regard to NRDC's request for an evidentiary hearing on issues it raised concerning the Gledhill study, the court determined that it did not need to resolve this question given its disposition of the FQPA safety factor issue. As the court pointed out, ''EPA may decide, on remand, not to rely on the Gledhill study or to rely on the study in a different manner or for different reasons.'' (Id. at 219).

VII. FQPA Safety Factor Determination for Gledhill-based Assessments

A. Introduction

FFDCA section 408(b)(2)(C) expressly requires EPA to apply a default additional 10X safety factor for the protection of infants and children unless EPA determines, based on reliable data, that a different factor would be safe. Under the terms of the statute, this additional safety factor is imposed ''to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.'' (21 U.S.C. 346a(b)(2)(C)). To implement these statutory commands, EPA has released detailed guidance that advises EPA risk assessors in making decisions on the FQPA safety factor to focus on potential pre- and post-natal toxicity and the completeness of the toxicity and exposure databases. In the dichlorvos IRED and the two orders responding to NRDC'S dichlorvos petition, EPA devoted several pages to explaining how its decision to apply a 3X FQPA safety factor complied with the statutory directives on the FQPA safety factor and was consistent with its policy guidance document. (See Ref. 3 at 128–132; 72 FR 68694–68695; 73 FR 42695–42696). From start to finish this discussion centered on the issues of completeness of the toxicity and exposure databases for dichlorvos and the potential increased sensitivity of infants and children to dichlorvos from pre- and post-natal toxicity.

Nevertheless, in vacating, in part, EPA's dichlorvos order, the Second Circuit court held that there was a complete absence of an explanation from EPA as to how EPA's choice of a safety factor protected infants and children. As the court repeatedly stated, ''EPA did not explain why a children's safety factor less than 10X would 'take into account potential pre- and post-natal toxicity and completeness of the data with respect to infants and children.' '' (658 F.3d at 217). In fact, the court rejected EPA's claim to have applied any FQPA safety factor at all. According to the court, the additional safety factor applied by EPA could not be considered a FQPA safety factor given what the court viewed as EPA's denial that the additional safety factor had anything to do with infants and children. (Id. at 211, 216).

Following a close review of EPA's prior explanations and the court's opinion, EPA now recognizes that the discussion of the FQPA safety factor in its dichlorvos IRED and orders was less than transparent. EPA's explanation for its position on the FQPA safety factor used, at times, a form of short-hand that hid rather than elucidated its reasoning. In particular, EPA's short-hand appears to have led the court to the following two misunderstandings: (1) That EPA's use of a 3X safety factor to address the lack of a NOAEL in the Gledhill study had nothing to do with the safety of infants and children; and (2) that EPA did not consider the animal developmental data in making a determination on the FQPA safety factor for assessments relying on the Gledhill study. Clarification of EPA's position on these two issues is critical to an understanding of EPA's FQPA safety factor decision. Accordingly, on remand, EPA has first addressed how the Gledhill-based assessments relate to protection of infants and children and how EPA used animal developmental data in these assessments. Only then does EPA offer its explanation as to how, in light of the court's opinion, its choice of a FQPA safety factor for the Gledhill-based risk assessment is protective of the safety of infants and children, as required by FFDCA section 408(b)(2)(C).

B. Clarifications

1. *Applying a FQPA safety factor to address the lack of a NOAEL in the Gledhill Study.* Numerous times in the IRED as well as its dichlorvos orders, EPA stated that an additional 3X safety factor was applied in risk assessments using the LOAEL in the Gledhill study as the Point of Departure due to a ''lack of a NOAEL'' in the study. (Ref. 3 at 133; 658 F.3d at 217 (collecting cites)). EPA explained that the safety factor was used to project a NOAEL for the study. The court interpreted these statements as meaning the 3X factor had nothing to do with the protection to infants and children. According to the court, ''EPA explained that the 3X factor [used in conjunction with the Gledhill study] was not based on any risk to children or infants, but accounted for EPA's 'failure to identify a NOAEL in the [Gledhill] study.' '' (Id. at 214). Certainly, the narrow issue addressed by the use of the 3X factor was the lack of a NOAEL in the Gledhill study. However, extrapolating a NOAEL through use of a safety factor is not an end in itself. Rather, the safety factor was used to ensure that dichlorvos risk assessments relying on the LOAEL in the Gledhill study adequately protect the population groups covered by those assessments. Importantly, the population groups covered by the Gledhill-based assessments include infants and children. Thus, the 3X factor to account for the lack of a NOAEL in the Gledhill study was critical to

protecting infants and children. However, EPA's orders and IRED failed to make this linkage between the 3X factor and the safety of infants and children clear. That linkage is fleshed out in detail below.

As discussed in Unit III.B.2.v., prior to the passage of FQPA, EPA had applied an additional uncertainty factor to address a data deficiency such as when adverse effects were seen in the lowest dose of a toxicological study (*i.e.,* when the study did not provide a NOAEL). Such a factor is used to essentially extrapolate a NOAEL for the study. Without an additional safety factor, there is uncertainty as to whether reliance on the LOAEL as a Point of Departure in calculating a RfD/PAD or MOE is adequately protective of the populations covered by the risk assessment scenario relying on that RfD/PAD or MOE.

EPA has interpreted the FQPA as codifying this LOAEL-to-NOAEL uncertainty factor as a FQPA safety factor when the factor is used in a portion of a risk assessment (i.e., in a particular exposure scenario) that assesses, at least in part, the risk to infants and children. (Ref. 10 at 11–16, A–3—A–4). The logic here is straightforward. A study that fails to produce a NOAEL is considered to be a data deficiency that affects the completeness of the toxicity database. The statute specifically references completeness of the toxicity database as a reason for requiring an additional safety factor for the protection of infants and children. Thus, when the LOAEL from a study that lacks a NOAEL is chosen for the Point of Departure for a risk assessment applying to infants, children, or women of child-bearing age (for the purpose of protecting fetuses), the safety factor used to address this data deficiency is a FQPA safety factor for the protection of infants and children. This is the case whether or not the Point of Departure is used for infants, children, or women of child-bearing age only or for both adults and all other population groups, including infants and children. Many risk assessments for particular exposure scenarios use the same Point of Departure for both adults and infants and children because frequently the relevant toxicity data show a lack of differential sensitivity between adults and the young. However, use in a risk assessment of the same Point of Departure for both adults and the young does not make the FQPA safety factor provision inapposite. EPA's position is that any assessment of risk for a particular exposure scenario that includes, at least in part, an assessment of risks to infants and children triggers the FQPA safety factor provision. Nothing in section 408(b)(2)(C) limits the safety factor provision only to situations where infants or children are more sensitive than adults. For similar reasons, it is also irrelevant to application of the FQPA safety factor provision whether the Point of Departure is from a study involving juveniles or adults. Points of Departure for assessing risks to infants and children are based on the studies showing the most sensitive effects, whether the studies are conducted in adults or juveniles. (See Ref. 17 at 452 (''[C]hronic and subchronic tests in [adult animals] have value in assessing potential risks to children by, for example, identifying target sites for toxicity and providing dose-response information that may be useful for human safety assessment, irrespective of life stage.''). The critical factor for the FQPA safety factor provision is whether the study is being used for a Point of Departure for assessing risk to infants and children.

With this background, the connection between the use of a 3X safety factor to address the Gledhill study LOAEL and the protection of the infants and children can now be explicated. Because the Gledhill study produced cholinesterase effects at the lowest level in the subchronic studies in the dichlorvos database and the database showed no age-related sensitivity, (see discussion in Unit VII.C.), EPA chose the Gledhill LOAEL as the Point of Departure for assessing risks for short- and intermediate-term exposure scenarios to all population groups, including infants and children. In other words, the Gledhill LOAEL was selected as the Point of Departure for all population groups for these exposure scenarios because the dichlorvos database demonstrated that the Gledhill study not only provided the best measure of cholinesterase inhibition for protecting adults but that it was the best measure for protecting infants and children. Nonetheless, EPA also recognized that the data deficiency in the Gledhill study—the failure of the Gledhill study to identify a NOAEL—raises uncertainty as to what that study indicates regarding the threshold below which exposure to dichlorvos will not result in cholinesterase inhibition. To address this uncertainty and thus protect the safety of all population groups covered by the risk assessments, including infants and children, EPA chose to apply an additional safety factor of 3X. This choice of a safety factor was made under the rubric of the FQPA safety factor provision because the uncertainty raised by reliance on a LOAEL both (1) affected the assessment of the risk to infants and children; and (2) was driven by a data deficiency affecting the completeness of the toxicity database. (73 FR 42695; 72 FR 68694–68695; Ref. 3 at 133, 134). Thus, the additional 3X safety factor used in assessments relying on the Gledhill study was not simply to address the lack of a NOAEL in that study but rather to ensure the protection of infants and children (among others) given that a LOAEL was used as the Point of Departure for assessing risk to infants and children for several exposure scenarios. Regrettably, the connection between a safety factor used to address the lack of a NOAEL in a study in adults and the protection of infants and children was not transparent in EPA's IRED or its denial of NRDC's petition and objections. That linkage should now be clear.

2. *Reliance on animal developmental data.* EPA's FQPA safety factor policy emphasizes the importance of considering the ''weight-of-evidence analyses for the completeness of the toxicity database, the degree of concern for pre- and postnatal toxicity, and results of the exposure assessments'' in making a safety factor determination. (Ref. 10 at 50). In particular, the policy stresses ''taking into account all pertinent information in evaluating potential pre- and postnatal toxicity.'' (Id. at 29). The policy recognizes that human data on pre- and postnatal toxicity is ''difficult to obtain'' and for that reason discusses, in detail, how animal developmental data should be considered in evaluating the potential for pre- and post-natal toxicity in humans. (Id. at 28–31). Although EPA did discuss the animal data on juvenile sensitivity in its FQPA safety factor determination, (72 FR 68694–68695), the court concluded that EPA had not considered that data in making a determination on the FQPA safety factor for assessments relying on the Gledhill study for the Point of Departure.

To support this conclusion, the court opined that EPA's orders specifically referenced the animal developmental studies in conjunction with the safety factor determination for the non-Gledhill-based assessments but had not done so as to the Gledhill-based assessments. The court is correct that EPA did not clearly explain that its discussion of the animal developmental data related both to the assessments based on a Point of Departure from animal data as well as the assessments relying on the Gledhill study for the Point of Departure. EPA's discussion of

the Gledhill study, and the data deficiency therein, followed the analysis of the animal developmental data but did not directly reference that data or the statutory considerations bearing on the FQPA safety factor decision. (Id.). To avoid this error in its revised safety factor finding below, EPA has included a discussion of the data deficiency in the Gledhill study under the topic of ''completeness of the data with respect to * * * toxicity'' and also explicitly discussed how the statutory consideration pertaining to the potential for pre- or post-natal toxicity, and the animal data bearing on this issue, was considered in the context of the Gledhill-based assessments.

The court also concluded that ''EPA explicitly stated that it did not rely on any animal studies'' in connection with the Gledhill-based assessments, (658 F.3d at 217), citing to language in the IRED that specified that where the Point of Departure was chosen from the Gledhill study ''there was no need to account for interspecies extrapolation * * * [s]ince the study was conducted in human subjects.'' (Ref. 3 at 133, 134). According to the court, ''[w]hen EPA did rely on the animal studies * * * [it] properly applied a safety factor of '10X for interspecies differences.' '' (658 F.23d at 217). The court appears to have drawn the conclusion that the interspecies factor should be applied whenever EPA considers animal studies in any aspect of the risk assessment. Thus, the court reasoned that because EPA did not apply an interspecies factor for the Gledhill-based assessments, it could not have considered the animal developmental data in the FQPA safety factor determination for dichlorvos.

The court has misapprehended the reason EPA uses an interspecies factor in risk assessments. The factor is not automatically applied whenever animal data are considered in any aspect of a risk assessment. Rather, as explained in Unit III.B.2., the interspecies factor is used when extrapolating from a dose in an animal study (generally a NOAEL or LOAEL) on a milligram-per-kilogram of body weight basis to a dose in humans. (See Ref. 10 at 10 (an interspecies factor is used ''if animal data have been used as the basis for deriving the hazard values''). The interspecies factor is designed to account for possible toxicokinetic and toxicodynamic differences in humans and laboratory animals that may result in differences in internal dose and organ sensitivity between humans and animals. Thus, in the dichlorvos animal assessments in which EPA relied on animal data for the Point of Departure, EPA did apply an interspecies factor. For those assessments, EPA was either extrapolating a RfD for humans from animal data or comparing the margin between human exposure and the dose in animals that was judged to be a NOAEL. No interspecies factor was necessary in assessments based on the LOAEL from the Gledhill study because EPA was not extrapolating from a NOAEL or LOAEL in laboratory animals to humans or comparing human exposure to a dose from an animal study. Rather, EPA had data in humans—the Gledhill study—and was relying on that data for the Point of Departure. There was no need to account for the toxicokinetic and toxicodynamics differences between humans and animals when deriving a safe dose for humans from a study conducted with humans.

EPA, however, did rely on the animal developmental data in the FQPA safety factor determination for the Gledhill-based assessments. But that reliance was for a purpose distinct and separate from use of the data for extrapolating a dose from animals to humans. In accordance with Agency FQPA safety factor policy, EPA considered the dichlorvos animal developmental data with regard to the important information it provides on whether the 10X intraspecies factor for dichlorvos is protective of infants and children. (Ref. 10 at 29). A primary focus of the animal developmental data (the rat and rabbit developmental studies, the rat reproduction study, the rat developmental neurotoxicity study, and comparative cholinesterase studies) is on the relative sensitivity of adult and juvenile animals. Because EPA would rarely have data on the relative sensitivity among different age groups of humans to a pesticide, these animal data help inform, as EPA policy makes clear, whether the 10X intraspecies factor is sufficiently protective of infants and children. (Id.).

Considering animal developmental data in evaluating the intraspecies factor is a standard part of EPA's risk assessment process. As discussed in Unit III.B.2 and above, animal developmental data are central both to establishing the justification for the 10X default value for the intraspecies factor and for evaluating the protectiveness of this default value for specific chemicals. Although broad-based surveys of data on adult/juvenile sensitivity in both humans and animals generally support the use of a 10X default value for the intraspecies factor, there is wide recognition that the possibility of heightened sensitivity in infants and children warrants obtaining particularized data on juvenile/adult animal sensitivity for individual chemical risk assessments. When these data are available, they may indicate that there is no heightened concern warranting an additional safety factor or that an additional factor is necessary above and beyond the default 10X value for the intraspecies factor. In a few cases, EPA has even relied, at least in part, on animal data as supporting a reduction in the default 10X intraspecies factor.

Yet, despite the centrality of animal data to the justification for and selection of the intraspecies factor, EPA is not aware of any instance where an interspecies factor has been applied solely for reliance on animal data on adult-juvenile sensitivity to evaluate the protectiveness of the human intraspecies factor. For example, EPA's long-established and consistent practice is not to apply an interspecies factor when relying on a human study for the Point of Departure even though a decision on the intraspecies factor is still an essential part of such assessments. Dourson et al. collected a summary of all EPA's RfDs on EPA's Integrated Risk Information System (IRIS) as of May 2000 that used human data for the Point of Departure. (Ref. 17). All 24 such assessments identified used an interspecies factor of 1X (*i.e.,* no factor). EPA has identified 9 additional such risk assessments on IRIS post-dating May 2000, and each one of those also does not apply an interspecies factor. (Ref. 30). Even more on point are EPA pesticide risk assessments relying on human data. Since the promulgation of the 2006 Human Research Rule, EPA has accepted 10 human studies for use in pesticide risk assessments other than the Gledhill study. (Id.). A Point of Departure was selected from 9 of those 10 studies.[1] Yet, in none of those assessments did EPA apply an interspecies factor in conjunction with a Point of Departure from a human study even though the assessments do not focus on the human data exclusively. Animal developmental data play a critical part in these assessments, particularly where a FQPA safety factor analysis is required.

[1] The one human study that was not used for selection of a Point of Departure was conducted with the pesticide oxamyl. The oxamyl human study was submitted for the purpose of justifying a reduction of the 10X interspecies factor despite use of an animal study for the Point of Departure. The Human Studies Review Board concluded that the ''intentional human dosing study of oxamyl was sufficiently robust to be used for reducing the 10x inter-species (i.e. animal to human) uncertainty factor in the cumulative risk assessment for the N-methyl carbamates.'' (Ref. 36 at 28). Thus, it is not even a given that a full interspecies factor will be applied when an animal study is relied upon to extrapolate a dose in humans.

The FQPA safety factor analysis in the tolerance reassessment document for the pesticide ethephon provides a good example of this. With ethephon, ''[t]he conventional UF of 10X for interspecies extrapolation was not applied because the endpoint selected for the risk assessment was from a human study.'' (Ref. 31 at 6). At the same time, EPA noted that:

> The Agency concluded that no FQPA Safety Factor is necessary to protect the safety of infants and children in assessing ethephon exposure and risks because the toxicology database for ethephon contains acceptable guideline developmental and reproductive studies as well as acute and subchronic neurotoxicity studies. [Guideline studies are conducted in animals. (40 CFR 158.500)]. The Agency also concluded that there is no quantitative or qualitative evidence of increased susceptibility following in utero or postnatal exposure in any of the developmental or reproductive studies. The RfDs and toxicity endpoints established are protective of pre/postnatal toxicity following acute and chronic exposures.

(Id.). A variation on the approach in ethephon is the safety/uncertainty factors chosen in assessing the risk of the pesticide methomyl. (Ref. 32 at 5). For the methomyl risk assessments that relied on a human study for the Point of Departure, the Agency applied a 10X intraspecies, a 1X interspecies factor (no extrapolation from a dose in animals to humans), and a 2X (data-derived) FQPA safety factor. The 2X FQPA factor was chosen because, unlike dichlorvos, the adult/juvenile comparative cholinesterase data in rats showed that juveniles were approximately twice as sensitive to methomyl as adults. Thus, a 2X FQPA safety factor was applied to ensure that the 10X intraspecies factor was sufficiently protective. However, just as with dichlorvos and ethephon, no interspecies factor (1X) was used because the Point of Departure was derived from a human, not animal, study. A final example illustrating that consideration of animal data in conjunction with choice of a Point of Departure from a human study does not result in use of a 10X interspecies factor is the assessment of the pesticide chloropicrin. With chloropicrin, EPA relied upon a human study for the Point of Departure and thus no interspecies factor (1X) was applied. However, EPA's consideration of the data from humans and animals also led EPA to conclude that no intraspecies factor (1X) was needed either. (Ref. 33). No interspecies factor was applied as a result of consideration of animal data in evaluating the need for an intraspecies factor.

Use of a 10X interspecies factor for reliance on animal developmental data to evaluate the protectiveness of the intraspecies factor would also lead to illogical results. For example, animal developmental data are now considered so critical to evaluating pre- and post-natal toxicity that the FQPA imposes a presumptive 10X safety factor in their absence. Yet, once the data are submitted, it does not make sense to replace the 10X safety factor that addressed their absence with a safety factor of equivalent value to address their mere use for evaluation of pre- and post-natal toxicity. Leaving aside what the animal developmental data show, there cannot be equal need for safety factors both in the absence and presence of adequate animal developmental data.

In sum, it would not only be unprecedented, but inconsistent with well-established safety factor practice, to suggest that the mere consideration of animal data in evaluating the protectiveness of the intraspecies factor triggers application of an interspecies factor. Importantly, under the FFDCA section 408, EPA is only authorized to consider ''safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.'' 21 U.S.C. 346a(b)(2)(D)(ix).

Unfortunately, EPA's short-hand description of its FQPA determination misled the court regarding EPA's consideration of the animal developmental data. Further, EPA's brief explanation for why it did not apply an interspecies factor did not clarify the situation. This, in turn, resulted in confusion regarding the role of the interspecies factor. EPA's revised FQPA safety factor explanation attempts to avoid such pitfalls.

C. Revised FQPA Safety Factor Decision

1. *Introduction and background.* The Second Circuit court has vacated that portion of EPA's order on NRDC's objections ''assessing the risk of dichlorvos based on the Gledhill study * * *.'' (658 F.3d at 220). The court found that EPA had ''failed to explain why it did not use a 10X children's safety factor'' for those assessments. (Id.).

In the IRED, EPA relied on the Gledhill human study for selection of the Point of Departure for assessing dermal (short-, intermediate-, and long-term), incidental oral (short-term), and inhalation (short- and intermediate-term) risk for all population subgroups, including infants and children. Agency-wide guidance on Reference Dose selection emphasizes that human data provides the best source for assessing human risk: ''Adequate human data are the most relevant for assessing risks to humans. When sufficient human data are available to describe the exposure-response relationship for an adverse outcome(s) that is judged to be the most sensitive effect(s), reference values should be based on human data.'' (Ref. 19 at 4–12; *see* Ref. 10 at 33 (''human data are the most relevant data for assessing health risks'')). EPA chose the Gledhill study, in particular, for determination of the Point of Departure because it evaluated cholinesterase inhibition, the most sensitive effect for dichlorvos as shown by animals studies, and because the Gledhill study has ''the lowest LOAEL established for RBC cholinesterase inhibition in a repeated oral exposure to dichlorvos.'' (Ref. 3 at 133). Specifically, it was the lowest LOAEL considering both the human and animal studies and cholinesterase effects in adults and juveniles. EPA's determination that the Gledhill study ''is sufficiently robust for developing a Point of Departure for estimating dermal, incidental oral, and inhalation risk from exposure to DDVP,'' was concurred in by the Human Studies Review Board, an independent expert panel of scientists. (72 FR 68675).

The level of concern for the risk assessments relying on the Gledhill study for the Point of Departure was expressed in terms of a target MOE of 30. That value was based on an intraspecies uncertainty factor of 10X and a FQPA safety factor of 3X. Although EPA concluded that neither the data on pre- or postnatal toxicity or on exposure to dichlorvos showed a need for a FQPA safety factor, EPA found that the data deficiency with regard to the Gledhill study—namely, its lack of a NOAEL—justified the retention of a 3X FQPA safety factor.

2. *FQPA safety factor decision.* In making a FQPA safety factor determination, EPA follows a weight-of-the-evidence approach that focuses on the three considerations explicitly noted in FFDCA section 408(b)(2)(C): the completeness of the toxicity database; the potential for pre- and post-natal toxicity; and the completeness of the exposure database. (Ref. 10 at iv). Each of those considerations is discussed below.

i. *Completeness of the toxicity database.* In ruling on NRDC's petition, EPA concluded that it had a complete toxicity database under the pesticide data requirements in 40 CFR part 158. This included all required data specifically pertaining to effects on the young—developmental studies in two

species (rat and rabbit); a two-generation reproduction study in rats; and a developmental neurotoxicity study in rats. EPA also had comparative cholinesterase inhibition data in adult and juvenile rats. EPA did not have data submitted pursuant to the Endocrine Disruptor Screening Program, but for the reasons explained in its order denying NRDC's petition, EPA has concluded that it has adequate data on dichlorvos' endocrine effects for the purposes of its FQPA safety factor decision. (73 FR 42697–42698).

In addition to these standard animal toxicity studies, the dichlorvos registrant had submitted one toxicity study in humans, the Gledhill study, that EPA had determined was in compliance with its Human Research Rule. (40 CFR part 26). As discussed below, there is a data deficiency issue with this study that is pertinent to the completeness of the toxicity database consideration. Although this study was conducted in adults, it is highly relevant to the protection of infants and children because EPA has, for the reasons explained in Units VII.B.1. and VII.C.1, selected the Gledhill study for identifying a Point of Departure for as to several risk assessment scenarios for all population groups, including infants and children. Thus, how EPA addresses the data deficiency in the Gledhill study will directly affect how it assesses risks to infants and children.

The Gledhill study was a repeat dose study measuring RBC cholinesterase inhibition in control and dichlorvos-treated human subjects. Only a single dose level (7 mg) was used in the study. Cholinesterase inhibition in the treated subjects reached a level of 16 percent by day 18 of treatment (i.e., cholinesterase activity levels declined to 84 percent of the pre-dose mean by day 18). As shown in Table 2 below (reprinted from EPA's Data Evaluation Record of the Gledhill study and the Gledhill study report), the statistical analysis of the results of the Gledhill study shows a high level of statistical significance (at the 1 percent level) [2] for cholinesterase activity levels both between controls and treated subjects and between pre- and post-dosing cholinesterase levels for treated subjects for most days post-dosing.

TABLE 2—RESULTS OF THE GLEDHILL STUDY

Timepoint	Placebo (n = 3)			Dosed (n = 6)		
	Mean	SD	% pre-dose mean	Mean	SD	% pre-dose mean
Pre-dose	18483.52	1346.91	100	17738.33	1713.50	100
Day 1	17930.00	1404.24	97	17628.33	1914.45	99
Day 2	18180.00	1564.7	98	16816.67*	1546.63	95
Day 4	18740.00	1771.13	101	16933.33**	1597.33	95
Day 7	18530.00	1888.36	100	16181.67** ††	1759.48	91
Day 9	18460	1007.03	100	16708.33	2504.97	94
Day 11	19210.00	1035.95	104	16036.67** ††	1654.38	90
Day 14	18490.00	1642.35	100	15333.33** ††	1250.34	86
Day 16	17706.67	2470.15	96	15191.67** ††	1062.59	86
Day 18	18260.00	2298.87	99	14855.00** ††	1198.51	84

* Statistically significant difference from pre-dose at the 5% level (paired t-test).
** Statistically significant difference from pre-dose at the 1% level (paired t-test).
†† Statistically significant difference between placebo and dose groups at the 1% level (t-test, based on repeated measures of analysis of covariance).

(Refs. 34 and 35).

EPA found these statistical results to be sufficiently ''robust'' to support use of the Gledhill study as the Point of Departure. This judgment was concurred on by the Human Studies Review Board. (Ref. 36). The Board relied upon the following aspects of the study: The repeated dose approach which allowed examination of the sustained nature of RBC cholinesterase inhibition; robust analysis of RBC cholinesterase inhibition both in terms of identifying pre-treatment levels and consistency of response within and between subjects; and the observation of a low, but statistically significant RBC cholinesterase inhibition response. (Id. at 39). The HSRB concluded that ''[a]lthough a study using a single dose level is not ideal for establishing a LOAEL, there was general consensus that RBC cholinesterase is a well-characterized endpoint for compounds that inhibit acetylcholinesterase activity and therefore, because the decreased activity in RBC cholinesterase activity observed in this study was at or near the limit of what could be distinguished from baseline values, it was unlikely that a lower dose would produce a measurable effect in RBC cholinesterase activity.'' (Id. at 41).

There is one significant deficiency with the Gledhill study, however. Because the study used a single dose level, and that dose was found to cause an adverse effect on RBC cholinesterase activity, the study does not identify a NOAEL. As discussed earlier, this type of deficiency is incorporated and addressed as part of the FQPA safety factor because it relates to the first consideration noted in FFDCA section 408(b)(2)(C)—completeness of the toxicity database. (*See* Unit III.B.2.vi.).

In deciding what level of safety factor is necessary to address this data deficiency, EPA is guided by EPA science policy on use of uncertainty factors, the scientific literature on safety factors, and EPA prior practice with regard to FQPA safety factor decisions. EPA's RfD policy recommends a default value of 10X for an uncertainty factor addressing the lack of a NOAEL but makes clear that ''[t]he size of the LOAEL-to-NOAEL uncertainty factor may be altered, depending on the magnitude and nature of the response at the LOAEL.'' (Ref. 19 at 4–44). Further, as discussed in Unit III.B.2.v, Dourson et al. concluded that ''[t]he data indicate that when faced with a LOAEL and not a NOAEL, the choice of uncertainty factor should generally depend on the

[2] Statistical significance is a term used to describe observed data that differ from the overall distribution of values by a level that is unlikely to be due to random error. Statistical significance is examined in terms of the probability of the observed differences occurring. By convention, observed values that have a 5 or 1 percent chance of occurring are treated as statistically significant, with 1 percent being the more rigorous standard. (Ref. 43).

severity of the effect at the LOAEL.'' (Ref. 9). In specific FQPA safety factor decisions, the magnitude of the response has frequently been an important consideration supporting use of a 3X FQPA safety factor to address reliance on a LOAEL for the Point of Departure. (*See, e.g.,* 75 FR 22245, 22249, April 28, 2010 (selecting a 3X FQPA safety factor for lack of a NOAEL where ''[t]he neurotoxic effects in this study showed a good dose response which resulted in minimal effects on motor activity and locomotor activity at the LOAEL.''); 74 FR 67090, 67094, December 18, 2009 (selecting a 3X FQPA safety factor for lack of a NOAEL where ''[t]he gastric lesions (most sensitive effect) are due to the direct irritant properties of endothall (i.e., portal effects) and not as a result of frank systemic toxicity; the severity of the lesions were minimal to mild; and there was no apparent dose-response for this effect.''); 74 FR 53172, 53177, October 16, 2009 (''The concern is low for the use of a LOAEL to extrapolate a NOAEL, given the relatively insignificant nature of the effect (transient diarrhea seen in the rat); the fact that diarrhea was only seen in studies involving gavage dosing in the rat but not in repeat dosing through dietary administration in rats, mice, rabbits, and dogs; the very high dose level needed to reach the acute oral lethal dose $(LD)_{50}$ (>5,000 milligrams/kilogram (mg/kg)), and the overall low toxicity of azoxystrobin.''); 74 FR 26536, 26541, June 3, 2009 (selecting a 3X FQPA safety factor for lack of a NOAEL where ''[t]he response was marginal at the LOAEL.''); 72 FR 41224, 41228, July 27, 2007 (''The uncertainty factor of 3X for use of the LOAEL instead of the NOAEL is considered appropriate because an increased incidence and severity of epithelial hyperplasia, hyperkeratosis and ulceration of the non-glandular region of the stomach in females were seen in few animals and were minimal in severity and observed in one sex only.''); 72 FR 33901, 33905, June 20, 2007 (''The 3X factor is considered to be protective because the incidence of the effects at the lowest dose tested was only marginally higher than the historical controls.''); 71 FR 71052, 71056, December 8, 2006 (''A 3x safety factor (as opposed to a 10x) for the lack of a NOAEL in this critical study is adequate because the magnitude of the response was low (low incidences without dose response) and the effect of concern was seen in an unusual strain (Chinchilla) of rabbits and not in the New Zealand strain commonly used in developmental toxicity studies.'')).

EPA's policy on cholinesterase inhibition provides important guidance on characterizing the magnitude of a RBC cholinesterase finding. The policy explains that cholinesterase activity data is treated ''like most continuous endpoints (*i.e.,* graded measures of response such as changes in organ weight, hormone levels or enzyme activity),'' in that ''no fixed generic percentage of change from the baseline is considered to separate adverse from non-adverse effects.'' (Ref. 27 at 14). Given the continuous nature of the inhibition response, ''OPP has used statistical significance, rather than a fixed percentage of response from baseline, as the primary, but not exclusive, determinant of toxicological and biological significance in selecting Points of Departure.'' (Id.) Nonetheless, the policy advises that, in examining what level of cholinesterase inhibition will be judged an adverse effect, the level of inhibition must be critically evaluated ''in the context of both statistical *and* biological significance.'' (Id. at 37) (emphasis in original). Although the policy notes that ''[n]o fixed percentage of change (e.g., 20% for cholinesterase enzyme inhibition) is predetermined to separate adverse from non-adverse effects,'' (Id.), it explains that ''OPP's experience with the review of toxicity studies with cholinesterase-inhibiting substances shows that differences between pre- and post-exposure of 20% or more in enzyme levels is nearly always statistically significant and would generally be viewed as biologically significant.'' (Id. at 37–38). The policy recommends that ''[t]he biological significance of statistically-significant changes of less than 20% would have to be judged on a case-by-case basis, noting, in particular the pattern of changes in the enzyme levels and the presence or absence of accompanying clinical signs and/or symptoms.'' (Id. at 38). The policy notes that similar or higher levels of cholinesterase inhibition are used ''in monitoring workers for occupational exposures (even in the absence of signs, symptoms, or other behavioral effects).'' (Id. at 31). For example, the policy points out that the California Department of Health Services requires that workers exposed to toxic chemicals such as organophosphate pesticides be removed from the workplace if ''red blood cell cholinesterase levels show 30% or greater inhibition,'' and that the World Health Organization ''has guidelines with the same RBC action levels (i.e., 30% or greater inhibition).'' (Id.). In conducting Benchmark Dose analyses for dichlorvos, as well as other organophosphate pesticides, EPA generally has used a 10 percent inhibition level as indicating an adverse effect for both RBC and brain compartments given that both of these compartments were used for developing Points of Departure. (Ref. 37 at I.B p.17). A close examination of the cholinesterase inhibition data for dichlorvos, however, has shown that, while both brain and RBC compartments have similar levels of inhibition for acute or very short-term exposures, for longer-term exposures brain cholinesterase inhibition is much less sensitive than RBC inhibition and thus 20 percent RBC inhibition would be adequately protective. (72 FR 68691; Ref. 38). RBC cholinesterase inhibition is not itself an adverse effect; rather, it is used as a surrogate for effects on the nervous system.

In the Gledhill study, the average level of RBC cholinesterase inhibition of the final day of treatment was 16 percent. Although the level of RBC cholinesterase inhibition was relatively low and not accompanied by clinical signs, EPA concluded, contrary to the study's author, that the 7 mg dose did produce an adverse effect. In reaching this conclusion, EPA relied on the uniform nature of the results in the subjects that showed a clear pattern of increasing response over time and a high level of statistical significance in the differences in cholinesterase inhibition both between treated and control subjects and between pre-treatment and post-treatment of individual subjects. Nonetheless, consistent with its cholinesterase policy and its conclusions in regard to other dichlorvos cholinesterase data, EPA found the magnitude of the change in cholinesterase levels to be marginal. The Human Studies Review Board agreed both with EPA's determination on adversity and the marginality of the response. As to the marginality of the response, the Board specifically noted that ''because the decreased activity in RBC cholinesterase activity observed in this study was at or near the limit of what could be distinguished from baseline values, it was unlikely that a lower dose would produce a measurable effect in RBC cholinesterase activity.'' (Ref. 36 at 41). Under EPA's cholinesterase policy, the level of cholinesterase inhibition in the Gledhill study falls at the low end of the scale of what might be considered an adverse effect and the policy recommends a case-by-case inquiry into the adversity determination for inhibition at this

level. Accordingly, EPA determined previously, and reaffirms in this order, that a full 10X safety factor is not needed to address the lack of a NOAEL in the Gledhill study. When a full order of magnitude of additional protection (i.e. 10^1) is unnecessary, EPA will generally use a half of that value (i.e, $10^{.5}$ or approximately 3X) if that value is protective. Here, EPA determined, and in this order reaffirms, that the marginal nature of the cholinesterase response shows that a 3X factor is safe.

In reaching its determination, EPA placed, and continues to place, great weight on the view of the Human Studies Review Board. This Board was created by EPA in response to a congressional mandate. (71 FR 6138 (February 6, 2006)). It is comprised of non-EPA scientists, overwhelmingly from academia, who are specialists in the field of bioethics, biostatistics, human health risk assessment, and human toxicology. (73 FR 42690). The members of the Board at the time the Gledhill study was considered are listed in Appendix 1 to EPA's prior denial order. (73 FR 42713). The Board is charged with reviewing both the ethics and scientific merit of intentional exposure human studies. Its proceedings are conducted in public and it accepted three rounds of public comment on review of the Gledhill study: (1) Written comment submitted prior to its open meeting on dichlorvos; (2) oral comments at the open meeting; and (3) oral comments at a telephone conference on its proposed decision. (73 FR 42692). No comments were submitted prior to the Board's review suggesting that the cholinesterase response was greater than a marginal response and no meaningful comments were submitted to the Board or EPA, following release of the proposed and final Board opinions, contesting the conclusions of this independent and expert scientific panel on this point. The Board's conclusion with regard to the marginality of the cholinesterase inhibition effects in the Gledhill study are strongly supportive of EPA's choice of a 3X factor to address the lack of a NOAEL in the Gledhill study. After all, the Board concluded that ''it was unlikely that a lower dose would produce a measurable effect in RBC cholinesterase activity.'' (Ref. 36 at 41). Use of a 3X factor is protective because it represents a choice of not simply of any lower dose (decreasing the dose by 10 percent fits this criterion) but of a significantly lower dose than that in the Gledhill study for estimating risk (by applying a 3X factor EPA was essentially dividing the dose by a factor of 3).

The court suggested in its opinion that EPA had not conducted an adequate statistical analysis to determine the accuracy of the 16 percent cholinesterase inhibition figure and thus had no basis for making a conclusion ''with any level of precision [as to] the magnitude of the cholinesterase inhibition.'' [3] 658 F.3d at 218. Although EPA scientists and the scientists on the Human Studies Review Board, including the three biostatisticians, found the statistical analysis sufficient to support their conclusion on the marginality of the cholinesterase effect, EPA agrees that a precision analysis, i.e., the calculation of confidence intervals, conveys valuable information on the plausible range in which, within a certain degree of probability, the true value lies. Accordingly, EPA has calculated the confidence intervals for the mean cholinesterase inhibition levels. (Ref. 39). For the days 14, 16, and 18 which had average cholinesterase inhibition levels of 14 percent, 14 percent, and 16 percent, respectively, this calculation shows a 95 percent confidence that average inhibition is between 9- and 18 percent, 9- and 19 percent, and 8- and 24 percent, respectively. Because these ranges of RBC cholinesterase inhibition consistently fall at the low end of what might be found to be a statistically and biologically significant effect on RBC cholinesterase activity, EPA reaffirms its conclusion that the RBC cholinesterase inhibition seen in the Gledhill study was marginal.

[3] The court stated that EPA had found the Gledhill study to ''have had sufficient *statistical power* to detect a cholinesterase inhibition greater than 0, [but] EPA did not explain whether the 9-person study (six dosed subjects, 3 placebo subjects) had sufficient power to determine with any level of precision the magnitude of the cholinesterase inhibition.'' (Ref. at 218) (emphasis added). To clarify, EPA did not do a ''statistical power'' calculation because statistical power is a way of determining the probability of whether a study would detect an effect of a given size if such an effect is there to find. The concern is that a study may indicate that there is no effect when, in fact, the study missed the effect because it had a low probability of finding it (i.e., the study gives a false negative). Because the Gledhill study identified the positive effect it was looking for (cholinesterase inhibition), EPA dismissed NRDC's arguments regarding statistical power as irrelevant. (73 FR 42704–42706). What EPA's statistical analysis of the Gledhill study did show was that there was a statistically significant difference (at the level of 1 percent) in cholinesterase inhibition between control and treated subjects and between pre- and post-dosing for treated subjects on most days of treatment. That is, the differences in cholinesterase inhibition between controlled and treated subjects and between pre- and post-dosing of treated subjects were very unlikely to have been due to chance.

Finally, the determination to retain a FQPA safety of 3X for assessments for which the Point of Departure was selected from the Gledhill study is also supported by two BMD analyses on the dose levels causing cholinesterase inhibition in animals performed in conjunction with the IRED. As explained earlier, BMD analysis is preferred by EPA to the NOAEL/LOAEL approach of selecting a Point of Departure from studies because all of the data from a study can be used in deriving a dose response curve. (Ref. 23). In the absence of the Gledhill study, these analyses would substitute for the LOAEL in the Gledhill study for selection of the Point of Departure for short- and intermediate-term risk assessments because they define the most sensitive effect for these exposure durations. The first of these analyses is a BMD analysis of comparative cholinesterase studies conducted in adult and juvenile rats. (This BMD analysis is discussed in more detail immediately below in the section on ''pre- and post-natal toxicity.'') The lowest BMDL from that analysis (focusing on pooled historical controls) is 0.38 mg/kg/day. (Ref. 42). The second BMD analysis is an analysis of the cholinesterase inhibition results of the subchronic toxicity rat study. (Ref. 40). There, the BMDL was calculated as 0.4 mg/kg/day. The only other potential animal study for use in selecting a Point of Departure for short- and intermediate-term exposures, the subchronic neurotoxicity study, had a significantly higher LOAEL (7.5 mg/kg/day) and produced percentage inhibition levels consistent with, or lower than, the other animal cholinesterase studies. (Ref. 41). A 100X safety factor to address interspecies extrapolation and interspecies variability would be used with these BMDLs if they were chosen as Points of Departure. No additional FQPA factor would be needed for the same reasons that a FQPA factor was not applied to the other assessments relying on animal data. (72 FR 68694–68695). Reliance on the BMD analyses for the Point of Departure with a 100X safety factor produces a level of concern that is comparable to using the Gledhill study for the Point of Departure with a 30X safety factor. This is most easily seen if alternative RfD/PADs are calculated using the BMD analyses from the comparative cholinesterase studies and the subchronic study and from the LOAEL in the Gledhill study. With Gledhill study, the LOAEL of 0.1 mg/kg/day would be divided by 30 (10X for intraspecies and 3X for FQPA) yielding a RfD/PAD of 0.0033 mg/kg/day. With

the BMD analyses, the BMDL of 0.38 mg/kg/day or 0.4 mg/kg/day would be divided by 100 (10x for interspecies and 10X for intraspecies) for a RfD/PAD of 0.0038 mg/kg/day or 0.004 mg/kg/day, respectively. The similarity of these results, whether extrapolating from the animal or human data, provides extra confidence in EPA's FQPA safety factor decision. Additionally, EPA notes that reliance of the Gledhill study produces a marginally lower and thus more protective level of concern.

Thus, the completeness of the toxicity database consideration indicates that an additional safety factor of no greater than 3X is needed to protect the safety of all populations, including infants and children, due to a data deficiency in the Gledhill study. This decision is consistent with EPA policies on RfD selection, the FQPA safety factor, and cholinesterase inhibition, and with the scientific literature on safety/uncertainty factors. It is also consistent with long-established practice in making FQPA safety factor decisions in circumstances where a LOAEL-to-NOAEL extrapolation is necessary. Finally, EPA's scientific conclusions underlying this determination have been concurred in by the Human Studies Review Board, an independent panel of scientific experts in the field of toxicology and bio-statistics.

ii. *Pre- and post-natal toxicity.* There was no evidence for increased susceptibility of rat and rabbit offspring to prenatal or postnatal exposure to dichlorvos. In both rat and rabbit developmental studies, no developmental effects were observed. In the rat reproduction study, the parental/systemic NOAEL/LOAEL was 2.3/8.3 mg/kg/day, which was identical to the reproductive/offspring NOAEL/LOAEL. The developmental neurotoxicity study showed evidence of sensitivity in one parameter, auditory startle amplitude. However, there are no residual concerns for sensitivity from this parameter because the effects in pups were seen at a dose well above the Points of Departure upon which EPA is regulating and a clear NOAEL for the effect (again, well above the Points of Departure) was identified.

In addition, EPA evaluated the relative sensitivity of adult and juvenile animals to cholinesterase inhibition from dichlorvos exposure using a Benchmark Dose (BMD) analysis. For dichlorvos, EPA did a BMD analysis of the rodent toxicity studies for adult and juvenile cholinesterase inhibition (in both brain and RBC) in acute and repeated dose scenarios. (Refs. 3 at 129; 42). EPA analyzed for a BMD showing a 10 percent inhibition of cholinesterase. EPA found similar results for BMDs and BMDLs for cholinesterase inhibition in both the acute and repeated dose scenarios for compartments (brain or RBC), sex, and age. In other words, this analysis indicated that there was no significant sensitivity difference with regard to cholinesterase inhibition between adults and juveniles.

These data showing a lack of sensitivity of juvenile animals relative to adults indicate a low level of concern that the intraspecies factor applied to the Point of Departure from the Gledhill study will fail to protect infants and children. Therefore, the potential pre- and post-natal toxicity consideration, by itself, indicates that risks to infants and children can be safely assessed absent an additional safety factor.

iii. *Completeness of the exposure database.* EPA has extensive data for estimating human exposure levels to dichlorvos. Although NRDC objected to portions of EPA's dietary exposure assessment, after a careful re-analysis of that assessment EPA concluded that its dichlorvos exposure estimate from food, if anything, overstates dichlorvos exposure given the many conservatisms retained in the food exposure assessment and dichlorvos' documented volatility and rapid degradation. (73 FR 42699; 72 FR 68686). Further, EPA concluded that drinking water exposure to dichlorvos was also likely to have over-estimated exposure because of conservative assumptions. (72 FR 68679–68680). A similar conclusion was reached as to residential exposure to dichlorvos after EPA revised this assessment taking into account concerns raised by NRDC. (72 FR 68691). Thus, the completeness of the exposure base consideration, by itself, also does not indicate a need for an additional safety factor to protect infants and children.

3. *Conclusion.* The FQPA safety factor provision requires EPA to presumptively retain an additional 10X safety factor for the protection of infants and children. EPA may apply a different factor only if reliable data show that factor to be safe. Under EPA policy, EPA considers whether the additional FQPA safety factor is warranted taking into account the other safety factors being applied.

For the Gledhill-based risk assessments, EPA has applied a 10X intraspecies safety/uncertainty factor to account for the potential for variable sensitivity among humans. EPA has not applied an interspecies factor in these risk assessments because the Point of Departure is drawn from a study in humans, not laboratory animals. (See Unit VII.B.2). Thus, the precise question under the FQPA safety factor provision for dichlorvos is whether EPA should retain the presumptive additional 10X factor for the protection of infants and children or whether there are reliable data showing that a different additional factor will, in conjunction with the 10X intraspecies factor, protect the safety of infants and children. As the above discussion of the all-important FQPA safety factor considerations indicates, there are (1) reliable data from animal studies on adult/juvenile sensitivity showing that the standard 10X intraspecies factor will be protective of potential pre- and post-natal toxicity to infants and children; (2) reliable data on human exposure to dichlorvos demonstrating that an additional safety factor is not needed to protect infants and children due to exposure concerns; and (3) reliable data with regard to the one toxicity data deficiency identified to show that a 3X additional factor will be protective of all human populations, including infants and children, as to the only toxicity data completeness issue. Therefore, EPA reaffirms its selection of a 3X FQPA safety factor for Gledhill-based assessments.

D. Conclusion

For all of the reasons set forth above, EPA denies NRDC's objection to the use of a 3X FQPA safety factor for assessments relying on the Gledhill study for a Point of Departure. Based on the revised explanation provided in this order, EPA concludes, like it did in the July 23, 2008 order, that a 3X additional safety factor will protect the safety of infants and children. Because this revised explanation addresses the court's reason for finding portions of the July 23, 2008 order to be arbitrary and capricious, EPA has not otherwise reopened or reconsidered that prior order.

VIII. Statutory and Executive Order Reviews

This action denies an objection to a denial of a petition to revoke tolerances, is in the form of an order and not a rule. (21 U.S.C. 346a(g)(2)(C)). Under the Administrative Procedure Act (APA), orders are expressly excluded from the definition of a rule. (5 U.S.C. 551(4)). Accordingly, the regulatory assessment requirements imposed on a rulemaking do not apply to this action, as explained further in the following discussion.

A. Executive Order 12866 and Executive Order 13563

Because this order is not a ''regulatory action'' as that term is defined in Executive Order 12866 entitled ''Regulatory Planning and Review'' (58

FR 51735, October 4, 1993), this action is not subject to review by the Office of Management and Budget (OMB) under Executive Orders 12866 and 13563 entitled ''Improving Regulation and Regulatory Review'' (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

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

C. Regulatory Flexibility Act

Since this order is not a rule under the APA (5 U.S.C. 551(4)), and does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply.

D. Unfunded Mandates Reform Act; and Executive Orders 13132 and 13175

This order denies an objection to a denial of a petition to revoke tolerances; it does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132 entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175 entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this order. In addition, this order does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538).

E. Executive Orders 13045, 13211 and 12898

As indicated previously, this action is not a ''regulatory action'' as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'', (62 FR 19885, April 23, 1997) and Executive Order 13211 entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'', (66 FR 28355, May 22, 2001). In addition, this order also does not require any special considerations under Executive Order 12898 entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

F. National Technology Transfer and Advancement Act

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), (15 U.S.C. 272 note).

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq. does not apply because this action is not a rule as that term is defined in 5 U.S.C. 804(3).

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List of Subjects in 40 CFR Part 180

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

Dated: August 29, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2012–21844 Filed 9–4–12; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 101

[WT Docket No. 10–153; RM–11602; FCC 12–87]

Facilitating the Use of Microwave for Wireless Backhaul and Other Uses and Providing Additional Flexibility To Broadcast Auxiliary Service and Operational Fixed Microwave Licensees

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission takes further steps to remove regulatory barriers and lowering costs for the wireless microwave backhaul facilities that are an important component of many mobile wireless networks. The steps we take will remove regulatory barriers that today limit the use of spectrum for wireless backhaul and other point-to-point and point-to-multipoint communications. This will also facilitate better use of Fixed Service (FS) spectrum and provide additional flexibility to enable FS licensees to reduce operational costs and facilitate the use of wireless backhaul in rural areas. By enabling more flexible and cost-effective microwave services, the Commission can help foster deployment of broadband infrastructure across America. In addition, a number of parties sought reconsideration of the *Backhaul Report and Order,* and we address those requests and deny reconsideration, for the most part.

DATES: Effective October 5, 2012.

The effective date for the Rural Microwave Flexibility Policy, which contains new or modified information collection requirements has not been approved by the Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of that policy.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. A copy of any comments on the Paperwork Reduction Act information collection requirements contained herein should be submitted to Judith B. Herman, Federal Communications Commission, Room 1–B441, 445 12th Street SW., Washington, DC 20554 or via the Internet at *Judith B. Herman@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: John Schauble, Wireless Telecommunications Bureau, Broadband Division, at 202–418–0797 or by email to *John.Schauble@fcc.gov*. For additional information concerning Paperwork Reduction Act information collection requirements contained in this document, contact Judith B. Herman at (202) 418–0214, or via the Internet at *PRA@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, FCC 12–87, adopted and released on August 3, 2012. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554. The complete text of the *Backhaul Second Report and Order, Order on Reconsideration, and Memorandum Opinion and Order* (*Backhaul 2nd R&O, OOR, and MO&O*) and related Commission documents may be purchased from the

Commission's duplicating contractor, Best Copy and Printing, Inc. (BCPI), Portals II, 445 12th Street SW., Room CY–B402, Washington, DC 20554, (202) 488–5300 or (800) 387–3160, contact BCPI at its Web site: *http://www.bcpiweb.com*. When ordering documents from BCPI, please provide the appropriate FCC document number, for example, FCC 12–87. The complete text of the *Backhaul 2nd R&O, OOR, and MO&O* is also available on the Commission's Web site at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-12-87A1.doc*. Alternative formats (computer diskette, large print, audio cassette, and Braille) are available by contacting Brian Millin at (202) 418–7426, TTY (202) 418–7365, or via email to *bmillin@fcc.gov*.

I. Introduction

1. In the *Backhaul 2nd R&O, OOR, and MO&O,* we take further steps to remove regulatory barriers and lower costs for the wireless microwave backhaul facilities that are an important component of many mobile wireless networks. Broadband is indispensable to our digital economy, and wireless technology is an increasingly important source of broadband connectivity. Microwave backhaul facilities are often used to transmit data between cell sites, or between cell sites and network backbones. Service providers' use of microwave links as an alternative to traditional copper circuits and fiber optic links has been increasing. Microwave is a particularly important high-capacity backhaul solution in certain rural and remote locations.

2. In this *Backhaul 2nd R&O, OOR, and MO&O,* we continue our efforts to increase flexibility in the use of microwave services licensed under our part 101 rules. The steps we take will remove regulatory barriers that today limit the use of spectrum for wireless backhaul and other point-to-point and point-to-multipoint communications. We also take actions that will reduce costs of deploying wireless backhaul in rural areas. By enabling more flexible and cost-effective microwave services, the Commission can help foster deployment of broadband infrastructure across America.

II. Background

3. On August 9, 2011, the Commission made additional spectrum available for Fixed Service (FS) use and provided additional flexibility to enable FS licensees to reduce operational costs, facilitating the use of wireless backhaul in rural areas. Specifically, in the *R&O,* the Commission allowed FS to share the 6875–7125 MHz and 12700–13150 MHz bands currently used by the Broadcast Auxiliary Service (BAS) and the Cable Television Relay Service (CARS). In addition, the Commission eliminated the ''final link'' rule that prohibits broadcasters from using FS stations as the final radiofrequency (RF) link in the chain of distribution of program material to broadcast stations. The Commission also modified the part 101 minimum payload capacity rule to allow temporary operations below the minimum capacity under certain circumstances, enabling FS links—in particular long links in rural areas—to maintain critical communications during periods of fading.

4. In the companion *FNPRM,* the Commission sought comment on additional proposals to remove regulatory barriers and facilitate backhaul deployment. Specifically, the Commission sought comment on (1) Allowing smaller antennas in the 6, 18, and 23 GHz bands without materially increasing interference; (2) exempting licensees in non-congested areas from the efficiency standards and allowing other licensees to seek relief from these standards; (3) allowing microwave operators to create higher capacity links by licensing 60 and 80 megahertz channels in the 6 and 11 GHz microwave bands, respectively; (4) revising our rule that requires microwave stations that point near the geostationary arc to obtain a waiver to conform our rule to International Telecommunications Union (ITU) regulations; and (5) modifying the definition of payload capacity in our part 101 rules to account for Internet protocol radio systems.

5. Additionally, four parties filed petitions for reconsideration of the *R&O* and/or *MO&O:* Engineers for the Integrity of Broadcast Auxiliary Services Spectrum (EIBASS), the Fixed Wireless Communications Coalition (FWCC), Motorola Solutions, Inc./Cambium Networks (Cambium), and Wireless Communications Association International, Inc. (WCAI).

III. Second Report and Order

A. Smaller Antennas in the 6, 18, and 23 GHz Bands

6. We adopt, with minor variations, the *FNPRM's* proposal to allow smaller antennas in the 6, 18, and 23 GHz bands. The record demonstrates that smaller antennas can be accommodated without materially increasing the interference risk to other licensees. Clearwire cites ''technology advancements and more sophisticated band sharing techniques'' as developments that would allow us to loosen the Category B antenna standards without an increased risk of interference. Furthermore, a variety of operators who use microwave support the proposed standards. Under our rules, if smaller antennas would cause an interference conflict with another applicant or licensee, the applicant proposing the smaller antenna must upgrade its antenna. Allowing smaller antennas will facilitate wireless backhaul deployments in two ways. As discussed in greater detail below, smaller antennas allow significant cost savings because they are cheaper to manufacture, install, and maintain. Smaller antennas also allow existing towers to accommodate more antennas and allow installations at sites that would not otherwise be able to accommodate larger antennas. Indeed, there could be instances where allowing the use of smaller antennas may be critical in allowing the use of wireless backhaul by broadband operators.

7. We adopt Comsearch's proposal to implement the proposed standards as Category B2 and keep the existing standards as Category B1, allowing applicants to choose between those standards. That approach will maximize flexibility for applicants and allow existing licensees to keep their antennas. We also adopt FWCC's and Comsearch's proposal to slightly loosen the proposed antenna standards for the 18 GHz band. No party argued that the revised standards would raise any interference concerns in any of the relevant bands.

8. We do not adopt Comsearch's proposal to adopt a power limit on licensees using smaller antennas. Adopting a power limit may artificially limit path length because path length is directly related to the EIRP. A particular path will require operation at the same EIRP whether the operator uses a Category A antenna or a Category B antenna. When EIRP is equivalent, a Category B antenna will radiate more energy in the side lobes than a Category A antenna. In areas where another operator is not in proximity, for example, rural and other uncongested areas, the extra side lobe radiation will not cause any additional interference. In those areas, a licensee can use a smaller and cheaper antenna without harming other FS operators. If we were to restrict power across the board, there may be instances where operators may not be able to realize the full benefits of smaller antennas. We find that our existing rules are sufficient to protect against the potential for increased side lobe radiation. If interference occurs, the rules require the licensee to upgrade its

antenna if the upgrade would mitigate the interference.

9. We find that permitting smaller antennas in the 6, 18 and 23 GHz bands will benefit operators and consumers alike and that these benefits outweigh any potential costs. Our actions today will enable these spectrum bands to be used more intensively for wireless backhaul, public safety, and other critical uses. Even for a single link, which consists of two transmitters and two antennas, the cost savings from allowing smaller antennas can be substantial. Savings in installation costs for the link would likely be over $2,000 for two antennas. MetroPCS estimates that if a smaller antenna eliminates the need for wind loading studies or structural changes to a tower, the cost savings could run ''into the tens of thousands, if not hundreds of thousands, of dollars.'' There would also be savings in operational costs. For example, if an operator using a 6 GHz link is able to use 3-foot antennas instead of 6-foot antennas, its site rental costs could decrease by $7,200 each year. There are also additional cost savings noted by FiberTower and others. When those cost savings are multiplied by the thousands of links that are authorized in the 6 GHz band each year, even if a relatively small percentage of authorized links could use smaller antennas, there could be many instances where operators could recognize cost savings. While the cost savings in the 18 and 23 GHz bands would be smaller, since there is less difference in the size of antennas, there would still be cost savings. On the other hand, there is some risk that a carrier taking advantage of these new rules may have to upgrade to a Category A antenna later. We believe that in many cases, this potential cost will be discovered and avoided in the coordination process. We also note that licensees are not required to use smaller antennas.

B. Updating Efficiency Standards

10. To promote efficient frequency use for various channel sizes in certain part 101 frequency bands, § 101.141(a)(3) of the Commission's rules requires FS operators to establish minimum payload capacities (in terms of megabits per second) and minimum traffic loading payloads (as a percentage of payload capacity). That rule lists a ''minimum payload capacity'' for various nominal channel bandwidths. The term ''payload capacity'' is not defined. The same rule also defines ''typical utilization'' of the required payload capacity for each channel bandwidth as multiples of the number of voice circuits a channel can accommodate.

11. The *FNPRM* sought comment on changes to modernize the payload capacity rule, particularly on a proposal made by Comsearch to de-emphasize the legacy voice-based data rates and instead emphasize a consistent efficiency requirement in terms of bits-per-second-per-Hertz (''bps/Hz''). Comsearch also asked the Commission to define ''payload capacity'' as ''the bit rate available for transmission of data over a radiocommunication system, excluding overhead data generated by the system.'' Comsearch argued that, while the examples based on voice-based data rates were typical when the rule was written, they are becoming outdated as systems support other interfaces such as the Internet Protocol. Comsearch also argued that the rule should be changed because the bandwidth efficiency requirements vary (from 2.46 to 4.47 bps/Hz) based on channel bandwidth, rather than having a uniform requirement for all channel bandwidths. Comsearch asked the Commission to obtain input from equipment manufacturers and other interested parties to develop an appropriate efficiency rate in terms of bits-per-second-per-Hertz.

12. The *FNPRM* asked whether the Commission should adopt Comsearch's definition of payload capacity, adopt an alternative definition or leave the term undefined. The *FNPRM* asked commenters to identify advantages and disadvantages to defining the efficiency requirement in terms of bits-per-second-per-Hertz or in terms of some other metric. It sought input on an appropriate benchmark value to use in the event the agency decided to define the efficiency requirement in terms of bits-per-second-per-Hertz. The Commission further inquired whether the value should be the same across all frequency bands and across urban as well as rural areas. It also asked for comments on whether there is any need to consider how the definition should be applied to legacy systems, *i.e.,* whether there would be a need to grandfather equipment that is currently installed or equipment that is currently on the market.

13. FWCC had originally recommended adoption of the efficiency requirements using bits/second/Hertz values adopted by Industry Canada, with appropriate adjustments for bands where Canada does not have FS services. Comsearch supported those standards. FWCC subsequently proposed an adjustment that would continue to express the standards based on bits/second/Hertz but tighten the standards for certain channel bandwidths in the 11 GHz and 13 GHz bands.

14. First, we convert the current voice-circuit based efficiency standards to bit/second/Hertz standards using standards recently proposed by FWCC. Commenters generally support the idea of replacing our existing payload capacity requirements with efficiency requirement expressed in terms of bits-per-second-per-Hertz. We have reviewed the most recent standards proposed by FWCC, and find that they closely approximate what our current rules require and are otherwise appropriate. This action will allow our payload capacity requirements to reflect modern technologies. Furthermore, if we allow new channel bandwidths in microwave bands, a bit/second/Hertz standard will automatically accommodate new channel bandwidths.

15. FWCC and Comsearch support the proposed definition of payload capacity as consistent with industry practice. We adopt the proposed definition because it is useful to define that term in our rules and the proposed definition is appropriate.

16. A second and related issue is the definition of ''throughput'' for purposes of the efficiency standards. The definition is important because FS operators use a variety of network configurations, and using an unnecessarily restrictive definition of throughput can prevent operators from using some of those network configurations. We consider two proposals offered by commenters and adopt an approach that meets both of their objectives.

17. Clearwire supports the idea of adjusting the minimum payload requirements to account for the increased capacity that would be available with wider bandwidth channels. It expresses concern, however, that simply establishing a bits/second/Hertz standard may not be appropriate for modern network topologies. Clearwire uses an Ethernet-based microwave mesh that relies on a ring topology to provide 99.999 percent network availability by providing redundant link diversity from every cell site location. Normally, a ring is split in half with traffic travelling clockwise on one half and counterclockwise on the other half. If a radio fails on a link, the traffic is aggregated and re-routed around the failed/downed link. Because each link must be designed to carry enough data to accommodate failures elsewhere in the system, the links must be designed to be less than fully loaded during normal operation. Clearwire proposes that the Commission require

applicants to designate each of its links with respect to its generic network topology. For example, a link would be certified as either a ring, mesh, or other resilient network path (links), or as a linear (nonresilient) network topology path. If the link were part of a ring, mesh, or other resilient network topology, the applicant would have to identify the link as either a ''traffic bearing link'' or a ''management/resiliency link.'' Under Clearwire's proposal, ''management/resiliency links'' would be exempt from the efficiency standards, while other links would have to comply with the applicable standards.

18. FWCC recommends a different approach. FWCC asks that we drop the voice circuit designations in § 101.141(a)(6) and (7) of the Commission's rules, which define ''loading'' for purposes of existing rules, and replace them with a new § 101.141(a)(6) to read as follows: ''Digital systems using bandwidths of 10 megahertz or larger will be considered 50% loaded when at least 50% of their total payload capacity is being used.''

19. We believe the objectives behind the Clearwire and FWCC proposals can be met through a simpler approach. Therefore, we update our existing traffic loading requirements, which are not expressed in terms of actual data throughput but in terms of the capacities of multiplexers attached to the transmitters. The definition we adopt today will ensure the efficient use of spectrum while allowing operators to use network configurations with redundant links in order to maintain continuity of service if a link fails. While we update our definition to take into account current technologies, the definition we adopt uses an approach that is consistent with our current rule.

20. To harmonize the proposals and respond to concerns expressed by Comsearch, FWCC, Clearwire and other commenters, we replace § 101.141(a)(6) and (7) with the following new § 101.141(a)(6) to read as follows: ''Digital systems using bandwidths of 10 MHz or larger will be considered 50 percent loaded when at least 50 percent of their total capacity is being used. For purposes of this subsection, a Fixed Service channel is being used if it is attached to a communications system that is capable of providing data to it at a rate that is sufficient to occupy at least 50 percent of the payload capacity of the Fixed Service channel, after header compression is applied.''

21. This definition should ensure that FS systems will be designed to carry the amount of data that is likely to be transmitted over them after IP radio systems remove extraneous header data, to the extent licensees use transmission systems that remove such data. It should also accommodate the needs of operators that deploy FS links in ring topologies, where excess capacity is needed to ensure network reliability.

C. Rural Microwave Flexibility Policy

22. In the *FNPRM,* the Commission sought comment on exempting licensees from complying with the efficiency standards if the environment was sufficiently noncongested to allow the use of antennas meeting performance Standard B. The Commission noted that Sprint Nextel Corporation, Cielo Networks, and Aviat Networks contended that providing relief from efficiency standards in rural areas could reduce the costs of deployments and allow for more microwave backhaul in rural areas. The Commission suggested that relaxing efficiency standards might substantially increase possible path lengths and thereby dramatically improve the business case for deploying microwave backhaul facilities in certain rural areas. The Commission noted that general relief may not be appropriate in congested areas because lowering efficiency standards could result in inefficient use of spectrum. In congested areas requiring use of antennas meeting performance Standard A, the Commission sought comment on allowing applicants to obtain relief from the efficiency standards if they show that: (1) The efficiency standards prevent the deployment of the requested link for economic or technical reasons; (2) the applicant does not have any reasonable alternatives (*e.g.,* use of different frequency bands, use of fiber); and (3) relaxing the efficiency standards would result in tangible and specific public interest benefits.

23. We adopt a new policy, the Rural Microwave Flexibility Policy, designed to provide operators relief, through our waiver process, from the efficiency standards that may not be necessary in noncongested rural areas. Granting licensees in noncongested areas relief from these efficiency standards can facilitate the use of microwave backhaul in rural areas by allowing substantial cost savings in deployment. Indeed, granting relief from the efficiency standards could allow the use of microwave in areas where such use would not be economically feasible under the current rules. In adopting this policy, we take into consideration concerns raised by commenters and institute a series of criteria to ensure that relief is appropriately tailored. If experience with this Policy suggests that a rule change is warranted in the future, we will reconsider that possibility at the appropriate time.

24. Exempting licensees from the efficiency standards in noncongested areas can reduce the cost of deploying microwave backhaul facilities and substantially increase possible path lengths, thereby spurring deployment of broadband in rural areas. The benefits of relaxing efficiency standards in rural areas could be considerable. For example, in 2010, Sprint, FiberTower, and the Rural Telecommunications Group estimated the cost of deploying and operating a 6 GHz link covering 100 miles and requiring four different relay towers would be over $3 million. Additionally, FWCC has demonstrated that allowing a 6 GHz licensee to vary its modulation between 256 Quadrature Amplitude Modulation (a throughput of 208 Mbps) and Quadrature Phase Shift Keying (a throughput of 45 Mbps, about one-fifth of the throughput of 256 QAM) could extend the usable length of a link from 24.56 kilometers to 66.45 kilometers, because the lower throughput allows the operator to maintain reliability over a longer distance.

25. An increase in usable path length would allow some operators to replace multiple paths with single paths. For each intermediate relay station that could be eliminated, the operator would save the cost of a transmitter, antenna, and site rental for that relay site. If one uses the $3 million cost estimate provided by Sprint, FiberTower, and the Rural Telecommunications Group, and assumes that each station contributes equally to the overall cost of the link (two end stations and four intermediate relay stations), the cost of each intermediate relay station would be approximately $500,000. A review of our licensing data shows that there are over 22,000 stations in the 6 GHz and 11 GHz bands that currently use Category B antennas that would potentially be eligible for such relief. Moreover, there may be many more sites where microwave service is not yet deployed because of the prohibitive cost of multiple hops. In these cases, a more flexible policy could spur increased broadband ''middle mile'' deployment.

26. Even if an intermediate relay station cannot be eliminated, providing relief from the minimum payload capacity rule can result in cost savings. Allowing use of lower data rates could allow licensees to use less expensive transmitters and lower power, both of which would result in cost savings. Under the revised minimum capacity requirements that we are adopting in this order, for example, a transmitter operating with a bandwidth of five

megahertz in congested areas must have a minimum capacity of 22 megabits per second (Mbits/s). By looking to publicly available sources of equipment pricing, it appears that an operator could realize significant cost savings.

27. Several commenters express concerns about the proposal in the *FNPRM* for an exemption from the efficiency standards. Comsearch believes that the Commission's actions in allowing use of adaptive modulation and allowing the use of smaller antennas in microwave bands provide sufficient cost savings such that relief from the efficiency standards would be unnecessary. FWCC believes that granting relief from the efficiency standards could ''lock in'' inefficient usage if an area subsequently becomes congested. Comsearch and FWCC believe that basing relief from the efficiency standards on the use of a Category B antenna could provide operators with incentives to use less efficient Category B antennas and lower capacity radio equipment and may punish applicants who have other reasons for using Category A antennas. As an alternative, Comsearch and FWCC propose granting relief from the traffic loading requirements in noncongested areas. FiberTower and US Cellular also support granting relief from the traffic loading requirements. FWCC also proposes a set of conditions for areas eligible for relaxed rural efficiency rules. These conditions are designed to ensure that such deployments do not occur in areas that may become congested, thereby protecting against the ''lock in'' problem.

28. We recognize commenters' concerns about the impact of providing relief from efficiency standards in rural areas, but we find there is a better approach than the alternatives presented. FWCC and Comsearch are concerned that providing relief from the minimum payload capacity requirements will provide incentives for licensees to use Category B antennas, which can increase interference. We do not agree with FWCC and Comsearch that allowing adaptive modulation and smaller antennas can be a substitute for relief from efficiency standards, because granting appropriate relief from the efficiency standards can result in much greater cost savings in rural areas. We disagree with those commenters who suggest that granting relief from the traffic loading standards would be an adequate substitute for granting relief from the minimum payload capacity requirements. If we merely provided relief from the traffic loading requirements, FS operators would have to build links that were fully capable of meeting the minimum payload capacity requirements. Denying permission to reduce payload capacities in such areas would all but eliminate any cost savings that would otherwise be made possible by reducing loading percentages alone, because most of the savings associated with granting relief from the efficiency standards would result from reduced up front equipment costs, as opposed to operating costs.

29. Given the concerns presented in the record, we opt to implement our proposal as a policy, listing specific criteria under which we will favorably consider waivers of the efficiency standards, as opposed to a blanket rule exempting licensees from those criteria. This approach responds to the concerns raised by Comsearch and FWCC. More specifically, the policy will not ''lock in'' inefficient usage because licensees will be required to upgrade facilities to use Category A antennas and comply with the efficiency standards if needed to accommodate new FS applicants (or to avoid interference). Furthermore, the criteria we establish will ensure that relief is limited to areas where the use of lower capacity radio equipment will be appropriate. This policy will provide a meaningful opportunity for relief for rural operators. Adopting relief as waiver policy will allow us to consider individual circumstances and to gain more information on when relief from the efficiency standards would be appropriate. As we gain more experience with such waiver filings, we may consider refining the criteria or codifying the policy as a Commission rule.

30. Specifically, we adopt a Rural Microwave Flexibility Policy and direct the Wireless Telecommunications Bureau (''Bureau'') to favorably consider waivers of the payload capacity requirements if the applicants demonstrate compliance with the following criteria:

- The interference environment would allow the applicant to use a less stringent Category B antenna (although the applicant could choose to use a higher performance Category A antenna);
- The applicant specifically acknowledges its duty to upgrade to a Category A antenna and come into compliance with the applicable efficiency standard if necessary to resolve an interference conflict with a current or future microwave link pursuant to § 101.115(c);
- The applicant uses equipment that is capable of readily being upgraded to comply with the applicable payload capacity requirement, and provide a certification in its application that its equipment complies with this requirement;
- Each end of the link is located in a rural area (county or equivalent having population density of 100 persons per square mile or less);
- Each end of the link is in a county with a low density of links in the 4, 6, 11, 18, and 23 GHz bands;
- Neither end of the link is contained within a recognized antenna farm; and
- The applicant describes its proposed service and explains how relief from the efficiency standards will facilitate providing that service (*e.g.,* by eliminating the need for an intermediate hop) as well as the steps needed to come into compliance should an interference conflict emerge.

31. By establishing our Rural Microwave Flexibility Policy, we do not intend to restrict licensees' ability to obtain such relief under §§ 1.925 and 1.3 of our rules. We direct the Bureau to carefully consider requests for waiver of the efficiency standards filed under the general waiver standard, consistent with the Commission's duty to take a ''hard look'' at applications for waiver and consider all relevant factors when determining if a grant of relief is warranted. The Bureau should not reject a waiver showing under the general waiver standard merely because the applicant has not shown all of the factors listed above. We would anticipate that as an applicant demonstrated compliance with more of the factors listed above, that an applicant would be more likely to have made the requisite showing in support of a waiver. We also direct the Bureau to consider other factors in support of a waiver request, if appropriate.

32. We agree with Comsearch and FWCC that licensees who could use Category B antennas but choose to use Category A antennas should not be foreclosed from seeking waiver relief under the waiver policy we establish today because of their voluntary decision to use a higher performance antenna. Accordingly, we clarify that licensees who could use Category B antennas are eligible for relief from the minimum payload capacity requirements, even if they choose to use a Category A antenna, so long as they meet all of the criteria specified in the Rural Microwave Flexibility Policy we adopt today.

33. Our action today will provide major benefits to FS operators in rural areas. Providing relief from the efficiency standards may allow longer path links, which can eliminate the need for intermediate relay stations. As noted above, the cost of operating an intermediate relay station can be up to

$500,000. Furthermore, providing relief from efficiency standards can also allow the use of less expensive transmitters and lower power. In theory, there are two types of costs that could result from today's action. First, a licensee who took advantage of the relief today could later be required to upgrade and comply with the efficiency standards. Second, the presence of a lower efficiency system using a Category B antenna could make it more difficult for other operators to share the spectrum in the same area. Under our rules, however, the decision to use a Category B antenna is voluntary, and existing operators must upgrade their antennas to Category A antennas if necessary to resolve interference conflicts. Accordingly, we anticipate that any costs will be outweighed by the benefits of our action.

D. Allowing Wider Channels in 6 GHz and 11 GHz Bands

34. The *FNPRM* invited comments on FWCC's request that the Commission allow FS operators to combine adjacent channels in the 5925–6425 MHz (Lower 6 GHz band) and 10700–11700 GHz band (11 GHz band), respectively, to form 60 and 80 megahertz wide channels, where the maximum authorized channel bandwidths at present are 30 and 40 megahertz, respectively. The *FNPRM* acknowledged that the proposal had the potential to allow backhaul operators to handle more capacity and offer faster data rates but noted that the record on this issue was otherwise quite limited.

35. Commenters generally support FWCC's proposal, primarily on the ground that smart phones and other mobile devices are generating increased data demands for cellular backhaul. Comsearch and US Cellular advise proceeding cautiously because the conventional approach to assigning channels of 30 megahertz bandwidth in the 6 GHz band and of 30 or 40 megahertz in the 11 GHz band has been to follow an adjacent-channel alternating-polarization (''ACAP'') plan. Comsearch states that this kind of cross-polarization is worth up to a 35 dB reduction in interference when compared with the amount of interference that a signal on the same polarization would cause. If we allow 60 or 80 megahertz channels to be assigned on a single license, it becomes harder to maintain the ACAP licensing plan, particularly when the wider channels are overlaid on existing 30 or 40 megahertz channels. Ultimately, however, in light of the potential cost savings, Comsearch supports allowing wider channels in the 6 and 11 GHz bands ''subject to appropriate safeguards.''

36. In response to FWCC's petition for rulemaking, NSMA suggested that the Commission should consider: (1) ''Requiring a showing of necessity and availability for applications planning use of more than one or two 60/80 MHz wide channels on any one path''; (2) designating certain slots as ''preferred'' slots for wider bandwidth channels (*e.g.,* starting at one of the band edges, so all licensees would first attempt use of these channels on the same frequencies); (3) adjusting the minimum payload requirements to account for the higher capacity capabilities of the wider bandwidth channels; and (4) adopting methods to better assure high utilization with more tightly drawn regulations. The *FNPRM* sought comment on NSMA's suggestion.

37. We find that allowing 60 megahertz and 80 megahertz channels in the 6 GHz and 11 GHz bands, respectively, would serve the public interest by allowing backhaul operators to handle more capacity and offer faster data rates. In light of the explosive growth in demand for broadband services, we believe it is important to provide operators with the capability to offer faster services wherever possible. Allowing wider channels can also result in more efficient spectrum utilization.

38. The only concern, which was raised by Comsearch and US Cellular, was whether wider channels would be consistent with assigning channels using ACAP. Neither of those parties opposes allowing wider channels, however, so long as appropriate safeguards are instituted against warehousing and inefficient use of spectrum. Commenting parties support the conditions suggested by NSMA. After reviewing the conditions, we will adopt NSMA's suggestion that wideband channels be assigned by preference to the highest available channels in the relevant bands, except where such a choice would impede the efficiency of local frequency coordination efforts. We also adopt today a broader revision of our payload efficiency rules to apply uniform bits-per-second-per-Hertz requirements across multiple bands and bandwidths. Together, we believe those actions will ensure that the 6 and 11 GHz bands are used efficiently while allowing licensees to benefit from wider channels.

E. Geostationary Orbital Intersections

39. To protect receivers on geostationary satellites from the potential for interference from FS transmitters, § 101.145 of the Commission's rules requires a waiver filing for: (1) FS transmitters in the 2655–2690 MHz and 5925–7075 MHz bands with an antenna aimed within 2° of the geostationary arc; and (2) FS transmitters in the 12700–13250 MHz range with an antenna aimed within 1.5° of the geostationary arc. To be approved, a waiver request must show, among other factors, that the transmitter EIRP is below listed limits. In contrast, Article 21 of the ITU Radio Regulations places the 2° restriction on the pointing azimuth of antennas of FS transmitters in the 1–10 GHz band only if the EIRP is greater than 35 dBW, and the 1.5° restriction on the azimuth of antennas in the 10–15 GHz band only if the EIRP is greater than 45 dBW.

40. The *FNPRM* sought comment on a Comsearch proposal to amend § 101.145 of the Commission's rules to require a waiver filing for FS facilities pointing near the geostationary arc only if the EIRP is greater than the values listed in the ITU Radio Regulations. Comsearch contends that the existing, more restrictive requirement in § 101.145 primarily protects satellites located over Europe, Africa, or the Atlantic or Pacific Oceans. Comsearch further believes that, because the ITU has determined that FS transmitters with EIRPs below the values listed in Article 21 are unlikely to cause interference to geostationary satellites, amending the Commission's rules would improve the administrative efficiency of licensing FS links for backhaul without any corresponding harm.

41. We adopt the proposal to require that a waiver filing be necessary for FS facilities pointing near the geostationary arc only if the FS station's EIRP is greater than the values listed in the ITU Radio Regulations. As noted in the *FNPRM,* this action can facilitate microwave deployments by allowing affected licensees to deploy more quickly, explaining that the Commission's rules provide many applicants with conditional authority to begin service immediately, without waiting for final approval from the Commission, once they complete frequency coordination, with the stipulation that they must take their stations down if the Commission later rejects their applications. The change will harmonize the Commission's regulations with international regulations, and as explained further below, can apparently do so without creating any increased risk of interference to satellite services. That rule change will limit the circumstances in which applicants will have go through the burden and expense of

filing waiver requests and the associated waiver fee.

42. We do not change the requirement that FS facilities protect previously authorized satellite facilities. Nor do we limit the right of satellite licensees to file petitions to deny or informal objections against FS facilities that they believe would cause interference to their facilities. The only change from the viewpoint of satellite providers is that FS operators proposing power below the limits contained in ITU regulations will now be able to operate pursuant to conditional authority.

43. Sirius XM Radio, Inc. (Sirius XM) is the only commenter to oppose the proposed change. Sirius XM operates feeder links in the 7025–7075 MHz band to uplink its digital radio transmissions to its satellites. It also has telemetry, tracking and control links in that band. Sirius XM expresses concern that, even if no single FS transmitter were to interfere with one of its satellites under the proposed rule change, several FS transmitters together might do so. On that basis, Sirius XM urges the Commission to establish a numeric limit on the aggregate amount of interference that FS transmitters impinge upon the geostationary satellite arc. In reply, Comsearch provides a detailed technical analysis demonstrating that it would be extremely rare for terrestrial microwave antennas in this country to be directed towards either of Sirius XM's satellite positions.

44. Comsearch's showing that there are currently only three microwave antennas in this country pointed toward one of Sirius XM's satellites demonstrates that the aggregate incremental effect of such multiple exposures is likely to be quite low. While the Commission is prepared to consider showings based on aggregate interference in appropriate circumstances, we decline to adopt Sirius XM's proposal at this time.

45. We find that reducing the circumstances under which FS operators must seek waivers when pointing towards the geostationary arc will produce substantial benefits. Each private FS applicant must pay an application fee of $180 when seeking a waiver. In 2011, we granted 275 applications requesting a waiver of § 101.145 of the Commission's rules where the EIRP was below the limits contained in the ITU Radio Regulations and the applicant had to pay a waiver fee. The total application costs associated with those waivers would be $49,500. Furthermore, each applicant must prepare a waiver exhibit at additional expense. Furthermore, every time a waiver is requested, the applicant cannot commence service until the waiver and applications are granted. While the cost of such delays cannot be quantified based on this record, it is apparent that such delays may be costly to FS providers and their customers. On the other hand, we find that the potential for increased interference or other costs would be minimal from this action. Accordingly, we find that the benefits of the Commission's actions outweigh the costs.

IV. Order on Reconsideration

A. Making 6875–7125 MHz and 12700–13150 MHz Available for Part 101 FS Operations

1. *Allowing FS Operations in Areas Where BAS Operates on Adjacent Channels*

46. In the *R&O,* the Commission authorized FS use of the 6875–7125 MHz and 12700–13150 MHz bands in areas where television pickup licenses are not authorized in those bands. The Commission prohibited FS paths from crossing the service areas of TV pickup authorizations in order to avoid interference. FWCC asks the Commission to limit the exclusion of FS from vacant 13 GHz channels in areas served by BAS and CARS to co-channel operations. In other words, under FWCC's proposal, FS could be licensed in areas where BAS and CARS have operations so long as the FS operations are not on the same channels as any licensed BAS or CARS stations.

47. The National Association of Broadcasters (NAB) and the Society of Broadcast Engineers, Inc. (SBE) contend that the ''introduction of new wireless backhaul operations would be incompatible with effective, unpredictable itinerant newsgathering and news reporting, and it would disserve the public if ENG services at the scene of breaking news were undermined by interference concerns caused by the presence of nearby wireless backhaul operations.'' NAB and SBE are also concerned that it would not be feasible to mix the formal coordination process used by FS applicants with the more informal coordination process used by broadcasters, because FS applicants do not have the same incentives as broadcasters to accommodate the needs of TV pick-up operations.

48. We decline to adopt FWCC's proposal to permit FS operations in channels adjacent to BAS/CARS operations at this time, for three reasons. First, as a technical matter, microwave signals that are being transmitted on adjacent channels can interfere with each other under some circumstances and, for that reason, require frequency coordination. Second, as discussed in the *R&O,* BAS operators are motivated to coordinate spectrum with each other rapidly and cooperatively because they engage in similar activities, such as covering breaking news events, and share a common motivation to ensure that spectrum continues to be made available for such activities on short notice. Allowing FS applicants into areas where BAS is authorized would necessitate a more formal coordination process, which we do not believe is compatible with the dynamic and rapidly changing nature of electronic newsgathering (ENG) operations. Finally, § 74.24 of the Commission's rules allows BAS licensees to engage in short-term operations on unlicensed BAS channels for as many as 720 hours annually per frequency. Therefore, in some locations, BAS operators could be making extensive short-term use of unlicensed BAS channels in the geographic areas where they have BAS licenses for other channels. Allowing FS operations to use these frequencies could result in interference and disruption to these operations.

2. Protection Criteria for BAS Stations

49. In comments filed during an earlier phase of this proceeding, EIBASS asked the Commission to prohibit newcomer Private Operational Fixed Service (POFS) stations in the 7 and 13 GHz bands from degrading the noise threshold of any existing electronic newsgathering-receive only (ENG–RO) site by more than 0.5 dB, citing as precedent the Commission's decision to apply that standard to Department of Defense uplinks when determining whether or not they are providing adequate protection to ENG–RO sites in the 2 GHz band. The *R&O* acknowledged that EIBASS's proposal might be an appropriate standard for evaluating a proposed FS facility but declined to adopt it as a rule, explaining that, in lieu of mandating specific interference criteria in our rules, we expect applicants and licensees to work out interference issues in the frequency coordination process. In a petition for partial reconsideration of the R&O, EIBASS now reiterates its request, arguing that a vague frequency coordination benchmark does neither the incumbent nor the newcomer any favor, because of the uncertainty it generates.

50. EIBASS's proposal is unnecessary because we are upholding the Commission's prior decision to prohibit the paths of FS stations operating in the 7 and 13 GHz bands from crossing the

service areas of TV pickup authorizations. The transmission paths of part 101 FS stations are fixed. That makes it possible for FS applicants to provide licensees and other applicants with detailed notifications that include proposed transmission azimuths, among other technical parameters, and to allow the other affected parties 30 days to respond. Although our rules provide for the Commission to resolve any differences that the parties are unable to resolve by reasoned discussions with each other, it is hardly ever necessary for the Commission to intervene in the frequency coordination process among parties that are subject to our part 101 coordination procedures. The chances that the affected parties would reach an impasse seem particularly remote under these circumstances, where FS paths are barred from crossing any of the geographic areas where ENG–RO stations are licensed. Further, there is no evidence in the record that EIBASS's proposal would reduce the costs associated with the coordination process. For those reasons, we remain confident that the existing frequency coordination procedures will ensure that part 101 FS operators will not interfere with ENG–RO operations in the 6875–7125 MHz and 12700–13150 MHz bands. We therefore decline to adopt EIBASS's proposal.

3. Efficiency Standards for 13 GHz Band

51. FWCC notes that the *R&O* did not specify a minimum throughput for the 13 GHz frequencies newly authorized for Fixed Service use. FWCC recommends that we set the same throughput requirements for 13 GHz as apply to the 11 GHz band, and that we augment those requirements to include capacity and loading requirements for transmitters using channel bandwidths of 12.5 megahertz.

52. Section 101.141(a)(3) of our rules applies minimum payload capacities to digital microwave transmitters operating in the 11 GHz band, depending upon their bandwidths. We agree with FWCC that the same standards should be applied to the 13 GHz band. Our decision above adopting the proposal in the *FNPRM* to apply uniform bits-per-second-per-Hertz requirements to all frequencies between 10,550 MHz and 13,150 MHz includes the frequencies in FWCC's request, and thus renders the request moot.

4. Allowing 50 Megahertz Channels in the 7 GHz Band

53. The *R&O* retained the 25 megahertz bandwidth limit that presently applies to the 7 GHz band because of the limited amount of spectrum available in that band, but it raised the maximum permissible bandwidth in the 13 GHz band to 50 megahertz. Cambium Networks (Cambium) urges that we also allow the 7 GHz band to accommodate 50 megahertz bandwidths. The NAB and SBE oppose this proposal on the ground that it would reduce the number of available channels for new ENG use. Cambium counters the broadcasters' concern by citing the *R&O's* observation that BAS and CARS operations have not been expanding geographically in recent years, with only one new BAS TV pickup license granted in the 7 GHz and 13 GHz bands in the past two years.

54. We deny the Cambium Petition because the benefits of allowing 50 megahertz channels in the 7 GHz band appear to be quite limited and because operators needing wider channels have alternatives. If we allowed 50 megahertz channels in the 7 GHz band, there would only be two channel pairs available in the 7 GHz band. Allowing 50 megahertz channels could limit the availability of FS spectrum for other operators who need narrower channels. Furthermore, operators who need 50 megahertz or wider channels have alternative options available. Today, we are allowing 60 megahertz channels in the 6 GHz band and 80 megahertz channels in the 11 GHz band. For shorter paths, 50 megahertz channels are available in the 18 GHz and 23 GHz bands. Under those circumstances, we believe the better use of the 7 GHz band would be to accommodate narrower band operations. We therefore deny the Cambium Petition.

B. Elimination of the Final Link Rule

55. The ''final link rule'' prohibited broadcasters from using part 101 stations as the final radiofrequency (RF) link in the chain of distribution of program material to broadcast stations. Concurrent with the Commission's decision to allow FS to share in the 7 and 13 GHz BAS and CARS bands, the *R&O* eliminated the final link rule. In doing so, the Commission noted that FS licensees were not objecting to elimination of the rule so long as FS were granted access to BAS and CARS spectrum in the 7 and 13 GHz bands.

56. In a petition for reconsideration, FWCC argues that the final link rule should only be eliminated in areas where the Fixed Service can use the 7 or 13 GHz bands. FWCC argues that a key rationale for the change was ''sharing of spectrum the other way''—i.e., a *quid pro quo* for opening the 7 and 13 GHz BAS/CARS bands for use by part 101 FS operators—but that excluding FS operators from geographic areas where BAS and CARS operations are licensed leaves FS with very limited access to those bands. The NAB and SBE oppose FWCC's petition, arguing that the convergence of digital video with digital data transmission has eliminated any technological reasons for broadcasters to maintain facilities to carry program material to transmitter sites that are separate from microwave transmission systems that handle other kinds of data. Reinstating the final link rule would therefore result in a duplication of facilities that would otherwise be unnecessary, they contend.

57. In the *R&O,* the Commission found that there would be significant benefits and no costs to eliminating the final link rule. It noted that no commenter had identified any cognizable harm that would result from eliminating the rule and concluded that, with increasing adoption of digital technologies, the final link rule had become an outdated regulation that imposed unnecessary, duplicative costs on broadcasters. That conclusion is consistent with one of the fundamental purposes of this proceeding: removing regulatory barriers that limit the use of spectrum for wireless backhaul and other point-to-point and point-to-multipoint communications.

58. The Commission's action maximized the ability of both FS operators and broadcasters to use the 7 and 13 GHz bands. While it is true that the Commission did not make those bands available for FS use everywhere, that decision was based on the fact that fixed links and ENG operations are different and difficult to coordinate with each other. In contrast, there is no technical reason why broadcasters, cable operators and part 101 FS operators cannot share the same spectrum when transmitting microwave signals between fixed locations.

59. The Commission's actions maximized the amount of spectrum available to both FS licensees and broadcasters. Furthermore, FWCC does not allege any harm from eliminating the final link rule; and therefore, the Commission's conclusion that there would be significant benefits and no costs to eliminate the final link rule remains unchanged. We therefore deny FWCC's Petition on this issue.

C. Upper Microwave Substantial Service Policies

60. In reply comments to the *NOI,* NSMA argued that in determining whether 24 GHz, 39 GHz, and Local Multipoint Distribution Service (LMDS) licensees have offered substantial service, the Commission fails to positively consider ''basic and

important steps that lead to successful band utilization.'' It gives the following examples of such activity: (1) Spending significant resources producing Requests for Proposals (RFPs) to develop equipment in its band; (2) utilizing the Secondary Markets rules to offer spectrum leases throughout the license area; (3) submitting proposals to carrier, government, or enterprise customers that rely on utilizing the wide-area license; and/or (4) building several links, but not yet meeting the safe harbor criterion (typically four links per million of population). NSMA asked the Commission to ''track and credit'' such activities.

61. The Commission rejected NSMA's request in the *MO&O.* The Commission concluded that NSMA's arguments ignored one of the Commission's overriding purposes of buildout requirements: providing ''a clear and expeditious accounting of spectrum use by licensees to ensure that service is indeed being provided to the public.'' It approved the Wireless Telecommunications Bureau rejection of substantial service showings based on preparatory activities of the type described by NSMA where there is no actual service being provided to the public. It noted that safe harbors are merely one means of demonstrating substantial service, and that given an appropriate showing, a level of service that does not meet a safe harbor may still constitute substantial service. It also emphasized that all substantial service showings that do not meet an established safe harbor would be evaluated on a case-by-case basis.

62. In a petition for reconsideration of the *MO&O,* the Wireless Communications Association International, Inc. (WCAI) challenges the Commission's decision to address that issue in this proceeding. WCAI argues that the Commission's consideration of this issue violates the Administrative Procedure Act because the issue was not raised in the *NPRM.* WCAI believes substantial service rules and policies relating to wireless backhaul should be addressed in the broader proceeding seeking to harmonize renewal standards for wireless radio services (WT Docket No. 10–112) that is currently pending.

63. WCAI argues that standards currently applicable to fixed point-to-point services, which require a certain number of links based on population, do not in fact promote service to the public because it requires operators to either build uneconomic links in the absence of demand for backhaul services or lose their licenses. According to WCAI, the standards create ''substantial investor uncertainty about the amount of capital required to preserve a license in the millimeter wave bands.'' WCAI asks the Commission to adopt an ''offer-based'' standard that would ''require only that an area-wide millimeter wave band licensee offer FP2P service or spectrum leases on commercially reasonable terms and conditions to commercial or government fixed or mobile telephony/broadband service providers or to the licensee's internal network planners.'' FWCC and Mary J. Kuiken support WCAI's Petition.

64. WCAI has filed its substantial service proposal for wireless backhaul in WT Docket No. 10–112 and we will consider it in that proceeding, consistent with WCAI's request. The *Memorandum Opinion and Order* merely explained the Commission's decision not to initiate a rulemaking to address NSMA's substantial service proposal that NSMA presented in reply comments filed in response to the *NOI,* and thus did not violate the notice-and-comment requirements of the APA, which are applicable to rulemaking proceedings, or prejudice our consideration of substantial service issues in WT Docket No. 10–112. The Commission's decision to dispose of NSMA's request also was appropriate because many LMDS and 39 GHz licensees were facing a June 1, 2012 deadline for providing substantial service. The Commission's response to NSMA's petition thus restated the applicable rules and policies in advance of that deadline and allowed licensees to plan accordingly. In explaining its decision, we note that the *MO&O* accurately stated the Commission's current policy, and we direct the Bureau to apply that policy to the June 1, 2012 substantial service filings made by LMDS and 39 GHz licensees. We also agree with the observation in the *MO&O* that any substantial service standard must provide ''a clear and expeditious accounting of spectrum use by licensees to ensure that service is indeed being provided to the public.'' Our action today is without prejudice to subsequent consideration of these issues in WT Docket No. 10–112.

V. Memorandum Opinion and Order

65. In this *MO&O,* we address various other proposals and issues that we believe are best considered in other contexts or do not require Commission consideration and therefore will not be considered in this proceeding at this time.

66. FWCC asks that the Commission authorize smaller antennas in the 71–76 and 81–86 GHz bands. We decline to initiate a rulemaking because we do not believe that FWCC has provided sufficient information to justify further action at this time in the context of this proceeding. The current antenna specifications for those bands were adopted after a detailed discussion of the tradeoffs involved. FWCC has not provided sufficient information to demonstrate that smaller antennas could be allowed without increasing interference. Our action today is without prejudice to consideration of a more detailed submission on this issue.

67. EIBASS, which supports the *R&O's* requirement that BAS licensees in the 7 and 13 GHz bands register their fixed receive sites, asks various questions about the effective date and other aspects of the requirement. Staff from the Bureau has met with broadcasters to discuss implementation of that requirement. We do not see the need for Commission intervention at this time, but we direct the Bureau to continue working with broadcasters on implementing the registration requirement.

68. Comsearch and FWCC ask the Commission to streamline application processing when applicants intend to use adaptive modulation by allowing adaptive modulation frequencies to be filed as a single row, as opposed to requiring each combination of modulation, capacity, bandwidth, and transmitter power to be licensed individually. No rule change is required to implement this change, and Bureau staff has started the process of modifying the Universal Licensing System to allow this change.

69. Comsearch and FWCC ask that the Commission eliminate the provision in the rules that allows operation of low power, limited coverage systems in the 23 GHz band because the rules are allegedly unnecessary and allow the use of inefficient antennas. According to Comsearch, that provision was used in the past for low cost analog video systems for purposes such as surveillance. Comsearch describes such systems as ''outmoded'' and claims to be unaware of any current usage of such systems. The frequencies in question are particularly important and most used in the 23 GHz band because they are available for conditional authority under § 101.31(b) of the Commission's rules. Clearwire also asks the Commission to allow licensees to aggregate channels in the 18 GHz and 23 GHz bands to allow 80 megahertz, 100 megahertz, 120 megahertz, or 150 megahertz channels.

70. We believe these requests should be considered together with other filings relating to the 23 GHz band and therefore defer consideration of them.

FWCC has filed a petition for reconsideration of the Commission's order authorizing conditional authority for additional channels in the 23 GHz band which raises the issue of authorizing low power systems on those additional channels. FWCC has also filed a petition for rulemaking asking that conditional authority be authorized throughout the 23 GHz band and seeking changes to the mechanism for coordinating operation with the National Telecommunications and Information Administration (NTIA). In light of the common issues raised by each of those pleadings, we believe those requests should be considered together, in consultation with NTIA. We therefore defer consideration of these requests.

71. We recognize that there are other pending matters and proceedings relating to wireless backhaul that are not addressed in this item. Those matters and proceedings include: (1) A petition for rulemaking asking that the 7125–8500 MHz band be allocated for non-federal use and allotted for FS use, (2) a request made in this proceeding to revise the Commission's policy of allowing a satellite earth station to coordinate for the full 360-degree azimuth range of the earth station even when it is communicating with only one satellite in a limited segment of the band, and (3) a petition for rulemaking asking that the Commission establish service rules for FS use in the 42–42.5 GHz band. We defer consideration of these issues and will address them separately or in future orders in this proceeding.

VI. Procedural Matters

Paperwork Reduction Analysis:

72. This document contains an information collection requirement subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507 of the PRA. Prior to submission to OMB, the Commission will publish a notice in the **Federal Register** seeking public comment on the modified information collection requirement. In addition, that notice will also seek comment on how the Commission might ''further reduce the information collection burden for small business concerns with fewer than 25 employees'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4). The information collection contained in this order will not go into effect until OMB approves the collection. We will publish a notice in the **Federal Register** announcing the effective date of the information collection.

Final Regulatory Flexibility Analysis of the Report and Order

73. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), we incorporated an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in the *Notice of Proposed Rulemaking (NPRM).* No comments were filed addressing the IRFA. Because we amend the rules in this *Second Report and Order,* we have included this Final Regulatory Flexibility Analysis (FRFA). This present FRFA conforms to the RFA.

A. Need for, and Objectives of, the Proposed Rules

74. In this *Second Report and Order,* we make four changes to our rules involving microwave stations. These changes are described in further detail below. First, we allow the use of smaller antennas in the 5925–6875 MHz band (6 GHz band), 17700–18300 MHz and 19300–19700 MHz bands (18 GHz band), and 21200–23600 MHz band (23 GHz band) fixed service (FS) bands. Second, we add a definition of ''payload capacity'' to our rules, and update our capacity and loading requirements to bits/second/Hertz standards reflect the increasing use of interfaces such as Internet Protocol. Third, we widen the permissible maximum channel size in the 5925–6425 GHz Band (Lower 6 GHz Band) (to allow 60 megahertz channels) and in the 10700–11700 MHz band (11 GHz Band) (to allow 80 megahertz channels) to allow faster data rates. Finally, we propose to revise the criteria under which microwave stations that are pointing in the direction of geostationary satellites must seek a waiver prior to operating to expedite service.

75. With respect to the first proposal, § 101.115(b) of the Commission's rules establishes directional antenna standards designed to maximize the use of microwave spectrum while avoiding interference between operators. The rule on its face does not mandate a specific size of antenna. Rather, it specifies certain technical parameters—maximum beamwidth, minimum antenna gain, and minimum radiation suppression—that, depending on the state of technology at any point in time, directly affect the size of a compliant antenna. Smaller antennas have several advantages. They cost less to manufacture and distribute, are less expensive to install because they weigh less and need less structural support, and cost less to maintain because they are less subject to wind load and other destructive forces. In addition, the modest weight of small antennas makes them practical for installation at sites incapable of supporting large dishes, including many rooftops, electrical transmission towers, water towers, monopoles and other radio towers. Smaller antennas raise fewer aesthetic objections, thereby permitting easier compliance with local zoning and homeowner association rules and generating fewer objections. On the other hand, smaller antennas have increased potential to cause interference because smaller antennas result in more radiofrequency energy being transmitted in directions away from the actual point-to-point link. We conclude that we can allow smaller antennas in the 6, 18 and 23 GHz bands without producing harmful interference.

76. Second, we add a definition of ''payload capacity'' to our rules, and update our capacity and loading standards to take into account the increasing use of interfaces such as Internet Protocol. Currently, § 101.141(a)(3) of the Commission's rules lists a ''minimum payload capacity'' for various nominal channel bandwidths. The same rule also defines ''typical utilization'' of the required payload capacity for each channel bandwidth as multiples of the number of voice circuits a channel can accommodate. These definitions are becoming outdated as systems support interfaces such as Internet Protocol. Accordingly, we update our rules to add a definition of payload capacity. We also revise our efficiency requirements to define those requirements in terms of bits-per-second-per-Hertz (''bps/Hz'') across all bands. Such changes could make our rules clearer and would be consistent with modern digital technologies.

77. Third, we allow the use of wider channels in the Lower 6 GHz Band and 11 GHz Band. Specifically, we allow 60 megahertz channels in the Lower 6 GHz Band and 80 megahertz channels in the 11 GHz Band. That action will allow backhaul operators to handle more capacity and offer faster data rates.

78. Finally, we amend § 101.145 of the Commission's rules to limit the circumstances under which fixed service transmitters must obtain a waiver in order to point near the geostationary arc. Specifically, we propose to require a waiver only if the EIRP is greater than 35 dBW for the 5925–7075 MHz band and is greater than 45 dBW in the 12700–13250 MHz

band. Limiting the circumstances where a waiver is necessary will be beneficial. Once the frequency coordination process is completed, the Commission's rules provide many applicants with conditional authority to begin service immediately, without waiting for final approval from the Commission, and with the stipulation that they must take their stations down if the Commission later rejects their applications. Conditional authority is not available, however, to applicants that must request waivers of existing rules. Accordingly, limiting the circumstances under which a waiver is needed will allow more applicants to rapidly commence service. Furthermore, we conclude that such a change would be consistent with international regulations and can be made without any increased risk of interference to satellite services.

B. Legal Basis

79. The actions are authorized pursuant to sections 1, 2, 4(i), 7, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 157, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333, and section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

80. The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules and policies, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

81. *Small Businesses, Small Organizations, and Small Governmental Jurisdictions.* Our action may, over time, affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three comprehensive, statutory small entity size standards. First, nationwide, there are a total of approximately 27.5 million small businesses, according to the SBA. In addition, a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of 2007, there were approximately 1,621,315 small organizations. Finally, the term ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' Census Bureau data for 2011 indicate that there were 89,476 local governmental jurisdictions in the United States. We estimate that, of this total, as many as 88,506 entities may qualify as ''small governmental jurisdictions.'' Thus, we estimate that most governmental jurisdictions are small.

82. *Wireless Telecommunications Carriers (except satellite).* The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census Bureau data for 2007, which now supersede data from the 2002 Census, show that there were 3,188 firms in this category that operated for the entire year. Of this total, 3,144 had employment of 999 or fewer, and 44 firms had employment of 1,000 employees or more. Thus under this category and the associated small business size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities that may be affected by our proposed action.

83. *Fixed Microwave Services.* Microwave services include common carrier, private-operational fixed, and broadcast auxiliary radio services. At present, there are approximately 31,549 common carrier fixed licensees and 89,633 private and public safety operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services. Microwave services include common carrier, private-operational fixed, and broadcast auxiliary radio services. They also include the Local Multipoint Distribution Service (LMDS), the Digital Electronic Message Service (DEMS), and the 24 GHz Service, where licensees can choose between common carrier and non-common carrier status. The Commission has not yet defined a small business with respect to microwave services. For purposes of the IRFA, the Commission will use the SBA's definition applicable to Wireless Telecommunications Carriers (except satellite)—*i.e.,* an entity with no more than 1,500 persons is considered small. For the category of Wireless Telecommunications Carriers (except Satellite), Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year. Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus under this category and the associated small business size standard, the majority of firms can be considered small. The Commission notes that the number of firms does not necessarily track the number of licensees. The Commission estimates that virtually all of the Fixed Microwave licensees (excluding broadcast auxiliary licensees) would qualify as small entities under the SBA definition.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

84. This *Report and Order* adopts no new reporting or recordkeeping requirements.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

85. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

86. The actions taken in the *Report and Order* would provide additional options to all licensees, including small entity licensees. Such actions will serve the public interest by allowing use of smaller antennas, allow the use of wider channels in the Lower 6 and 11 GHz bands, eliminate the need for unnecessary waivers, and update our minimum payload capacity rules to reflect current technology. The rules will therefore open up beneficial economic opportunities to a variety of spectrum users, including small businesses. Because the actions in the *Report and Order* will improve beneficial economic opportunities for all businesses, including small businesses, a detailed discussion of alternatives is not required.

87. With respect to the proposal to allow smaller antennas in the 6 GHz band, an alternative approach would be

to establish technical criteria that would allow the use of 4-foot antennas, as opposed to the 3-foot antennas proposed. Such an approach would reduce the cost savings FS licensees could realize. We conclude that limiting relief to 4-foot antennas is unnecessary to reduce the potential for interference.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

88. None.

VII. Ordering Clauses

89. It is further ordered that the rules adopted herein will become effective October 5, 2012. It is further ordered that the Rural Microwave Flexibility Policy, which contains new information collection requirements that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), will become effective after the Commission publishes a notice in the **Federal Register** announcing such approval and the relevant effective date.

90. It is further ordered, pursuant to sections 1, 2, 4(i), 7, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 157, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333, and section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302, that this *Memorandum Opinion and Order* is hereby adopted.

91. It is further ordered, pursuant to sections 1, 2, 4(i), 7, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, 333, and 405 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 157, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, 333, and 405, and section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302, that this *Order on Reconsideration* is hereby adopted.

92. It is further ordered that the Commission shall send a copy of this *Report and Order* to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

93. It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this *Second Report and Order, Order on Reconsideration, and Memorandum Opinion and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 101

Communications equipment, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Sheryl Todd,

Deputy Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 101 as follows:

PART 101—FIXED MICROWAVE SERVICES

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

■ 2. Amend § 101.3 by adding the definition ''Payload Capacity'' to read as follows:

§ 101.3 Definitions.

* * * * *

Payload Capacity. The bit rate available for transmission of data over a radiocommunication system, excluding overhead data generated by the system.

* * * * *

■ 3. Amend § 101.109(c), in the table by revising the entries ''5,925 to 6,425'' and ''10,700 to 11,700'' to read as follows:

§ 101.109 Bandwidth.

* * * * *

(c) * * *

Frequency band (MHz)	Maximum authorized bandwidth (MHz)
* * * * *	
5,925 to 6,425	[1] 60
10,700 to 11,700	[1] 80
* * * * *	

[1] The maximum bandwidth that will be authorized for each particular frequency in this band is detailed in the appropriate frequency table in § 101.147. If contiguous channels are aggregated in the 928–928.85/952–952.85/956.25–956.45 MHz, the 928.85–929/959.85–960 MHz, or the 932–932.5/941–941.5 MHz bands, then the bandwidth may exceed that which is listed in the table.

* * * * *

■ 4. Amend § 101.115 by revising paragraph (b) introductory text and the entries ''5,925 to 6,425'', ''6,525 to 6,875'', ''6,875 to 7,075'', ''17,700 to 18,820'', ''18,920 to 19,700'', and ''21,200 to 23,600'' in the table in paragraph (b)(2) to read as follows:

§ 101.115 Directional antennas.

* * * * *

(b) Fixed stations (other than temporary fixed stations and DEMS nodal stations) operating at 932.5 MHz or higher must employ transmitting and receiving antennas (excluding second receiving antennas for operations such as space diversity) meeting the appropriate performance Standard A indicated below, except that in areas not subject to frequency congestion, antennas meeting performance Standard B may be used, subject to the requirements set forth in paragraph (d) of this section. For frequencies with a Standard B1 and a Standard B2, in order to comply with Standard B an antenna must fully meet either Standard B1 or Standard B2. Licensees shall comply with the antenna standards table shown in this paragraph in the following manner:

* * * * *

(2) * * *

Frequency	Category	Maximum beam-width to 3 dB points[1] (included angle in degrees)	Minimum antenna gain (dBi)	Minimum radiation suppression to angle in degrees from centerline of main beam in decibels						
				5° to 10°	10° to 15°	15° to 20°	20° to 30°	30° to 100°	100° to 140°	*140° to 180°*
* *		*	*		*		*		*	
5,925 to 6,425[5]	A	2.2	38	25	29	33	36	42	55	55
	B1	2.2	38	21	25	29	32	35	39	45
	B2	4.1	32	15	20	23	28	29	60	60

Frequency	Category	Maximum beam-width to 3 dB points[1] (included angle in degrees)	Minimum antenna gain (dBi)	Minimum radiation suppression to angle in degrees from centerline of main beam in decibels						
				5° to 10°	10° to 15°	15° to 20°	20° to 30°	30° to 100°	100° to 140°	*140° to 180°*
* *		*	*		*		*		*	
6,525 to 6,875[5]	A	2.2	38	25	29	33	36	42	55	55
	B1	2.2	38	21	25	29	32	35	39	45
	B2	4.1	32	15	20	23	28	29	60	60
6,875 to 7,075	A	2.2	38	25	29	33	36	42	55	55
	B1	2.2	38	21	25	29	32	35	39	45
	B2	4.1	32	15	20	23	28	29	60	60
* *		*	*		*		*		*	
17,700 to 18,820	A	2.2	38	25	29	33	36	42	55	55
	B1	2.2	38	20	24	28	32	35	36	36
	B2	3.3	33.5	18	22	29	31	35	55	55
18,920 to 19,700[10]	A	2.2	38	25	29	33	36	42	55	55
	B1	2.2	38	20	24	28	32	35	36	36
	B2	3.3	33.5	18	22	29	31	35	55	55
21,200 to 23,600[7, 11]	A	3.3	33.5	18	26	26	33	33	55	55
	B1	3.3	33.5	17	24	24	29	29	40	50
	B2	4.5	30.5	14	19	22	24	29	52	52
* *		*	*		*		*		*	

* * * * *

[5] These antenna standards apply to all point-to-point stations authorized after June 1, 1997. Existing licensees and pending applicants on that date are grandfathered and need not comply with these standards.

* * * * *

[7] Except for antennas between 140° and 180° authorized or pending on January 1, 1989, in the band 10,550 to 10,565 MHz for which minimum radiation suppression to angle (in degrees) from centerline of main beam is 36 decibels.

* * * * *

[10] DEMS User Station antennas in this band must meet performance Standard B and have a minimum antenna gain of 34 dBi. The maximum beamwidth requirement does not apply to DEMS User Stations. DEMS Nodal Stations need not comply with these standards. Stations authorized to operate in the 24,250–25,250 MHz band do not have to meet these standards, however, the Commission may require the use of higher performance antennas where interference problems can be resolved by the use of such antennas.

[11] Except as provided in § 101.147(s).

* * * * *

■ 5. Amend § 101.141 by revising paragraphs (a)(3), (a)(6), and (a)(7) to read as follows:

§ 101.141 Microwave modulation.

(a) * * *

(3)(i) Except as noted in paragraph (a)(7) of this section, the payload capacity of equipment shall meet the following minimum efficiency standards:

Frequency	Emission bandwidth ≤5 MHz	Emission bandwidth >5 MHz and ≤20 MHz	Emission bandwidth >20 MHz
3,700–10,550 MHz	2.4 bits/second/Hertz	4.4 bits/second/Hertz	4.4 bits/second/Hertz.
10,550–13,250 MHz	2.4 bits/second/Hertz	4.4 bits/second/Hertz	3.0 bits/second/Hertz.

(ii) Traffic loading payload shall exceed 50 percent of payload capacity within 30 months of licensing. During anomalous signal fading, licensees subject to the capacity and loading requirements may adjust to a modulation specified in their authorization if such modulation is necessary to allow licensees to maintain communications, even if the modulation will not comply with the capacity and loading requirements specified in this paragraph. Links that must comply with the capacity and loading requirements that use equipment capable of adjusting modulation must be designed using generally accepted multipath fading and rain fading models to meet the specified capacity and loading requirements at least 99.95% of the time, in the aggregate of both directions in a two-way link.

* * * * *

(6) Digital systems using bandwidths of 10 MHz or larger will be considered 50 percent loaded when at least 50 percent of their total capacity is being used. For purposes of this subsection, a Fixed Service channel is being used if it is attached to a communications system that is capable of providing data to it at a rate that is sufficient to occupy at least 50 percent of the payload capacity of the Fixed Service channel, after header compression is applied.

(7) Equipment placed in service after June 1, 1997 and prior to October 5, 2012 may comply with the provisions of § 101.141(a)(3) in effect as of the date the equipment was placed in service.

* * * * *

■ 6. Amend § 101.145 by revising paragraph (b) introductory text and paragraph (c) to read as follows:

§ 101.145 Interference to geo-stationary-satellites.

* * * * *

(b) *2655 to 2690 MHz and 5925 to 7075 MHz.* No directional transmitting antenna utilized by a fixed station operating in these bands with EIRP greater than 35 dBW may be aimed

within 2 degrees of the geostationary-satellite orbit, taking into account atmospheric refraction. However, exception may be made in unusual circumstances upon a showing that there is no reasonable alternative to the transmission path proposed. If there is no evidence that such exception would cause possible harmful interference to an authorized satellite system, said transmission path may be authorized on waiver basis where the maximum value of the equivalent isotropically radiated power (EIRP) does not exceed:

* * * * *

(c) *12.7 to 13.25 GHz.* No directional transmitting antenna utilized by a fixed station operating in this band with EIRP greater than 45 dBW may be aimed within 1.5 degrees of the geostationary-satellite orbit, taking into account atmospheric refraction.

* * * * *

■ 7. Amend § 101.147 by revising paragraph (i) introductory text, adding paragraph (i)(9), revising paragraph (o) introductory text, and adding paragraph (o)(8) to read as follows:

§ 101.147 Frequency assignments.

* * * * *

(i) *5,925 to 6,425 MHz.* 60 MHz authorized bandwidth.

* * * * *

(9) 60 MHz bandwidth channels: [1]

Transmit (receive) (MHz)	Receive (transmit) (MHz)
5964.97	6217.01
6024.27	6276.31
6083.57	6335.61
6142.87	6394.91

[1] The highest available channel should be selected, except where such a choice would impede the efficiency of local frequency co-ordination efforts.

* * * * *

(o) *10,700 to 11,700 MHz.* 80 MHz authorized bandwidth.

* * * * *

(8) 80 MHz bandwidth channels: [1]

Transmit (receive) (MHz)	Receive (transmit) (MHz)
10745	11235
10825	11315
10905	11395
10985	11475
11065	11555
11145	11635

[1] The highest available channel should normally be selected, except where such a choice would impede the efficiency of local frequency coordination efforts.

* * * * *

[FR Doc. 2012–21335 Filed 9–4–12; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2010–0049; 4500030113]

RIN 1018–AX89

Endangered and Threatened Wildlife and Plants; Determination of Endangered Status for Arctostaphylos franciscana (Franciscan manzanita) Throughout Its Range

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine that *Arctostaphylos franciscana* (Franciscan manzanita) meets the definition of an endangered species under the Endangered Species Act of 1973, as amended (Act). This final rule implements the Federal protections provided by the Act for this species. We are simultaneously publishing a proposed rule to designate critical habitat for *Arctostaphylos franciscana* in a separate **Federal Register** notice.

DATES: This rule becomes effective October 5, 2012.

ADDRESSES: This final rule is available on the Internet at *http://www.regulations.gov* and at the Sacramento Fish and Wildlife Office. 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, Sacramento Fish and Wildlife Office, 2800 Cottage, Room W–2605, Sacramento, CA 95825; 916–414–6600 (telephone); 916–414–6712 (facsimile).

FOR FURTHER INFORMATION CONTACT: Susan Moore, Field Supervisor, Sacramento Fish and Wildlife Office (see **ADDRESSES** section). If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. This is a final rule to list *Arctostaphylos franciscana* as an endangered species under the Endangered Species Act. Under the Act, if a species is determined to be an endangered or threatened species we are required to promptly publish in the **Federal Register** and make a determination on our proposal within one year. We were petitioned in 2010 to list *A. franciscana* as an endangered or threatened species. We determined in our 12-month finding that listing was warranted, and we proposed to list the species as an endangered species in September 2001. This final rule constitutes our final determination for this species as required by the Act.

The basis for our action. Under the Endangered Species Act, we are required to determine whether a species is endangered or threatened because of any of the following 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 reviewed all available scientific and commercial information pertaining to these factors in our status review of the species and determined that the species was limited to one plant remaining in the wild. We proposed that the species was endangered due to threats in the five factors, as follows. The primary threat to *Arctostaphylos franciscana* is from the present or threatened destruction, modification, or curtailment of the species' habitat or range. All original occupied habitat of the species has been lost, and its current range has been reduced to a single location that supports a single *A. franciscana* plant. Furthermore, limited suitable habitat remains available to support a viable population of the species. The remaining plant is vulnerable to overcollection or damage if visitors harvest cuttings or seeds. Sudden oak death, which is caused by the pathogen *Phytophthora cinnamomi,* and infections caused by other *Phytophthora* species are serious threats to *Arctostaphylos franciscana* because only one plant occurs in the wild and the diseases are easily spread. Predation is an ongoing but lesser threat. Additional threats include climate change, altered fire regime, soil compaction from visitor use, vandalism, loss of genetic diversity, loss of pollinators, stochastic events, effects of small population size, and hybridization. In the proposed rule, we considered these threats to be significant and ongoing, but we did not find that we had sufficient information

to determine critical habitat at the time. In this final rule, we utilize public comments and peer review to inform our final determination, as required under the Act.

Peer review and public comments. In this final rule, we present and respond to peer reviewer and public comments. We obtained peer reviews from knowledgeable individuals with the scientific expertise to review our technical assumptions, analysis, adherence to regulations, and whether or not we had used the best available information. These peer reviewers generally concurred with our methods and conclusions, and they provided additional information, clarifications, and suggestions to improve this final rule. In particular, peer reviewers provided information on the physical and biological features required by the species, and on locations of remnant natural habitat that retained these features, suggesting that proposal of critical habitat would be determinable and prudent. Accordingly, a proposed rule to designate critical habitat is being published concurrently with this final rule to list the species as endangered.

Background

It is our intent to discuss only those topics directly relevant to the listing of *Arctostaphylos franciscana* under the Act (16 U.S.C. 1531 *et seq.*) in this final rule. For further information on the species' biology and habitat, population abundance and trend, distribution, demographic features, habitat use and conditions, threats, and conservation measures, please see the September 8, 2011, proposed listing for the species (76 FR 55623) published in the **Federal Register**, or the Recovery Plan for Coastal Plants of the Northern San Francisco Peninsula (Service 2003). These documents are available from the Environmental Conservation Online System (ECOS) (*http://ecos.fws.gov/ecos*), the Sacramento Fish and Wildlife Office Web site (*http://www.fws.gov/sacramento/*), or from the Federal eRulemaking Portal (*http://www.regulations.gov*).

Prudency Determination

In our proposed listing rule for *Arctostaphylos franciscana* (76 FR 55623; September 8, 2011), we stated that we believed that critical habitat was not determinable at the time of the proposal due to a lack of knowledge of what physical or biological features were essential to the conservation of the species, or what other areas outside the site that is currently occupied may be essential for the conservation of the species. Subsequently, we requested information from the public during the public comment period and solicited information from peer reviewers on whether the determination of critical habitat was prudent and determinable. We also asked for information about the physical or biological features that are essential to the conservation of the species and what areas contained those features or were otherwise essential for the conservation of the species. Based on the information we received on the physical or biological features for *A. franciscana,* and information on areas otherwise essential for the species, we have determined that the designation of critical habitat is prudent and determinable. We are therefore proposing critical habitat elsewhere in today's **Federal Register**. For more information regarding our determination to designate critical habitat please see our response to comments below and the proposed rule to designate critical habitat for *A. franciscana* published in the Proposed Rules section of today's **Federal Register**.

Species Information

Arctostaphylos franciscana is a low, spreading-to-ascending, evergreen shrub in the heath family (Ericaceae) that may reach 0.6 to 0.9 meters (m) (2 to 3 feet (ft)) in height when mature (Chasse *et al.* 2009, p. 5). Its leaves are about 1.5 to 2 centimeters (cm) (0.6 to 0.8 inches (in)) long, are isofacial (have the same type of surface on both sides), and are oblanceolate (longer than they are wide and wider towards the tip) (Eastwood 1905, p. 201; Chasse *et al.* 2009, p. 39). Its mahogany brown fruits are about 6 to 8 millimeters (mm) (0.24 to 0.32 in) wide, while its urn-shaped flowers measure about 5 to 7 mm (0.2 to 0.28 in) long (Wallace 1993, p. 552; Service 2003, p. 57).

A closely related species, *Arctostaphylos hookeri* ssp. *ravenii* (Presidio or Raven's manzanita), which was federally listed as endangered on October 26, 1979 (44 FR 61909), looks similar but has a growth habit that is more prostrate, leaves that are more rounded, fruits that are smaller and less red in color, and flowers that are smaller and more spherical (Service 2003, pp. 55, 57). *Arctostaphylos hookeri* ssp. *ravenii* has recently undergone a taxonomic revision to *A. montana* ssp. *ravenii,* and we will be referring to the listed species by this name throughout this rule (see Genetics and Taxonomy section below). Another somewhat similar appearing species, though not as closely related, is *A. uva-ursi* (bearberry), which can be distinguished by its lack of isofacial leaves (Chasse *et al.* 2009, p. 39).

In the wild, *Arctostaphylos franciscana* is an obligate-seeding species (it reproduces primarily from seed rather than from burls) (Vasey 2010, p. 1). *Arctostaphylos* (manzanita) species are members of the chaparral plant community, which have a variety of triggers for seed germination including heat, smoke, and light (Keeley 1987, p. 434). *Arctostaphylos* species have germinated after being exposed to charate (ground charred wood) (Keeley 1987, pp. 435, 440), which suggests that fire or conditions that simulate fire stimulate germination of the seeds.

Based on work with other species of *Arctostaphylos,* the establishment of successful populations of *A. franciscana* may require the presence of a pollinator community (primarily bumblebees (*Bombus* spp.) but also other insects), a fruit dispersal community (primarily rodents), and a mutually beneficial soil mycorrhizal fungi community (see Historical Distribution and Habitat below) (Parker 2011, p. 1). The seeds of *Arctostaphylos* are dispersed primarily by rodents that consume the fruits, but also by other mammals, including coyotes (*Canis latrans*) and foxes (T. Parker 2011, pers. comm.; Vasey 2011a, p. 1). Seed-eating animals such as coyotes, gray foxes (*Urocyon cinereoargenteus*), red foxes (*Vulpes vulpes*), raccoons (*Procyon lotor*), California quail (*Callipepla californica*), and rodents such as the California vole (*Microtus californicus*) are known to occur on the Presidio of San Francisco (Presidio), a unit of the National Park System, on the San Francisco peninsula where *A. franciscana* is found (National Park Service (NPS) 2012). Animals such as coyotes and foxes eat the *Arctostaphylos* fruit and may travel long distances before depositing their scat. Any undigested fruit left in the scat can then be harvested by rodents and either eaten or buried. Parker (2010b, p. 1) found that 70 percent of the fruits buried by rodents were located deeper than 2 cm (0.78 in), which is the maximum soil depth at which seeds are typically killed by wildfire. Seed has been removed from the wild plant, and, although it has not been directly observed, California voles have been trapped near the wild plant and are likely responsible for the seed harvesting (Carlen 2012, p. 1; Estelle 2012d, p. 1).

Listed Entity Analysis

The *Arctostaphylos franciscana* plants that exist in cultivation fall into three categories: (1) Cuttings and rooted specimens collected from the Laurel Hill Cemetery and transplanted to various managed botanical gardens in

San Francisco, Berkeley, and Claremont prior to 1947; (2) specimens currently propagated in greenhouses from cuttings and layers taken from the wild plant in 2010; and (3) specimens, some of which may be of unknown origin, sold in the nursery trade or transplanted into home gardens. We consider the single wild plant and plants identified in (1) and (2) above to be the listed entity under the Act. Our rationale for not including plants identified in item (3) above is outlined below.

The *Arctostaphylos franciscana* plants found in botanical gardens may represent from one to six genetically distinct plants other than the single wild plant (Chasse *et al.* 2009, p. 7; Chasse 2011a, p. 1; Chasse 2011b, p. 1; Vasey 2011b, pp. 2, 3), and cuttings from those plants may contribute genetic material to efforts to expand the number of wild plants. The botanical garden plants are not considered part of the wild population and, therefore, are not considered in the assessment of species status, although they will be considered to be listed when this final rule becomes effective (see the **DATES** section above). The cuttings and layers collected from the wild plant currently propagated in greenhouses are being considered in the assessment of the species' status. These cuttings from the wild plant will be planted with *A. franciscana* specimens propagated in botanical gardens to establish additional populations of the species. We have concluded that the third category of plants, those cultivated for private or commercial uses, will not aid in the conservation or recovery of the species in the wild because some cultivated plants may be hybrids and bred for landscape use and thus offer minimal contribution to conservation.

Current Distribution

In October 2009, an ecologist identified a plant growing in a concrete-bound median strip along Doyle Drive in the Presidio as *Arctostaphylos franciscana* (Chasse *et al.* 2009, pp. 3, 4; Gluesenkamp 2010, p. 7). The plant's location was directly in the footprint of a roadway improvement project designed to upgrade the seismic and structural integrity of the south access to the Golden Gate Bridge (California Department of Transportation (Caltrans) *et al.* 2009, p. 1; Chasse *et al.* 2009, p. 10).

Several agencies, including the Service, established a Memorandum of Agreement (MOA) and conservation plan for the species (see *Previous Federal Actions* section below) (Caltrans *et al.* 2009). The conservation partners concluded that leaving the plant undisturbed at its original site would compromise public safety and cultural resources by the potential curtailment or redesign of the roadway improvement project (Chasse *et al.* 2009, pp. 9, 10).

The conservation plan evaluated potential translocation sites, established procedures for preparation of the new site and for the translocation itself, and called for management and monitoring (both short- and long-term) of the translocated plant, with the goal of eventually establishing self-sustaining populations of the species in the wild (Chasse *et al.* 2009, pp. 23–27, 29–30). Following recommendations in the conservation plan, the *Arctostaphylos franciscana* plant was moved successfully to a new site within the Presidio in January 2010. The Presidio site was chosen after careful consideration of its appropriate soil type and the management and monitoring capabilities of the NPS and the Presidio Trust. Subsequent monitoring reports indicate the translocated plant continues to do well at its new location (Yam 2010, pp. 1, 3–14; Young 2010a, p. 1; Young 2012, p. 1).

Historical Distribution and Habitat

Known historical occurrences and collections of *Arctostaphylos franciscana* are from serpentine maritime chaparral, a plant community dominated by *Arctostaphylos* and *Ceanothus* (California lilac) species, on the San Francisco peninsula. This area is part of a region that Willis Linn Jepson named the Franciscan Area, one of 10 areas he considered to have the highest concentration of endemic plant species in California (Jepson 1925, pp. 11–14). An endemic species is one that is native to, and restricted to, a particular geographical area. Native habitats on the San Francisco peninsula have been largely converted to urban areas of the City of San Francisco, and habitat that might have supported *A. franciscana* is now mostly lost to development or habitat conversion from the introduction of nonnative plant species (Chasse 2010, p. 2; Gluesenkamp 2010, p. 7; Chasse 2011c, p. 1).

Chasse (2009, pp. 6, 7) has noted that information on the plant community that historically included *Arctostaphylos franciscana* is largely missing from the literature. Early records describe the species as growing ''on rocky ground'' (Eastwood 1905, p. 202), on ''bare, stony bluff on Laurel Hill Cemetary [sic]'' (Brandegee 1908), and with coast live oak (*Quercus agrifolia*), coast blue blossom (*Ceanothus thyrsiflorus*), and coyote brush (*Baccharis pilularis*) (Wieslander 1938). *Arctostaphylos franciscana* was also observed ''forming flat masses over serpentine outcroppings and humus-filled gravel and flopping down over the sides of gray and chrome rocks. *Ericameria, Baccharis,* Ferns, Buckwheats, and Golden Yarrow grow among it; and over it stand Toyons and Live Oaks.'' Additionally, *A. montana* ssp. *ravenii* was found at nearly all *A. franciscana* locations. These observations, along with the geology and climate of historical sites, indicate that the species' historical community likely consisted of a mosaic of coastal scrub, barren serpentine maritime chaparral, perennial grassland, and occasional woodlands of coast live oak and toyon shrubs and small trees (Chasse 2009, pp. 6, 7).

Arctostaphylos franciscana is considered to be endemic to the San Francisco peninsula, and historically occurred in areas with serpentine soils, bedrock outcrops, greenstone, and mixed Franciscan rock, typically growing in mixed populations with *A. montana* ssp. *ravenii* (Service 2003, pp. 95, 96; Chasse *et al.* 2009, p. 6). The Doyle Drive *A. franciscana* site was comprised of disturbed soil over serpentinite (Chasse *et al.* 2009, p. 3). Serpentine soil restricts the growth of many plants due to its high nickel and magnesium concentrations, and thus tends to support unique plant communities (Brooks 1987, pp. 19, 53; Service 2003, p. 16) because relatively few plant species can tolerate such soil conditions. These conditions generally result in semibarren soil and a lack of competing plants, which benefits serpentine-tolerant plants (Bakker 1984, p. 79) such as *A. franciscana.*

The coastal upland habitat of *Arctostaphylos franciscana* is influenced by cool, humid conditions and frequent summer fog. Summer fog is important to upland coastal vegetation and partly determines the distribution of coastal species (Johnstone and Dawson 2010, p. 4533). Besides serpentine soil and cool air temperatures (Parker 2010c, p. 1), summer fog is one of the primary habitat requirements for *A. franciscana* (Vasey 2010, p. 1). Summer fog results from two phenomena upwelling of cold coastal ocean water and temperature inversion of hot air flowing toward the ocean over a cool humid marine air layer below (Johnstone and Dawson 2010, p. 4533; Vasey 2010, p. 1). Fog reduces sunlight and air temperature, and raises humidity. Summer fog provides a source of water for plants, including *Arctostaphylos* species, by condensing in the plant canopy and falling directly as water to the soil

where it is taken up by the plant's roots or directly by leaves (Johnstone and Dawson 2010, p. 4533; Vasey 2010, p. 1).

Historically, the maritime serpentine chaparral plant community, of which *Arctostaphylos franciscana* is a part, may have been present in the southeastern portion of the San Francisco area (for example, Potrero Hill and Bayview Hill), but the cumulative effects of burning by native Americans, grazing during the Spanish/Mexican period, and later more grazing and firewood gathering during the U.S. military period may have converted the maritime chaparral to grassland or depauperate coastal scrub (Chasse 2010, p. 2). Prior to 1947, *A. franciscana* was known from three locations: the Masonic and Laurel Hill Cemeteries in San Francisco's Richmond District, and Mount Davidson in south-central San Francisco (Service 2003, pp. 16, 62, 95; Chasse *et al.* 2009, p. 4). Unconfirmed sightings were also noted at a possible fourth location near Laguna and Haight Streets (Chasse 2012, p. 1). By 1947, the Masonic and Laurel Hill Cemetery sites were removed and the grounds were destroyed in preparation for commercial and urban development (Chasse *et al.* 2009, p. 7). The Mount Davidson and Laguna and Haight Streets locations were lost to urbanization as well. Until October 2009, *A. franciscana* had not been recorded in the wild since 1947 (Chasse *et al.* 2009, pp. 3, 7), although no systematic surveys are known to have taken place to search for potential remaining individuals (Chasse 2010, p. 1).

Cultivated Arctostaphylos franciscana

Between 1930 and 1947, prior to the loss of the wild plants, botanists collected cuttings and rooted specimens from confirmed wild *Arctostaphylos franciscana* plants, possibly representing between one and six distinct genotypes, and propagated them in botanical gardens (Chasse *et al.* 2009, p. 7; Chasse 2011a, p. 1; Chasse 2011b, p. 1; Service 2003, p. 96; Vasey 2011b, p. 2). The number of distinct genotypes depends on whether the botanical garden specimens were started from cuttings of the same individual (which would mean multiple plants have identical genotypes (genetic constitutions)), or whether each specimen originated from a separate plant (in which case they would have different genotypes) (Chasse 2011a, p. 1; Chasse 2011b, p. 1; Vasey 2011b, pp. 2, 3).

Modern collections of this plant at East Bay Regional Park District's Botanical Garden at Tilden Regional Park, San Francisco Botanical Garden (formerly known as Strybing Arboretum), Rancho Santa Ana Botanic Garden, Claremont, and University of California (UC) Berkeley Botanical Garden include some of the original specimens from Laurel Hill, as well as specimens propagated vegetatively after the species was thought to be extinct in the wild (Chasse *et al.* 2009, pp. 6–8). Accession records for the botanical garden specimens indicate that some specimens collected and planted prior to 1947 did not survive and others are duplicates of original collections, leaving possibly only two specimens confirmed to have been original plants transplanted from Laurel Hill (Chasse 2011b, p. 1; Smisko 2012, p. 1). Further genetic work will verify whether plants with differing morphological features prove to be additional *Arctostaphylos franciscana* individuals. Although some of the botanical garden specimens may have different genotypes, which is generally the result of sexual reproduction (sprouting from seed) rather than clonal reproduction (vegetative reproduction from cuttings or plant parts other than seeds), all of the botanical garden specimens are considered to be *A. franciscana* until further genetic work can be conducted. The number of existing distinct genotypes cannot currently be determined because a suitable genetic sampling technique has not yet been developed (Chasse 2011a, p. 1).

Under the conservation plan for the relocated wild plant, cuttings and rooted specimens from the wild plant are also being cultivated. Cuttings from the plant, both nonrooted stems and layering stems (stems that have rooted at their leaf nodes), were taken for vegetative propagation prior to translocation of the *Arctostaphylos franciscana* plant in January 2010 (Chasse *et al.* 2009, pp. 10–16, 40–42, Young 2010a, p. 1). This material was distributed to seven locations, including UC Berkeley Botanic Garden, Regional Parks Botanic Garden, UC Santa Cruz Botanical Garden, San Francisco Botanical Garden, Cal Flora Nursery, Presidio Nursery, and the Presidio Trust Forester (Young 2011, p. 1 of attachment 2). As of February 2012, 351 clones continue to survive at these locations (Young 2012, p. 1). A total of 1,346 *A. franciscana* seeds were collected from the plant in 2009, before it was transplanted; an estimated 2,100 seeds were collected in July and August 2010; and 19 seeds were collected in 2011 (Frey 2010, p. 1; Young 2010a, p. 1; Young 2012, p. 1). The numbers of seeds collected are estimates based on weight of seed collected (Laskowski 2012, p. 1). No attempts have yet been made to germinate *A. franciscana* seeds (Young 2012, p. 1). Two rooted *A. franciscana* cuttings were outplanted to managed sites at the UC Santa Cruz Arboretum in January 2011 (Kriegar 2011, unpaginated). The conservation plan calls for eventual propagation of seeds (including any seeds collected from the soil around the plant's original location), and for genetic testing of resulting plants. Seeds fertilized in the wild could result from cross-pollination from another individual *Arctostaphylos franciscana* or a closely related species to produce a genetically unique individual (Chasse *et al.* 2009, p. 13). Additionally, because the roots of most *Arctostaphylos* individuals establish a mutually beneficial association with mycorrhizal fungi in the soil, the conservation plan establishes means by which the soil for propagating cuttings and seeds should be inoculated with spores from such fungi (Chasse *et al.* 2009, p. 9). Propagation of *A. franciscana* seed and inoculation of seeds and cuttings by mycorrhizal fungi have not yet occurred. Soil surrounding the wild plant has been examined for presence of a seedbank, but no *A. franciscana* seeds have been found (Young 2011, p. 1; Young 2012, p. 1).

Genetics and Taxonomy

At one time *Arctostaphylos franciscana* and *A. montana* ssp. *ravenii* were considered to be subspecies of *A. hookeri* (Hooker's manzanita). However, recent taxonomic revisions have established *A. montana* ssp. *ravenii* and *A. franciscana* as separate species. These revisions have been based primarily on genetic comparisons, including the fact that *A. franciscana* is diploid while *A. montana* ssp. *ravenii* is tetraploid (having four sets of chromosomes, 26 chromosome pairs) (Service 2003, p. 95; Parker *et al.* 2007, pp. 149, 150; Chasse *et al.* 2009, p. 6). The identification of the wild plant as *A. franciscana* has since been confirmed with 95 percent confidence based on morphological characteristics (Chasse *et al.* 2009, pp. 3, 4; Vasey and Parker 2010, pp. 1, 5). Additional tests indicate that the plant is diploid, consistent with *A. franciscana* (Vasey and Parker 2010, p. 6). Molecular genetic data also indicate that the plant is *A. franciscana* (Parker 2010a). Based on the best available scientific information, we consider the individual found along Doyle Drive in October 2009 to be *A. franciscana* (Vasey and Parker 2010, pp. 1, 5–7).

Previous Federal Actions

Arctostaphylos franciscana was originally proposed for listing as an endangered species under the Act in 1976 (41 FR 24524; June 16, 1976). In 1980, it was included in the list of Category 1 candidates for listing as one of the taxa retaining a high priority for addition to the list, subject to confirmation of extant wild populations. At that time, the species was thought to be extinct in the wild, although it was known to be extant in cultivation (45 FR 82479; December 15, 1980). It was included as a species of concern in the Recovery Plan for Coastal Plants of the Northern San Francisco Peninsula (Service 2003, pp. 95–96).

On December 23, 2009, we received a petition dated December 14, 2009, from Wild Equity Institute, Center for Biological Diversity, and California Native Plant Society requesting that *Arctostaphylos franciscana* be listed as endangered on an emergency basis under the Act and that critical habitat be designated. Included in the petition was supporting information regarding the species' taxonomy and ecology, historical and current distribution, present status, and actual and potential causes of decline. On January 26, 2010, we acknowledged the receipt of the petition in a letter to Wild Equity Institute. In that letter, we responded that we had reviewed the information presented in the petition and determined that issuing an emergency rule to temporarily list the species, under section 4(b)(7) of the Act, was not warranted. Our rationale for this determination was that, although only a single plant of this species remained in the wild, the individual had recently been transplanted to a new location on Federal land. Additionally, a conservation plan (Chasse *et al.* 2009, pp. 1–44) and associated MOA (cited herein as Caltrans *et al.* 2009) signed by five Federal and State wildlife and land management agencies (conservation partners) successfully addressed the concerns raised by the petition to the extent that none of those concerns constituted an ''emergency posing a significant risk to the well-being of the species'' (50 CFR 424.20(a)). The Federal agencies participating in the MOA are the NPS and the Service. The State of California is represented by Caltrans and the California Department of Fish and Game (CDFG). The Presidio Trust, a wholly owned government corporation that jointly manages the Presidio with NPS, also participates (71 FR 10608; March 2, 2006).

The transplanted plant is considered to be the single remaining plant in the wild, despite having been transplanted to the Presidio. The original habitat of the plant was threatened by the ongoing redevelopment of Doyle Drive, but that threat was removed by moving the plant to a new location (translocation). Potential immediate threats in the new location, including the danger that the plant might not survive the move and transplantation, were addressed by provisions in the conservation plan for collecting and propagating rooted clones, seeds, and cuttings from the original plant prior to translocation. The conservation plan provides for the long-term propagation, and eventual reestablishment in wild populations, of all remaining genetic lines, including those from the surviving wild plant and from the individuals located in two botanical gardens, which were collected from historically confirmed locations. It also includes long-term monitoring provisions. While these provisions do not remove the need for further review of the species' status, they appear to be effective for protecting the species in the short term.

We published a 90-day finding in the **Federal Register** on August 10, 2010 (75 FR 48294), in which we found that the petition presented substantial scientific or commercial information indicating that listing this species may be warranted. On June 14, 2011, Wild Equity Institute filed a complaint that alleged that, given our 90-day finding, the Service had failed to make the required 12-month finding on the petition in a timely manner. On September 8, 2011, we published a combined 12-month finding and proposed rule in the **Federal Register** in which we determined that listing *Arctostaphylos franciscana* was warranted, and, as a result, we proposed to list the species as endangered (76 FR 55623). We also stated that we did not find critical habitat to be determinable at that time, and requested information and comments on whether designation of critical habitat for the species was prudent and determinable.

The Presidio is under joint management by the Golden Gate National Recreation Area (GGNRA), a part of NPS, and the Presidio Trust. The wild *Arctostaphylos franciscana* plant is located in the portion of the Presidio managed by the Presidio Trust. The plant is considered to be wild because it has been moved to an undeveloped area of the Presidio that is managed as natural habitat. Although the plant is currently receiving care (monitoring and insect removal) associated with its transplantation and recent infestation by insects, it is not receiving the level of protection, water, or nutrients given to the plants in botanical gardens or to those within the nursery trade.

Summary of Comments and Recommendations

In the proposed rule published on September 8, 2011 (76 FR 55623), we requested that all interested parties submit written comments on the proposal by November 7, 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. A newspaper notice inviting general public comment for a period of 15 days was published in the San Francisco Chronicle on June 5, 2012. A question and answer sheet and news release regarding the species was posted online on our Web site for the public. We did not receive any requests for a public hearing.

During the comment periods for the proposed rule, we received eight comment letters directly addressing the proposed listing of *Arctostaphylos franciscana* as endangered. All public commenters supported listing the species as endangered. Three commenters supported designation of critical habitat and provided opinions on the value of critical habitat designation and the threats resulting from lack of this designation. One commenter opposed critical habitat designation. All substantive information provided during the comment periods has either been incorporated directly into this final determination or is addressed below.

Peer Review

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion from five knowledgeable individuals with scientific expertise that included familiarity with *Arctostaphylos franciscana* and its habitat, biological needs, and threats. We received responses from four of the peer reviewers.

We reviewed all comments received from the peer reviewers for substantive issues and new information regarding the listing and critical habitat of *Arctostaphylos franciscana.* The peer reviewers generally concurred with our methods and conclusions regarding listing and provided additional information, clarifications, and suggestions to improve the final rule; however, three reviewers disagreed with our comments that designation of critical habitat was not prudent or determinable, and they provided supporting information regarding critical habitat. The fourth peer reviewer

indicated that publicizing the location of the transplanted plant could increase the threat of infection by *Phytophthora* species. Additionally, this peer reviewer noted that the threat to *A. franciscana* was greater than stated in the proposed rule due to the presence of other species of *Phytophthora* in the San Francisco Bay area. Peer reviewer comments are addressed in the following summary and incorporated into the final listing rule as appropriate. A proposed rule to designate critical habitat for *A. franciscana* is published in the Proposed Rules section of today's **Federal Register**. Please see that proposed rule for information on submitting a comment on our proposed designation of critical habitat for *A. franciscana.*

Peer Reviewer Comments

(1) *Comment:* All peer reviewers provided comments on conservation measures, recommendations for outplanting cuttings and selection of planting sites, and additional information on threats to the species from the five factors discussed below in **Summary of Factors Affecting the Species**.

Our Response: Recommendations regarding outplanting and selection of planting sites have been reviewed for the proposed critical habitat and will be considered during the development of a recovery plan. All other appropriate information was incorporated into this final rule.

(2) *Comment:* Three peer reviewers and three public commenters stated that designation of critical habitat is prudent and determinable.

Our Response: Critical habitat is defined in section 3 of the Act as: (1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features that are essential to the conservation of the species, and which may require special management considerations or protection; and (2) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. The peer reviewers provided information on the ecological requirements of *Arctostaphylos franciscana* and areas with the highest potential for establishing new populations. Based on this information, we have determined that the designation of critical habitat is prudent and determinable. All known remaining historic locations as well as the site of the transplanted wild plant have been evaluated, and the areas that have met our criteria to be included as proposed critical habitat have been identified. We are proposing to designate critical habitat for the species concurrently with this final rule. That proposal is published in the Proposed Rules section of today's **Federal Register**. Please see that proposed rule for information on submitting a comment on our proposed designation of critical habitat for *A. franciscana.*

(3) *Comment:* Two peer reviewers disagreed with our statement that small sites on the order of 0.4 hectare (ha) (1 acre (ac)) may not be suitable for *Arctostaphylos franciscana.* One peer reviewer stated that while small sites may facilitate the growth of nonnative plant species, *A. franciscana* would be started from cuttings, not from seed, and management efforts could easily accommodate competition from nonnative plants, as established woody species are not easily displaced by weeds. The second peer reviewer noted that there are many natural occurrences of rare *Arctostaphylos* species existing in small, isolated remnants of habitat where soils and climate are suitable.

Our Response: Some invasive plant species in the Presidio and in other San Francisco peninsula areas have been shown to be difficult to control. For example, on Mount Davidson, which previously supported a population of *Arctostaphylos franciscana,* invasive plant species, including *Eucalyptus* spp., invasive ivy, and other species, have largely displaced native vegetation on portions of the site. We agree that some rare species of *Arctostaphylos* have persisted on small parcels of suitable habitat; however, in order to maximize the potential of establishing multiple, successful populations of *A. franciscana,* selection of suitable sites that require the least amount of long-term maintenance and promise the greatest opportunity for growth is necessary. However, we will evaluate small sites during our process to designate critical habitat for the species.

(4) *Comment:* Two peer reviewers questioned our statement under Factor A in the proposed rule that small, isolated areas of habitat can be drier than larger ones due to evaporation and lack of surrounding vegetation. One reviewer stated that this does not apply to small urban or near-urban sites because hard surfaces such as asphalt and cement provide additional runoff and available moisture in these areas.

Our Response: Many of the remnant parcels of potential habitat on the peninsula are isolated and surrounded by urban development or nonnative landscaping rather than native vegetation. One of the general effects of this abrupt transition from natural habitat to urban landscape or hard surfaces is a change in the abundance and distribution of species in the natural habitat due to physical conditions near the edge (the edge effect). These conditions include desiccation and changes in wind and light. We agree with one peer reviewer's premise that hard surfaces such as rooftops, streets, and parking lots increase urban runoff; however, our understanding is that when rain or irrigation water falls on urban hard surfaces, it flows predominately into storm water control systems, including gutters and storm drains, and is carried away from urban areas rather than being absorbed into the soil and providing more moisture to plants.

(5) *Comment:* We stated under Factor A that remaining areas of greenstone and serpentine habitat on the peninsula are frequently 0.4 ha (1 ac) or less in size and may no longer be appropriate sites for re-establishment of *Arctostaphylos franciscana* due to fragmentation and loss of native plant diversity in the small remnant areas. One peer reviewer pointed out the loss of native diversity in existing stands of vegetation is not a relevant argument because new populations of *A. franciscana* would be newly created in the small sites.

Our Response: We appreciate the reviewer's point and agree that if small remnant habitat areas were to support *Arctostaphylos franciscana,* it would be through restoration with newly assembled populations of the species, which could permit establishment of other naturally co-occurring natives. However, we remain concerned that small sites may insufficiently support the pollinator, fruit-dispersal, and mycorrhizal communities that are thought to contribute to successful establishment of the species. We will be looking at all potential sites when selecting locations for outplanting.

(6) *Comment:* One peer reviewer noted that the threat to *Arctostaphylos franciscana* from nonnative, root-rotting *Phytophthora* species is greater than noted under Factor C in the proposed rule. He noted that species of *Phytophthora* differ in their ecological requirements, such as optimum temperature range. Several species of *Phytophthora* have become established in a variety of San Francisco Bay area microclimates and could be introduced to the vicinity of *A. franciscana.* He also noted that other factors discussed under Factor E, including climate change, soil compaction, and low genetic diversity, have the potential to increase the risk to

the existing wild plant from *P. cinnamomi* and other *Phytophthora* species.

Our Response: This information has been incorporated into this final rule. Please see Factor C discussion on threats to *Arctostaphylos franciscana* associated with disease below.

(7) *Comment:* One peer reviewer noted that the general strategy to recover *Arctostaphylos franciscana* should be two-fold: (A) Identify other genotypes of *A. franciscana* that have been cultivated in botanical gardens and use their cuttings to propagate large numbers of plants for future outplantings in restored habitats, and (B) identify and secure sites for outplanting these clones and create as many populations within the historical range as feasible.

Our Response: This information has been incorporated into this final rule where appropriate and will be considered during development of the proposed critical habitat and recovery actions for the species.

(8) *Comment:* One peer reviewer noted that the potential risks of failure of small, restored populations are outweighed by benefits of having a large number of isolated populations within the range of *Arctostaphylos franciscana.* These populations would buffer the wild *A. franciscana* from the threats noted in this rule, including disease, disturbance, predation, and climate change. The peer reviewer further noted that having many scattered populations will optimize the potential for at least some populations to adjust to climate change.

Our Response: We concur with this opinion and are considering this during our development of proposed critical habitat and recovery actions for the species.

Comments from States

Section 4(i) of the Act states, ''the Secretary shall submit to the State agency a written justification for his failure to adopt regulations consistent with the agency's comments or petition.'' No comments were received from the State regarding the proposal to list *Arctostaphylos franciscana* as an endangered species.

Federal Agency Comments

No comments were received from any Federal agencies.

Public Comments

(9) *Comment:* All seven commenters noted that the species should be listed and protected in the wild because only one plant is known to exist.

Our Response: Comments noted.

(10) *Comment:* One commenter noted that not all nursery stock of *Arctostaphylos franciscana* is of unknown origin. The commenter stated that UC Berkeley Arboretum and Yerba Buena Nursery sell plants of known origin. Plants from Yerba Buena Nursery have been planted in Golden Gate Park Arboretum, which validates their legitimacy. The commenter further stated that specimens from verified sources are a vital repository and should not be disregarded.

Our Response: The UC Berkeley Botanical Garden does not sell *Arctostaphylos franciscana* plants; however, their stock was originally from the Laurel Hill Cemetery and may have been the source for plants sold by California Native Plant Society (Forbes 2012, p. 1). We agree that some *A. franciscana* plants in the nursery trade originated from plants salvaged from the Laurel Hill Cemetery prior to its destruction in 1947; however, it is difficult to trace the lineage of all nursery plants in the intervening 65 years. Some currently available, nursery-grown *A. franciscana* plants could be cultivars selected for specific growth characteristics, and others could be the product of hybrid seed. Plants from Yerba Buena Nursery that were planted at Golden Gate Park Arboretum, now known as the San Francisco Botanic Garden, are believed to be *A. franciscana* (D. Mahoney 2012, pers. comm.). We encourage the use of plants that are proven to be *A. franciscana* to generate stock for additional populations of *A. franciscana.* However, introgression (the spread of genes of one species into the gene pool of another by hybridization) could occur if hybrid nursery stock is outplanted near the wild plant and cross-fertilization occurs. Because of the uncertainty of the origin or subsequent hybridization, we currently only consider the plants of confirmed origin at East Bay Regional Parks Botanic Garden at Tilden Regional Park and at UC Botanical Garden at Berkeley, and the wild plant on the Presidio to be *A. franciscana* and the listed entity.

(11) *Comment:* One commenter noted that there is no apparent incentive for anyone to poach or vandalize plants in natural settings that are available in the nursery trade.

Our Response: Plants have been vandalized in Golden Gate Park, including species that are also available in nurseries such as elm and sycamore trees, and rose bushes (King 2010, unpaginated; Gordon 2010, unpaginated). The fact that a plant is available in the nursery trade does not protect it from being vandalized or poached.

(12) *Comment:* A commenter noted that leaving the nursery trade specimens of *Arctostaphylos franciscana* unlisted may result in introgression. The commenter suggests that including nursery stock in the listed entity will help to regulate this threat.

Our Response: Arctostaphylos franciscana has been available to the public in the nursery trade for many years, and introgression of this species with other manzanitas may have already occurred. Including *A. franciscana* nursery stock as part of the listed entity will have no effect on controlling hybridization of these plants. Only the removal of *A. franciscana* from nursery production could minimize its hybridization with other species of *Arctostaphylos* while in the nursery setting.

(13) *Comment:* A commenter noted that if the *Arctostaphylos franciscana* plants in the nursery trade are not considered to be the listed species, they should be protected under the similarity of appearance provisions of the Act.

Our Response: We acknowledge that similarity of appearance is a tool available to us under the Act. Section 4(e) of the Act states that the Secretary may treat any species as an endangered species or threatened species even though it is not listed pursuant to section 4 of the Act if he finds that: (1) Such species so closely resembles in appearance, at the point in question, a species which has been listed that enforcement personnel would have substantial difficulty in attempting to differentiate between the listed and unlisted species; (2) the effect of this substantial difficulty is an additional threat to an endangered or threatened species; and (3) such treatment of an unlisted species will substantially facilitate the enforcement and further the policy of the Act. It should be noted, however, that the basic intent of section 4(e) of the Act is to prevent the inadvertent harm to the listed species in the wild resulting from its similarity to a different species that is not protected by the Act. The *Arctostaphylos franciscana* plants in the nursery trade do not need the protection of the Act, and including them in this listing under section 4(e) will provide no or minimal benefit to the wild specimen or any future outplantings of the listed entity. Similarity of appearance protections can be effective in situations where collection of a species is highly desirable (such as for insects or butterflies) and such collection is the primary threat or a threat of such an extent that not including the similar

species with the listed entity would greatly affect the listed species' status. Although collection of the remaining wild plant and any future outplantings is a potential threat, no known collection has occurred to date, and we would not consider this threat to be of such a high level as to greatly affect the species' status. As a result, we have determined that treating *A. franciscana* plants in the nursery trade as endangered under section 4(e) of the Act would not substantially facilitate enforcement or the policy of the Act, and the Secretary is not invoking section 4(e) of the Act for *A. franciscana.*

(14) *Comment:* One commenter disagreed with information we reported, which indicated that lands in Area B of the Presidio, which are managed by the Presidio Trust, could be dispersed to the private sector and become available for development if the Presidio Trust is not financially self-sufficient by 2013. Further, the commenter does not agree that differences in the missions of the Presidio Trust and NPS would cause uncertainty in the future management of the *Arctostaphylos franciscana* and its habitat.

Our Response: The Presidio Trust Act of 1996 states in section 105(b) that the Presidio Trust must be self-sufficient within 15 complete fiscal years of the first meeting of the Presidio Board of Directors, thereby requiring that the Trust be self-sufficient by 2013 (Presidio Trust Act, p. 9; Presidio Trust Management Plan 2002, p. 1). Because this timeframe extends into the future, there is no assurance that this goal will be met. The Presidio Trust, as stated in the Presidio Trust Management Plan (2002, pp. 1, 12), is directed to preserve natural, scenic, cultural, and recreation resources, and at the same time ensure that the Presidio becomes financially self-sufficient. Again, as stated in the Presidio Trust Management Plan (2002, pp. 1, 12), ''Congress gave the Trust the authority to lease property and generate revenues, and required the Presidio to be financially self-sufficient by 2013. Once appropriations cease, the Trust must use the park's building assets to fund its rehabilitation and to pay for its ongoing operation. No other area within the National Park System is managed in the same way or operates under the same financial requirement.'' The mission of NPS on the Presidio, as stated in the Golden Gate National Recreation Area Addition Act of 1992 (16 U.S.C. 460bb), while similar to the Presidio Trust Act in protecting values and resources, does not include the mandate that the public lands under NPS authority become financially self-sufficient.

(15) *Comment:* One commenter stated that there are no remaining landfill remediation sites on the Presidio that have the potential to impact *Arctostaphylos franciscana,* and that all waste material has been removed from the landfill remediation site closest to where the wild plant is located. The commenter noted that this work was completed without impacts to *A. franciscana* and asked that we delete the text under Factor A that refers to the Presidio Environmental Remediation Program.

Our Response: Remediation of the landfill site closest to the *Arctostaphylos franciscana* on the Presidio is being completed without apparent impact to the wild plant, and no further remediation projects are located within the vicinity of the plant. Remediation of this landfill site has been deleted as a current threat from the Factor A discussion.

(16) *Comment:* A commenter noted that under Factor E we stated that the *Arctostaphylos franciscana* plant is located near an area available for public events and threatened by foot traffic. The commenter stated that this area is available one afternoon per week for wedding ceremonies and does not present a threat to the plant, and requested that reference to this event space be removed as a threat.

Our Response: As stated in the proposed rule, the Presidio is a highly popular, easily accessible National Park contiguous with the City of San Francisco, which receives 5 million visitors each year. The public area described in the proposed rule, which is available for public events, provides views of the San Francisco Bay and the City of San Francisco, and attracts a large number of visitors year round. The best information available to us indicates that the public has unrestricted access to this area 24 hours a day, every day of the year; therefore, this site may be a different location than that referred to by the commenter. Additionally, the *Arctostaphylos franciscana* plant has been located near common-use trails with unrestricted access. Because of its proximity to these heavily used areas, the plant could be damaged accidentally or intentionally by park users. The Presidio Trust and NPS are concerned that authorized and unauthorized group tours by plant enthusiasts could overwhelm the plant and compact the soil (T. Thomas, pers. comm., 2011).

(17) *Comment:* One public commenter stated that designation of critical habitat is not prudent or determinable for the reasons stated in the proposed rule.

Our Response: As noted in our response to comment 2, the peer reviewers provided information on the ecological requirements of *Arctostaphylos franciscana* and areas with the highest potential for establishing new populations. Based on this information, we have determined that the designation of critical habitat is prudent and determinable. As a result, a proposed rule to designate critical habitat for *A. franciscana* is published in the Proposed Rules section of today's **Federal Register**. Please see that proposed rule for information on submitting a comment on our proposed designation of critical habitat for *A. franciscana.*

Summary of Changes From Proposed Rule

Based on peer review and public comments (see comments 1, 6, 7, and 15 in the **Summary of Comments and Recommendations** section above), and monitoring of the wild plant, we have added new information in the *Species Information* section and additional threats information in the **Summary of Factors Affecting the Species** section to better characterize our knowledge of the species' habitat requirements and threats. After input from peer reviewers and public comment, we have determined that the designation of critical habitat is prudent and determinable, and we are proposing to designate critical habitat, as described in a separate proposed critical habitat rule in today's **Federal Register**.

Summary of Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act: (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. Listing actions may be warranted based on any of the above threat factors, singly or in combination. Each of these factors is discussed below.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

All areas of habitat originally known to be occupied by *Arctostaphylos franciscana* have been lost to urban development or to habitat conversion through the introduction of nonnative plant species (Chasse *et al.* 2009, pp. 4, 7; Chasse 2011c, p. 1). The largest historical occurrence was at the quarry area of the former Laurel Hill Cemetery in San Francisco (Chasse 2011c, p. 1). Most of this area was converted to residential housing and city streets after the late 1940s. A small remaining area of open space at Laurel Hill is dominated by ornamental shrubs and invasive understory plants, although serpentine rock is visible in several openings (Chasse 2011c, p. 1). Lawns, pathways, and buildings, part of the University of San Francisco campus, now occupy the location of the Masonic Cemetery occurrence (Chasse 2011c, p. 2). The precise location of the third historical occurrence of *A. franciscana,* at Mount Davidson, is unknown but thought to be on one of the greenstone outcrops (Chasse 2011c, p. 2). The upper portions of Mount Davidson are covered with nonnative trees and invasive understory species; some grassland and scrub persist on the south and northeast sides (Chasse 2011c, p. 2). The species' range is now limited to the single transplanted location on the Presidio. In January 2010, after the newly discovered wild plant was moved to the Presidio, the plant's habitat at Doyle Drive was destroyed as part of a Caltrans highway improvement project.

Past urban development on the San Francisco peninsula has limited the remaining areas of potential habitat for *Arctostaphylos franciscana* by habitat conversion and habitat degradation and, to a lesser degree, habitat fragmentation. Some of these small remnant areas may no longer be suitable for reestablishment of *A. franciscana* due to factors such as dominance by other plant species (Chasse pers. comm., 2011). Currently, these small, isolated parcels are subject to edge effects, such as changes in soil moisture, changes in light, and potential increased invasion of weed species that would compete with *A. franciscana* for limited resources (water, nutrients, space).

Urban barriers, such as streets and buildings, have been found to impose a high degree of isolation on chaparral species and, over time, to result in decreased numbers of native plant species and concurrent increased numbers of nonnative plant species in the habitat fragments (Alberts *et al.* (unpubl.) as cited in Soule *et al.* 1992, p. 41; Soule *et al.* 1992, pp. 41–43). These effects of urbanization on the San Francisco peninsula are expected to continue to affect these remnant parcels into the future, and to pose a threat to the establishment of additional *Arctostaphylos franciscana* plants, without assistance to restore suitable habitat conditions and to restore plants to suitable locations.

Additionally, nitrogen deposition may modify habitat by increasing soil nutrients, thus posing a current and continuing threat to remnant habitat that might otherwise be suitable for *Arctostaphylos franciscana.* Weiss and Luth (2003, p. 1) have conducted research on the effects of nitrogen deposition in a serpentine grassland south of the San Franciscan peninsula. They found that nitrogen deposition from automobiles on Highway 280 (a north-south oriented highway on the peninsula) was responsible for higher nitrogen levels in the soil within 400 m (1,312 ft) on the west side and 100 m (328 ft) on the east side of the roadway. Nitrogen deposition was correlated with increased nonnative grass cover in these areas, resulting in competition for space for native plants. Native species within this zone are thought to be at long-term risk from invasions of nitrogen-loving grasses and other weedy plant species (Weiss and Luth 2003, p. 1). An increase in nonnative grass cover through changed habitat conditions could threaten the wild *A. franciscana* by competing for soil moisture and nutrients and could inhibit successful germination of *A. franciscana* seed. The entire northern San Francisco peninsula, with the exception of the Presidio and Golden Gate Park, has been urbanized, and four major highways (Highways 1, 101, 280, and 480) and other urban roadways dissect the peninsula. Urban areas and roadways are a continuous source of nitrogen deposition from automobiles, trucks, and industrial and home heating (Weiss 1999, p. 1477). Invasions of nitrogen-loving plants into nitrogen-limited grasslands and shrublands appears to be a common response to atmospheric nitrogen deposition (Weiss and Luth 2003, p. 1), and may partly explain why the ecosystem that existed on the San Francisco peninsula has been so altered.

The one remaining wild *Arctostaphylos franciscana* plant is subject to multiple threats. The Presidio Trust Act contains a sunset clause that could result in the transfer of Presidio holdings to the General Services Administration (GSA) for disbursement if the Presidio Trust operations are not self-sufficient by 2013 (the Presidio Trust Act is discussed under *Factor D* below). In the unlikely event that the Presidio Trust is not self-sufficient within that timeframe, the potential that lands could be transferred and become available for development presents a threat of additional habitat loss in the future.

Based on the best scientific and commercial information available, we consider the present or threatened destruction, modification, or curtailment of the species' habitat or range to be a high-magnitude and ongoing threat to the wild population of *Arctostaphylos franciscana.* The current fragmented and degraded condition of most remaining serpentine or greenstone soil habitat on the San Francisco peninsula threatens the ability of *Arctostaphylos franciscana* to expand its range. The threats of possible development and change in management of the habitat may further limit the species' propagation and expansion, and could potentially threaten the only remaining wild plant. The loss of the plant's native serpentine chaparral habitat to development and the curtailment of its range restrict the species' current and future ability to naturally reproduce and expand its range.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Overutilization of *Arctostaphylos franciscana* is possible due to its popularity for landscape use, as evidenced by the widespread use of cultivars of this species in the commercial nursery trade. *Arctostaphylos franciscana* is specifically recommended for use in erosion control on steep slopes (Theodore Payne Foundation 2009, p. 1; Sierra Club 2011, p. 1).

The attention and media coverage generated by the discovery of a species thought to be extirpated from the wild may result in efforts by the public to visit the plant and possibly collect cuttings or seed. Although the location of the transplanted plant has not been disclosed, it was planted in a heavily used area in the Presidio, near common-use trails with unrestricted access by the public. The Presidio is a National Park and is part of the GGNRA; it is open to the public 24 hours a day, every day of the week and receives 5 million visitors annually. The Presidio receives heavy use because of its proximity to the City of San Francisco, and because the National Park has no entrance fees and contains restaurants, trails, and businesses that can be accessed by car, foot, or public transport. The Presidio

Trust and NPS are making serious efforts to avoid disclosing the location of the translocated plant. The Presidio Trust and NPS are concerned that public knowledge of the plant's location would lead to authorized and unauthorized group tours by plant enthusiasts (T. Thomas, pers. comm., 2011).

No damage to the plant has been observed to date; however, trampling or the taking of cuttings could occur if the identification and location of the plant becomes known. Similarly, another extremely rare plant, *Arctostaphylos montana* ssp. *ravenii,* is also located on the Presidio. Although it was federally listed in 1979, its location has not been revealed to the public by the Presidio Trust or NPS in order to protect the plant from vandalism. There has been no evidence of cuttings being taken from *A. franciscana* or the similar *A. montana* ssp. *ravenii* (Chasse 2011c, p. 3); however, the fact that the sole remaining wild *A. franciscana* is located in a heavily used public area subjects this species to the threat of collection.

Based on the best scientific and commercial information available, we consider overutilization for commercial and recreational purposes to be a threat to the wild *Arctostaphylos franciscana* plant. Although nursery-grown *A. franciscana* are available to residents for use in private gardens, collection of the wild plant is a threat to the species, and we expect it may be a threat in the future, particularly if the location of the plant becomes known to the public.

C. Disease or Predation

Disease

Transplantation of the single wild *Arctostaphylos franciscana* plant may have caused stress to the plant, and thereby made it more susceptible to predation and disease. In transplanted plants, stress and root damage may occur from a variety of factors, including soil compaction from foot traffic around the plant (Hammitt and Cole 1998, p. 52), too little or too much water, and improper planting depth; these stressors may result in increased susceptibility to disease (see further discussion in Visitor Use section below). A fungal infection called twig blight, usually caused by *Botryosphaeria* species in *Arctostaphylos,* is also a potential concern, particularly during wet years (Service 2003, p. 69). Twig blight was observed in the wild plant during the winter of 2009–2010, but it subsided during the dry summer months (Chasse 2010, p. 2). These fungi can cause both twig blighting and perennial branch cankers that can eventually kill large branches (Swiecki 2011, p. 1). While these pathogens would not likely pose a serious threat to a large population, they could threaten *A. franciscana* because the wild population is limited to a single plant, and infection by this group of fungi is one of the major factors leading to the decline of older *Arctostaphylos* sp. plants (Swiecki 2011, p. 1). Additionally, cankers caused by *Botryosphaeria* are more severe in plants that are stressed by lack of water. The transplanted plant may have experienced water stress due to loss of roots during the transplanting process (Swiecki 2011, p. 1).

Arctostaphylos franciscana is also threatened by various pathogens in the genus *Phytophthora.* An oak tree infected with sudden oak death disease was discovered on the Presidio in 2010 (Fimrite 2011). Sudden oak death is caused by *Phytophthora ramorum. Phytophthora* is a fungus-like organism most closely related to diatoms and kelp (Kingdom Stramenopila) rather than to the true fungi (Kingdom Fungi or Eumycota). *Phytophthora ramorum* has so far been observed to cause only a foliar blight in species of *Arctostaphylos,* rather than the lethal bark cankers that occur on members of the black oak group (Swiecki 2012a, p. 1). However, a related species, *P. cinnamomi* has presented a serious threat to other *Arctostaphylos* species and is expected to be a serious threat to *A. franciscana. Phytophthora cinnamomi,* a soil-borne pathogen, has long been known as a world-wide threat to commercial and ornamental plants. It is an introduced exotic pathogen in North America; its native range is unknown, but is suspected to be southeast Asia. Human-related activities, including the international plant trade, have facilitated the spread of *P. cinnamomi* into many habitats worldwide (Swiecki *et al.* in press, p. 3). *Phytophthora cinnamomi* was introduced to California early in the 20th century, and recently has been identified as a serious threat to the State's native plants and their habitats (Swiecki *et al.* in press, p. 3).

Phytophthora cinnamomi has been the cause of the decline and death of rare *Arctostaphylos* species, including the federally threatened *A. pallida* (pallid manzanita) in the Oakland Hills of the East San Francisco Bay region and the federally threatened *A. myrtifolia* (Ione manzanita) near Ione in the Sierra Nevada foothills of Amador County. The pathogen is also noted in the decline of other woody native species in the San Francisco Bay area (Swiecki *et al.* in press, pp. 3–5). The organism causes root decay but can also kill above-ground portions of some plants (Swiecki *et al.* in press, p. 3). *Phytophthora cinnamomi* is persistent in soil, and once introduced to native habitat it cannot be eradicated (Swiecki *et al.* in press, p. 3). *Phytophthora cinnamomi* is transmitted by contaminated shoes, tools, and infested soil clinging to tires, and by contaminated nursery stock, including native plant stock. Many areas showing plant mortality caused by *P. cinnamomi* are associated with hiking trails, landscapes with ornamental plants, and, in one case at the Apricum Hill Preserve in Amador County, California, use by visitors, including researchers, agency personnel, students, and the general public (Swiecki *et al.* in press, p. 4).

Phytophthora cinnamomi poses a significant current and future threat to *Arctostaphylos franciscana* because of the potential for infestation caused by the public and staff who regularly work with the plant. It is not possible to predict if or when the pathogen might infect the wild plant because the disease is generally transmitted directly or indirectly by humans or human activity. The pathogen could be introduced from soil on contaminated shoes and tools, or from cuttings of *A. franciscana* plants currently grown in a number of San Francisco Bay area nurseries that could become contaminated. Swiecki *et al.* (in press, p. 6) tested *A. menziesii* plants purchased from four nurseries and found them to be infested with four *Phytophthora* species that cause root infections or stem cankers, including *P. cinnamomi.* Crown rot, which is caused by *P. cinnamomi,* is known to occur in *A. myrtifolia* and *A. viscida* (Swiecki *et al.* in press, p. 3), and is a concern when outplanting nursery-grown plants to wild locations (Chasse *et al.* 2009, p. 17). However, crown rot has not been observed in the wild *A. franciscana* plant (Chasse 2010, p. 2).

Conservation proposals include recommendations that *Arctostaphylos franciscana* cuttings be planted with the transplanted *A. franciscana* to facilitate cross-pollination of the different genotypes. Should the wild plant become contaminated with *P. cinnamomi,* the result would be the decline and death of the wild plant and permanent contamination of the soil and seedbank beneath the plant. Any seedlings that germinate from this seedbank would also very likely be contaminated and not survive. Any cuttings that become contaminated are also expected to die of the pathogen. The Golden Gate National Parks Conservancy Nurseries staff in charge of propagation and care of *A. franciscana*

cuttings are aware of the threat of contamination and rigorously follow clean procedures to prevent infection to the cuttings or the wild plant; however, a risk of contamination continues to exist because current fungicides do not eradicate 100 percent of *Phytophthora* spores (Young 2010b, p. 1). The cuttings and layers from the single wild plant have been dispersed to seven different locations and growers, which, while decreasing the risk of complete loss of plant material, also increases the risk of exposure to disease.

Phytophthora cinnamomi is not the only introduced soil-borne *Phytophthora* species that may threaten *Arctostaphylos franciscana.* Swiecki (2011, p. 1; 2012b, p. 1) notes that at least five other species of *Phytophthora* associated with the decline and death of woody plants have been found in the Crystal Springs watershed 27 to 40 kilometers (km) (17 to 25 miles (mi)) south of the Presidio. These nonnative *Phytophthora* species include *P. cambivora, P. cactorum,* and *P. megasperma;* all are known to occur in natural and cultivated landscapes and are common in nursery stock (Swiecki 2011, p. 1). *Phytophthora cinnamomi* and *P. cambivora* have been detected in China Camp State Park, 22.4 km (14 mi) north of the Presidio, and *P. cinnamomi* has been found in the East Bay area 24 km (15 mi) east of the Presidio. Because several of these soil-borne pathogens have become established in the San Francisco Bay area, the likelihood is increased that one or more could be introduced to the vicinity of the wild *Arctostaphylos franciscana* plant (Swiecki 2011, p. 1).

Predation

After being transplanted, the wild plant became severely infested with the larvae of a native leaf roller moth (*Argyrotaenia franciscana*) (Estelle 2010, p. 1). Treatment for the infestation was hand removal of the larvae and all infected leaves, which resulted in the removal of some of the new growth on the plant (Estelle 2010, p. 1; Young 2010a, p. 1). A parasitic wasp emerged from one captured leaf roller moth larva, indicating that the moth has natural enemies (Frey 2010, p. 2). The moth has not been known to kill plants and does not appear to be a serious threat at this time; however, the moth species was found to have five overlapping generations in a year (Estelle 2010, p. 1). Monthly removal of moth larvae and pupae is conducted as needed (Estelle 2012a, p. 1). The leaf roller moth infestation in early 2010 did not permanently damage the plant, and new growth was observed (Frey 2010, p. 2). Fewer leaf roller moth larvae were seen on the wild plant in 2011 than in 2010 (Estelle 2012a, p. 1).

Damage to *Arctostaphylos franciscana* branches by California voles has been observed by Presidio Trust staff (Chasse 2011c, p. 2). Several voles have been observed in and around the wild *A. franciscana* plant, and some branch dieback has been attributed to gnawing by voles and other rodents (Chasse 2011c, p. 2).

Based on the best scientific and commercial information available we consider the effects from disease and predation to be a threat to *Arctostaphylos franciscana.* Infection of the plant by *Phytophthora cinnamomi* or other *Phytophthora* species has been determined to be a serious threat to *A. franciscana* because only one plant occurs in the wild, the disease is easily and quickly spread by multiple vectors, and at least six species of *Phytophthora* are known to be present in the vicinity of the San Francisco peninsula. Additionally, we consider predation to be a relatively minor but ongoing threat to the wild population of the species. Although the leaf roller moth has not been known to kill *Arctostaphylos* species, the moth produces five overlapping generations per year and severely damaged the leaves in 2010. Predation on branches by California voles has occurred and is also relatively minor but ongoing threat.

D. The Inadequacy of Existing Regulatory Mechanisms

Regulatory mechanisms protecting *Arctostaphylos franciscana* derive primarily from the location of the single known wild plant on GGNRA lands on the Presidio, which are administered by the Presidio Trust. The Presidio Trust was established by the Presidio Trust Act of 1996 to manage the leasing, maintenance, rehabilitation, repair, and improvement of property within the Presidio (Presidio Trust Act, as amended, sec. 104(a)). The Presidio Trust is directed to preserve the natural, scenic, cultural, and recreational resources on the Presidio, but also is directed to ensure that the Presidio becomes financially self-sufficient by 2013 (Presidio Trust 2002, pp. 1, 2, 12). The Presidio Trust Act directed that the Presidio Trust design a management program to reduce NPS expenditures and increase revenues to the Federal Government to the maximum extent possible (Presidio Trust Act, pp. 5, 6). The Presidio Trust Management Plan was published in May 2002. The Presidio Trust manages most of the Presidio (Area B), and NPS retains jurisdiction over Area A as defined in the Presidio Trust Management Plan (Presidio Trust 2001, p. 3). The Presidio Trust and NPS coauthored the Presidio Vegetation Management Plan. For special status plants, the plan provides an objective to preserve and enhance rare plant habitats by evaluating species-specific habitat needs, giving high priority to actions that preserve and enhance those habitats (Presidio Trust 2001, Chapter 3, unpaginated).

Federal regulations for the Presidio Trust, which offer some protection to *Arctostaphylos franciscana,* include prohibitions on disturbing, injuring, removing, possessing, digging, defacing, or destroying from its natural state, any plant or parts thereof. Unauthorized introduction of plants and plant seeds is also prohibited, offering limited protection against invasive, nonnative species. Additional regulations require that special events be permitted by the Presidio Trust, and provide for restricting visitor use to address resource conflicts (36 CFR part 1002).

The Presidio Trust is a new model for National Park management in that the Presidio Trust is directed to preserve the natural, scenic, cultural, and recreational resources on the Presidio and at the same time ensure that the Presidio becomes financially self-sufficient by 2013 (Presidio Trust 2002, pp. 1, 12). This means that generation of revenue is a consideration for the Presidio Trust's activities, as well as resource protection. The cost of operation and care are higher for this park than for most National Parks because of the Presidio's large number of structures and cultivated landscapes (Presidio Trust 2011, unpaginated). The mission of NPS on the Presidio, as stated in the Golden Gate National Recreation Area Addition Act of 1992 (16 U.S.C. 460bb), although similar to the Presidio Trust Act regarding the protection of natural, historic, scenic, and recreational values, does not include the mandate to ensure that the Presidio becomes financially self-sufficient.

The future status of the Presidio as National Park land is uncertain, as explained in the Presidio Trust Act's section 104(o) (Reversion), which states: ''If, at the expiration of 15 years, the Trust has not accomplished the goals and objectives of the plan required in section 105(b) of [the Presidio Trust Act], then all property under the administrative jurisdiction of the Trust pursuant to section 103(b) of [the Presidio Trust Act] shall be transferred to the Administrator of the General Services Administration to be disposed of in accordance with the procedures outlined in the Defense Authorization

Act of 1990 (104 Stat. 1809), and any real property so transferred shall be deleted from the boundary of the Golden Gate National Recreation Area. In the event of such transfer, the terms and conditions of all agreements and loans regarding such lands and facilities entered into by the Trust shall be binding on any successor in interest.'' This clause indicates that lands currently considered National Parks lands could be disbursed to the private sector and subject to development within the near future. The Presidio Trust states, however, that since 2004, the Trust's earned revenue has offset operating costs and expects that the Presidio will meet the goal of being a self-sustaining National Park in 2012 (Middleton 2011, p. 2).

Arctostaphylos franciscana is not listed under the California Endangered Species Act. The conservation plan and MOA are not regulatory in nature and not legally enforceable by third parties (Caltrans 2009, p. 8; Chasse *et al.* 2009, p. 3), limiting their usefulness in enforcing protections for the plant. Although general protections are provided for plants on National Parks, no regulatory language in any Park Service or Presidio Trust documents specifically addresses protection of *A. franciscana.*

Based on the best scientific and commercial information available, we consider the inadequacy of existing regulatory mechanisms not to be a threat to the species.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

Potential threats to *Arctostaphylos franciscana* include changes in environmental conditions resulting from climate change, trampling or disturbance by people visiting the Presidio, altered fire regime, loss of genetic diversity, loss of pollinators, and stochastic (chance) events.

Climate Change

Our analyses under the Act include consideration of ongoing and projected changes in climate. The terms ''climate'' and ''climate change'' are defined by the Intergovernmental Panel on Climate Change (IPCC). ''Climate'' refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2007, p. 78). The term ''climate change'' thus refers to a change in the mean or variability of one or more measures of climate (e.g., temperature or precipitation) that persists for an extended period, typically decades or longer, whether the change is due to natural variability, human activity, or both (IPCC 2007, p. 78). Various types of changes in climate can have direct or indirect effects on species. These effects may be positive, neutral, or negative and they may change over time, depending on the species and other relevant considerations, such as the effects of interactions of climate with other variables (*e.g.,* habitat fragmentation) (IPCC 2007, pp. 8–14, 18–19). In our analyses, we use our expert judgment to weigh relevant information, including uncertainty, in our consideration of various aspects of climate change.

Changes in environmental conditions resulting from climate change may cause presently suitable habitat to become unsuitable for endemic California plants, due to projected changes in temperature and rainfall (Loarie *et al.* 2008, pp. 1–2). A U.S. Geological Survey (USGS) study in National Park lands in northern California and Oregon is underway to examine trends in climate, ocean conditions, and other features (Madej *et al.* 2010, p. 7). In these National Park lands, variation in abiotic factors (for example, precipitation, fog, and air and ocean temperatures) regulates many ecological processes, including the distribution of vegetation and frequency of disturbance from fires, floods, landslides, and pest species. The preliminary results of the USGS study show an increase in average maximum summer air temperatures at GGNRA, near the Presidio (Madej *et al.* 2010, p. 24).

Summer fog and overcast along the California coast has been identified as ecologically important to endemic plant species by increasing water availability during the dry summer months, reducing loss of water from leaves (evapotranspiration), and decreasing the frequency of drought stress (Fischer *et al.* 2009, pp. 792–794). Fog frequency along the Pacific coast is highest in north and central California and declines in Oregon and southern California (Johnstone and Dawson 2010, p. 4534). Climate change may be affecting the amount and duration of fog and cloud cover along the California coast including within the San Francisco Bay area. Mean fog frequency in the California region, quantified by cloud ceiling height measured at airports, has decreased since 1951 (Johnstone and Dawson 2010, p. 4535). Research by Vasey (2010, p. 1) suggests that most coastal endemic *Arctostaphylos* species are more vulnerable to drought stress than those found in interior California, and could be threatened by a decrease in coastal summer fog. He found that obligate-seeding *Arctostaphylos* species, such as *A. franciscana,* are better hydrated in areas that receive fog. He also found that coastal obligate-seeding species are more vulnerable to vascular cavitation (blockage forming in water vessels in the plant) when the rate of water loss through the leaves becomes too great, such as during drought (Vasey 2010, p. 1). This disruption of water flow can lead to branch death and possibly death of the entire plant (Vasey 2010, p. 1).

Reduced soil moisture from decrease in summer fog may also result in reduced seed germination and seedling survival. Additionally, the ability of *Arctostaphylos franciscana* to respond to future climate changes by establishing new plants in new habitat may be limited because of the plant's association with serpentine and greenstone bedrock outcrops (Service 2003, pp. 95, 96), and because soils derived from serpentine and greenstone bedrock on the peninsula are limited in area and largely fragmented (Chasse 2010, p. 1). Natural movement of the species by seed dispersal to reach cooler, moister areas to the north would be impeded by barriers such as the San Francisco Bay.

Increased temperatures within *Arctostaphylos franciscana* habitat could also result in higher soil temperatures that would favor *Phytophthora cinnamomi,* which reproduces best at warmer soil temperatures. Higher temperatures would also increase the likelihood of water stress on *A. franciscana,* increasing its susceptibility to other *Phytophthora* species (Swiecki 2011, p. 1).

Alteration of the Natural Fire Regime

In addition to soil type and climate, fire plays a critical role in the determination of plant distribution (Keeley 2007, p. 19). The chaparral plant community, of which *Arctostaphylos* is an important member, is adapted to specific fire regimes that vary in different parts of California. In the San Francisco East Bay region, the current fire return interval is estimated at about 100 years (Keeley 2007, p. 20). Factors that affect the fire frequency in the San Francisco Bay area include a short fire season, moist climate, the local human population density, and changes in human behavior. Due to prevailing ocean winds and frequent fogs, the average relative humidity along the coast is moderate to high throughout the year. The exceptions typically occur in the fall, when changing prevailing weather patterns allow dry northeasterly winds from the State's interior to reduce

humidity in the coastal area to around 20 percent, thereby creating dry and windy conditions that typify high fire danger (GGNRA 2005, pp. 136, 140).

Fire frequency in the San Francisco Bay area has varied substantially in the last several thousand years. Not only have the fire regimes changed with changing climate, fire regimes have changed as patterns of human utilization of the landscape have changed. Disturbances by fire occurred at long intervals in the prehuman period, then at shorter intervals during the late Native American and Spanish-Mexican periods, and at moderate intervals during the European settlement period. Fire disturbance intervals since the 1900s have generally returned to long intervals in the modern period due to active fire suppression (GGNRA 2005, pp. 144–147). The natural fire regime has been heavily altered by the urbanization of San Francisco and fragmentation of remaining undeveloped lands. Nearly all land within the City of San Francisco has been developed, with the exception of small, isolated parcels and undeveloped hilltops. Lands administered by NPS and the Presidio Trust are surrounded by other land uses, and are close to the wildland-urban boundary where landscape plants and nonnative plants contribute to vegetative buildup (GGNRA 2005, pp. 130–131) that can increase fire danger. Additionally, fire suppression over the last 100 years has led to an increase in crown and surface fuels, which contribute to high-intensity fires (GGNRA 2005, p. 147). In spite of the increased fire danger on these managed lands, they could eventually be identified as suitable for outplanting *Arctostaphylos franciscana* seedlings due to the limited amount of remaining habitat.

As stated above in the *Species Information* section above, *Arctostaphylos franciscana* is an obligate-seeding species and reproduces primarily from seed rather than from burls after a fire (Vasey 2010, p. 1). Two opposing types of changes in fire frequency can threaten chaparral species such as *Arctostaphylos franciscana.* First, ''senescence risk'' occurs when too little fire leads to the loss of a species dependent on fire for regeneration. The second, ''immaturity risk,'' is a threat primarily to obligate-seeding species such as *A. franciscana.* In this case, wildfires that occur too frequently may kill plants before they can reach reproductive maturity and produce seed (Keeley 2007, p. 18). Wildfire can substantially reduce the number of live seeds in the soil (Odion and Tyler 2002, p. 1). Odion and Tyler (2002 p. 1) found that a controlled burn in a 40-year-old stand of *A. morroensis* (Morro manzanita), a species also occurring in maritime chaparral, reduced the seedbank to 33 percent of that which had accumulated in the soil since the previous burn 40 years earlier. Three years after the burn, the new population of *A. morroensis* that had germinated from the seedbank was less than half the size of the original population (Odion and Tyler 2002, p. 1). Odion and Tyler (2002 p. 2) concluded that if viable seed densities in the soil are low because fires are too frequent to allow seeds to accumulate in the soil, the population may risk extinction.

The fire return interval for this general area, and, therefore, for *Arctostaphylos franciscana,* is currently approximately 100 to 125 years (Parker pers. comm., 2011; Vasey 2011a, p. 1). The long fire return interval is not thought to be a threat to the mature *A. franciscana* plant at the Presidio or to any seedlings likely to be outplanted on the Presidio in the future. Infrequent fire would allow the mature plant at the Presidio to produce seed and build up a sufficiently large seedbank to withstand seed loss from wildfire, and would allow the growth of outplantings in other suitable areas. However, if fire continues to be excluded from the plant's location at the Presidio and the fire return interval greatly exceeds the natural return interval, over time the loss of fire may also result in the loss of the mature plant and individual outplanted seedlings due to competition by other plants, including nonnative plants, that could encroach upon the manzanita.

Other aspects of the altered fire regime within the remaining undeveloped lands of San Francisco pose greater threats to the species. Alteration of the fire regime has led to an increase in crown and surface fuels in some areas, leading NPS fire planners to conclude that it is difficult to predict the effects of the changed fire regime, given the trend to warmer and drier climate conditions (Johnstone and Dawson, 2010, p. 4535; Madej *et al.* 2010, p. 24) and the relationship between climate and fire frequency (GGNRA 2005, pp. 147, 148). In the past, large fires have occurred within areas that are typically subject to maritime climatic conditions. Such fires include the 1923 Berkeley Fire, the October 1991 Oakland Fire (Keeley 2005, p. 286) that burned 607 ha (1,500 ac), the October 1995 fire at Point Reyes National Seashore that burned 4,999 ha (12,354 ac) (GGNRA 2005, p. 151), and the 1,133-ha (2,800-ac) 2009 Lockheed Fire north of the City of Santa Cruz (The Associated Press 2009). On the Presidio, fire history data show that 17 fires occurred between 2000 and 2009, with no fires in some years and as many as 5 fires in other years. All fires were contained at 0.04 ha (0.1 ac) or less (A. Forrestel, pers. comm., 2011a, 2011b). In the same period, approximately four wildfires occurred in the Marin Headlands, directly north of the Presidio across the Golden Gate, while recent fire history records for all areas of the GGNRA show the potential for larger wildfires in the maritime zone (GGNRA 2005, pp. 150–155).

Although the Presidio is located within a highly urbanized setting, substantial areas of open space within the Presidio itself and within the adjacent GGNRA lands contain an interspersed mixture of vegetative types, including native vegetation, landscaped grounds, and forest (GGNRA 2005, pp. 190–199; Presidio Trust 2011, unpaginated). Grasslands are now dominated by nonnative annual grasses and forbs, which burn with greater intensity and at a more rapid rate of spread than grasslands dominated by native species (GGNRA 2005, p. 192). According to a fire model prepared by the GGNRA, areas that they manage on the western and southwestern borders of Presidio Trust lands present a moderate and moderate-high fire hazard (GGNRA 2005, p. E–7). The altered fire regime may result in infrequent fires that burn larger and hotter than previously, with the potential for greater loss of the seedbank. Alternatively, the incidence of wildfire could increase, which would be detrimental to *Arctostaphylos franciscana* by killing mature plants, seedlings, and seeds in the seedbank. In obligate-seeding species, such as *A. franciscana,* fire normally kills the adult plants, which are then replaced by plants that germinate from seed in the soil seedbank. A wildfire that would kill the single wild *A. franciscana* plant would be an especially serious threat to the future of the species because no *A. franciscana* seedbank has been found in soil collected from the area beneath the wild plant (Young 2011, p. 1).

Visitor Use

Impacts due to visitor use could harm the wild plant. The translocated wild plant has been planted in an active native plant management area that receives heavy public use, although it is protected from public access by a post and cable fence and is monitored (Chasse *et al.* 2009, pp. 20–28). The post and cable fence is placed along an adjacent trail so that people do not enter the immediate area around the plant;

however, an event in which a visitor treads on the plant could result in damage to the wild plant. Over time, incremental damage could result in the decline of the plant. The fence appears to be effective, although its wire mesh has been bent either by employees and volunteers or by the general public crossing the fence (Estelle 2012b, p. 2). Presidio Trust staff has stated that, on a few occasions, volunteers and members of the general public have asked permission to visit and photograph the plant, and that volunteers who work with the plant have been requested to not disclose its location (Estelle 2012c, p. 1). As noted under *Factor B,* the Presidio Trust and NPS have made serious efforts not to reveal the location of *Arctostaphylos franciscana* because they are concerned that public knowledge of its location would attract large numbers of plant enthusiasts who may damage the *A. franciscana* and compact the soil (Thomas, pers. comm., 2011). If trampling of the *A. franciscana* occurs, the Presidio Trust could take three protective actions: a fence could be placed around the plant, interpretive signs could be placed near the plant, and volunteers or interns could be made available to talk to visitors (Thomas, pers. comm., 2012).

The wild *Arctostaphylos franciscana* plant may be susceptible to damage from soil compaction due to foot traffic. Roots grow into soil to maintain stability and extract water and nutrients; however, soil compaction increases the resistance of the soil to root penetration and thus diminishes the plant's ability to extract sufficient water and nutrients (Hammitt and Cole 1998, p. 52). Soil compaction also reduces water infiltration rates and soil aeration by collapsing the larger pores in the soil. Reduced soil oxygen levels from loss of soil pores also can impact root growth, which would further reduce water and nutrient uptake (Hammitt and Cole 1998, p. 52). Additionally, soil compaction has been found to cause considerable damage to mycorrhizal fungi in seedling roots (Waltert *et al.* 2002, p. 1). As noted in the Historical Distribution and Habitat section, most *Arctostaphylos* species form strong symbiotic associations with soil mycorrhizal fungi, which develop an external sheath surrounding the plant's roots. All water and nutrients pass through this sheath to the plant's roots rather than directly from the soil to the plant's roots (Chasse 2009, p. 12). Damage from soil compaction would not only impact the wild plant by reducing its ability to take up water and nutrients, but could also reduce the survival of seedlings near the wild plant.

Soil compaction also favors the growth of *Phytophthora.* Poor drainage resulting from compaction facilitates the dispersal of swimming zoospores that infect the host plant (Swiecki 2011, p. 2). Additionally, anaerobic (lack of oxygen) stress associated with saturated soil conditions increases the susceptibility of roots to *Phytophthora* infections (Swiecki 2011, p. 2).

Vandalism

The location of the *Arctostaphylos franciscana* plant within the Presidio is near common-use trails and an area available for private and public events. Threats to *A. franciscana* include damage from vandalism. Vandalism to trees was reported in the Presidio in the early 2000s (Thomas pers. comm. 2011). Severe vandalism was observed in Golden Gate Park, located approximately 1.5 mi (2.4 km) south of the Presidio, in summer 2010, when more than 40 trees and 30 rose bushes were destroyed by unknown persons for unknown reasons (Gordon 2010, unpaginated; King 2010, unpaginated). The post and cable fence that protects the wild *A. franciscana* plant is approximately 30 ft (9.1 m) from the plant and is not constructed to completely exclude visitors. In the unlikely event that vandalism occurs, the results could be serious because there is only one wild plant.

Stochastic Events and Small Population Size

Chance events constitute a serious threat to *Arctostaphylos franciscana.* Because the known population of *A. franciscana* in the wild is currently limited to a single plant, the species is extremely vulnerable to stochastic events—normal but damaging environmental perturbations and catastrophes such as droughts, storm damage, disease outbreaks, and fires, from which large, wide-ranging populations can generally recover, but which may lead to extirpation of small, isolated populations (Gilpin and Soule 1986, pp. 25–31). The majority of the remaining habitat associated with *A. franciscana* occurs within rock outcrops on hilltops or slopes surrounded by development or along coastal cliffs. These areas, because of their limited size and proximity to developed areas, are more likely to experience inadvertent fire or environmental degradation (altered hydrologic regime; increased introduction of nonnative, invasive plants; and increased spread of disease). The nature of the habitat associated with *A. franciscana* (rock outcrops, thin soils, sloped or hilltop terrain) may also increase the effects of drought. By nature these habitats generally do not have the water-holding capacity of deeper soiled, level habitats. Because some of the remaining habitat associated with the species is along coastal bluffs or on hillsides, these areas may also be more susceptible to landslides or erosion during excessively wet precipitation events. As a result, we consider stochastic events to be of significant threat for this species.

Any new population that starts from the single wild plant is likely to have reduced genetic variation compared to historical populations. Even if the number of plants increases, it may not reverse the previous genetic loss, known as the bottleneck effect (Allendorf and Luikart 2007, p. 158). Bottlenecks generally have a greater and more lasting effect on the loss of genetic variation in species with slow growth rates (long-lived species with few offspring) (Allendorf and Luikart 2007, p. 133). The age of the single wild *Arctostaphylos franciscana* plant is estimated at 60 years, and no other *A. franciscana* plants or seedlings were found associated with the wild plant. Reduced genetic variation may result in the inability of future generations of the plant to adapt to changes in habitat, such as decrease in fog and increase in temperature (see Climate Change discussion above) or loss of pollinators (see discussion below). While *Arctostaphylos franciscana* may be capable of self-pollination, in general, self-pollination results in decreased genetic variation in the offspring of a plant (Allendorf and Luikart 2007, p. 123). Therefore, loss of genetic variation is expected if *A. franciscana* is dependent on self-pollination to produce seed. Based on the above discussion, we have determined that the loss of genetic variation is a significant threat for this species.

The wild plant is also threatened by the Allee effect, a decline in population growth rate due to declining plant density (Akçakaya *et al.* 1999, p. 86). For the wild *Arctostaphylos franciscana* plant, the Allee effect may result from a lack of other available *A. franciscana* plants with which to cross-pollinate and produce viable seed. The wild plant, the single remaining individual of its species in the wild, is currently dependent on its ability to self-pollinate, which may be limited, and the efforts of researchers and Presidio staff to provide additional plants of different genotypes (if they are proven to be *A. franciscana*) from botanical garden specimens to cross-pollinate

with the wild plant to produce new individuals and populations.

Loss of Pollinators

Suitable pollinators may be critical for seed production for this obligate-seeding species. If pollinators are absent, or present in insufficient numbers, there may be a lack of viable seeds to develop and maintain the seedbank. In a study of the effects of habitat fragmentation on a non-self-pollinating plant (Lennartsson 2002, pp. 3065, 3066, 3068), the author found that fragmented populations exhibited dramatically reduced seed set and population viability, both of which were caused by a reduction in the number of pollinators.

Pollinators have been observed on the wild *A. franciscana* plant; however, no surveys have been completed to identify the most important pollinators. The most frequent pollinators seen have been bees and bumblebees. Hummingbirds and butterflies have also been observed visiting the flowers, likely because few other plants are blooming during the winter months when *A. franciscana* blooms (Vasey, pers. comm. 2010). Although the loss of seed produced in a single year would not likely lead to the extirpation of the species, the continued reduction of the seed crop or dependence on self-pollination would reduce the seedbank, genetic variation, and the potential for population expansion.

Hybridization

Cultivars of *Arctostaphylos franciscana* are used in the commercial nursery trade. The cultivars (varieties of a plant produced and maintained by cultivation) are likely descended from some of the last wild *A. franciscana* plants known to exist in the 1940s, and are located in at least four botanical gardens (Chasse *et al.* 2009, pp. 7, 8). Because hybridization between diploid species of *Arctostaphylos* is well recognized (Chasse *et al.* 2009, p. 5), there is a good chance that many of these commercially available specimens have resulted from hybrid seed. Because of the threat of cross-pollination from hybrids or other species (Allendorf *et al.* 2001, pp. 613, 618–621), any propagation or reintroduction programs for *A. franciscana* must account for subsequent contamination of the *A. franciscana* gene pool. The conservation plan takes this into account by recommending that future outplantings of nursery-raised cuttings or seedlings of the recently discovered *A. franciscana* plant avoid areas that could facilitate cross-pollination (Chasse *et al.* 2009, p. 31). Appropriate outplanting areas will be determined by *A. franciscana* experts, in cooperation with NPS, the Presidio Trust, and the Golden Gate National Parks Conservancy (Chasse *et al.* 2009, p. 31). Although cross-pollination of the wild plant with hybrids and the production of hybrid seed is possible, we do not know if this is a substantial threat to the species.

Based on the best scientific and commercial information available, we consider that *Arctostaphylos franciscana* is negatively impacted by other natural or manmade factors affecting its continued existence which include changes in environmental conditions resulting from climate change, altered fire regime, soil compaction from visitor use, vandalism, loss of genetic diversity, loss of pollinators, stochastic events, effects of small population size, and hybridization. Cumulatively, we consider these threats to be significant and ongoing.

Cumulative Impacts

Some of the threats discussed in this finding could work with one another to cumulatively create situations that potentially impact *Arctostaphylos franciscana* beyond the scope of the individual threats we have already analyzed. In particular, climate change may exacerbate many of the threats discussed in this final rule. For example, warmer, drier conditions in the range of the species could result in not only less summer fog and increased water stress leading to plant death, but could also create more suitable conditions for infection by *Phytophthora* species and result in more fires. The loss of native habitat due to urban development within the range of *A. franciscana* has likely reduced pollinator nesting areas and numbers of native plants that provide nectar and pollen. Climate change could increase the loss of pollinators if the abundance of flowers preferred by pollinators decreases and the synchrony of bloom periods and pollinator emergence is disrupted. Although there currently are no data available regarding changes in plant bloom periods or emergence dates of pollinators in the Presidio in response to climate change, Forister and Shapiro (2003, p. 1130) found that over a period of 31 years warmer and drier winter conditions were associated with earlier butterfly appearance in the Central Valley of California. The ability of *A. franciscana* to self-pollinate may be limited (Parker 2011, p. 1); therefore, we expect that bumblebees, bees, and other insects are likely needed for *A. franciscana* to produce seed. Nitrogen enrichment of the soil from atmospheric deposition may encourage the growth of nonnative, invasive grasses in the vicinity of the wild plant. The grasses could, in turn, provide additional habitat for rodents such as California voles that feed on the wild plant.

Determination

We have carefully assessed the best scientific and commercial information available regarding past, present, and future threats to *Arctostaphylos franciscana.* The primary threat to *A. franciscana* is from the present or threatened destruction, modification, or curtailment of the species' habitat or range (Factor A). All original occupied habitat of the species has been lost, and its current range has been reduced to a single location that supports a single *A. franciscana* plant. The last wild plant was moved from its native habitat, which was subsequently destroyed during a highway construction project, and transplanted to natural habitat on the Presidio in San Francisco. Limited remaining suitable habitat is available to support a viable population of the species. Although greenstone and serpentine soils remain on the peninsula, the majority of this land has been fragmented and may be subject to edge effects and nitrogen deposition. Additionally, the possible transfer of Presidio lands to the GSA and the private sector may result in potential future loss of the plant or modification of its habitat.

Overutilization (Factor B) is a threat because the current known wild population consists of one individual plant, and *Arctostaphylos* plants are popular for landscaping and other horticultural purposes. *Arctostaphylos franciscana* is thus vulnerable to overcollection or damage if visitors harvest cuttings or seeds.

Disease and predation (Factor C).is also a threat to *Arctostaphylos franciscana.* Stress from transplanting the wild plant may have weakened the plant and made it more susceptible to disease and predation. The plant was heavily infested with a native leaf roller moth after being transplanted; however, the caterpillars and damaged foliage were removed and the plant has produced new foliage and flowers. Minor damage to *Arctostaphylos franciscana* branches from gnawing by California voles and other rodents has also been observed. Twig blight, a fungal infection, was observed on the plant during the winter of 2009–2010, but the infection subsided during the dry season. Infection by *Phytophthora* species, especially *Phytophthora cinnamomi,* is a serious and lethal problem among *Arctostaphylos* species

in the wild and in the native plant nursery trade. *Phytophthora cinnamomi* cannot be controlled once introduced to a plant or habitat, and results in plant death. Many *A. franciscana* cuttings are being grown in commercial or university nurseries for outplanting with the wild plant. Although the use of clean propagation techniques has been requested by the staff in charge of the project, the risk of infection of the cuttings and wild plant by *P. cinnamomi* is still a threat. At least six other species of *Phytophthora* are also found south of the San Francisco peninsula and could be introduced into the vicinity of the wild plant. In addition, the pathogen that causes sudden oak death has been discovered in the Presidio; however, the threat of this disease to *A. franciscana* is likely not severe.

Existing regulatory mechanisms (Factor D) afford certain protections for *Arctostaphylos franciscana* because the plant is located on lands administered by NPS, GGNRA, and the Presidio Trust. However, as mentioned above, these protections are not specific to *A. franciscana.* Because no existing regulatory mechanisms exist specific to *A. franciscana,* we do not consider the existing regulatory mechanisms to be inadequate to protect the species.

Other natural or manmade factors affecting *Arctostaphylos franciscana's* continued existence (Factor E) include environmental effects resulting from climate change, alteration of the natural fire regime, soil compaction from visitor use, vandalism, loss of genetic diversity, stochastic events, small population size, loss of pollinators, and hybridization are also threats to this species. Changes in the climate are expected to include increased air temperature and reduced summer fog, both resulting in warmer and drier conditions to which the plant may be less well-adapted. Additionally, climate change may result in divergence between the timing of flowering of *A. franciscana* and the availability of suitable pollinators, negatively affecting the plant's ability to set seed. Climate change may also reduce pollinator species and numbers. Warming and drying of the plant's habitat would likely also increase the frequency of wildfire, which could result in death of the wild plant and its future seedlings if fire occurred before the plants were able to produce viable seeds. Loss of mature *Arctostaphylos* plants to fire is a natural phenomenon; however, this species is currently represented by a single mature plant. Therefore, to our knowledge, the loss of the plant would result in extinction of the species in the wild. Loss of genetic diversity has likely already occurred due to the reduction of the species to a single wild plant and is expected to continue because this generally outcrossing species will be limited to self-pollination. Reduced genetic diversity may also limit the species' ability to adapt to changes in habitat, such as those resulting from climate change or loss of pollinators. The species is extremely vulnerable to stochastic events such as droughts, storm damage, and fires, from which large wide-ranging populations can generally recover, but which would likely drive a species consisting of a single plant to extinction.

Based on our evaluation of the best available scientific and commercial information regarding the past, present, and future threats faced by *Arctostaphylos franciscana,* we have determined that the continued existence of *A. franciscana* is threatened by overutilization for commercial and recreational purposes, disease, and predation, climate change, alteration of the natural fire regime, soil compaction from visitor use, vandalism, loss of genetic diversity, stochastic events, small population size, loss of pollinators, and hybridization. Because the species faces these threats throughout its extremely limited range, we find that *A. franciscana* is in danger of extinction throughout its entire range and, therefore, it is unnecessary to analyze its status in any significant portion of its range.

The Act defines an endangered species as one that is in danger of extinction throughout all or a significant portion of its range. A threatened species is one that is likely to become an endangered species in the foreseeable future throughout all or a significant portion of its range. The species in the wild currently exists as a single plant on the San Francisco Presidio. Because the range of the species is restricted to a single plant, the risks presented by the threats discussed herein are more intensified than they would be were the species more widespread or numerous. Based on our evaluation of the best available scientific and commercial information, and given the current population size (one wild plant) and severely limited distribution throughout its historical range, we have determined the species is currently on the brink of extinction in the wild and therefore is in danger of extinction throughout all of its range. As a result, this species meets the definition of an endangered species under the Act. Because the species is in danger of extinction now due to its limited population size and the severity of existing threats, as opposed to in the foreseeable future, *A. franciscana* meets the definition of an endangered species rather than a threatened species. On the basis of our careful evaluation of the best available scientific and commercial information regarding the past, present, and future threats to the species as discussed above relative to the listing factors, we are listing *Arctostaphylos franciscana* as an endangered species throughout its range.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation by Federal, State, and local agencies; private organizations; 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 requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. 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. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both, as described in the preceding paragraph, include land management, road construction, and any other landscape altering activities, such as invasive tree and plant removal, within the known range of the species or within any designated critical habitat.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply

to endangered plants. All prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.61, apply. When this final rule becomes effective (see **DATES** section above), *Arctostaphylos franciscana,* the last wild specimen (including any plants propagated from the wild plant) and the botanical garden specimens (those plants previously collected from the wild and subsequently propagated), will be protected by all prohibitions of section 9(a)(2) of the Act, which protects listed plants in areas of Federal jurisdiction such as the Presidio. Plants that have been or are being sold in the nursery trade or have been transplanted into home gardens will not be considered part of the listed entity.

These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale in interstate or foreign commerce, or remove and reduce the species to possession from areas under Federal jurisdiction. In addition, for plants listed as endangered, the Act prohibits the malicious damage or destruction on areas under Federal jurisdiction and the removal, cutting, digging up, or damaging or destroying of such plants in knowing violation of any State law or regulation, including State criminal trespass law. Certain exceptions to the prohibitions apply to agents of the Service and State conservation agencies.

A*rctostaphylos franciscana* has not been listed by the State of California. Listing also requires Federal agencies to avoid actions that might jeopardize the species (16 U.S.C. 1536(a)(2)), and provides opportunities for funding of conservation measures and land acquisition that would not otherwise be available to them (16 U.S.C. 1534, 1535(d)).

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 17.62 for endangered plants, and at 17.72 for threatened plants. With regard to endangered plants, a permit must be issued for the following purposes: for scientific purposes or for enhancing the propagation or survival of the species, and for take to to prevent undue economic hardship (see 50 CFR 17.63).

Required Determinations

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by Office of Management and Budget (OMB) under the Paperwork Reduction Act. This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), need not be prepared in connection with regulations pursuant to section 4(a) of the 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 all references cited in this rule is available on the Internet at *http://www.regulations.gov* or upon request from the Field Supervisor, Sacramento Fish and Wildlife Office (see **ADDRESSES**).

Authors

The primary authors of this document are the staff members of the Sacramento Fish and Wildlife Office (see **ADDRESSES**).

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 follows:

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 § 17.12(h) by adding an entry for ''*Arctostaphylos franciscana*'' (Franciscan manzanita) to the List of Endangered and Threatened Plants in alphabetical order under FLOWERING PLANTS, to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*		*		*
Arctostaphylos franciscana.	Franciscan manzanita	U.S.A., (CA)	Ericaceae	E	809	NA	NA
*	*	*	*		*		*
*	*	*	*		*		*

Dated: August 24, 2012.

Rowan W. Gould,

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

[FR Doc. 2012–21742 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

[Docket No. FWS–R9–MB–2012–0005; FF09M21200–123-FXMB1231099BPP0L2]

RIN 1018–AX97

Migratory Bird Hunting; Migratory Bird Hunting Regulations on Certain Federal Indian Reservations and Ceded Lands for the 2012–13 Early Season

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This rule prescribes special early-season migratory bird hunting regulations for certain tribes on Federal Indian reservations, off-reservation trust lands, and ceded lands. This rule responds to tribal requests for U.S. Fish and Wildlife Service (hereinafter Service or we) recognition of tribal authority to regulate hunting under established guidelines. This rule allows the establishment of season bag limits and, thus, harvest, at levels compatible with populations and habitat conditions.

DATES: This rule takes effect on September 1, 2012.

ADDRESSES: You may inspect comments received on the special hunting regulations and tribal proposals during normal business hours in room 4107, Arlington Square Building, 4501 N. Fairfax Drive, Arlington, VA or at *http://www.regulations.gov* at Docket No. FWS–R9–MB–2012–0005.

FOR FURTHER INFORMATION CONTACT: Ron W. Kokel, U.S. Fish and Wildlife Service, Department of the Interior, MS MBSP–4107–ARLSQ, 1849 C Street NW., Washington, DC 20240; (703)–358–1714.

SUPPLEMENTARY INFORMATION: The Migratory Bird Treaty Act (MBTA) of July 3, 1918 (40 Stat. 755; 16 U.S.C. 703 *et seq.*), authorizes and directs the Secretary of the Department of the Interior, having due regard for the zones of temperature and for the distribution, abundance, economic value, breeding habits, and times and lines of flight of migratory game birds, to determine when, to what extent, and by what means such birds or any part, nest, or egg thereof may be taken, hunted, captured, killed, possessed, sold, purchased, shipped, carried, exported, or transported.

In the August 16, 2012, **Federal Register** (77 FR 49680), we proposed special migratory bird hunting regulations for the 2012–13 hunting season for certain Indian tribes, under the guidelines described in the June 4, 1985, **Federal Register** (50 FR 23467). The guidelines respond to tribal requests for Service recognition of their reserved hunting rights, and for some tribes, recognition of their authority to regulate hunting by both tribal members and nonmembers on their reservations. The guidelines include possibilities for:

(1) On-reservation hunting by both tribal members and nonmembers, with hunting by nontribal members on some reservations to take place within Federal frameworks but on dates different from those selected by the surrounding State(s);

(2) On-reservation hunting by tribal members only, outside of usual Federal frameworks for season dates and length, and for daily bag and possession limits; and

(3) Off-reservation hunting by tribal members on ceded lands, outside of usual framework dates and season length, with some added flexibility in daily bag and possession limits.

In all cases, the regulations established under the guidelines must be consistent with the March 10–September 1 closed season mandated by the 1916 Migratory Bird Treaty with Canada. We have successfully used the guidelines since the 1985–86 hunting season. We finalized the guidelines beginning with the 1988–89 hunting season (August 18, 1988, **Federal Register** [53 FR 31612]).

In the April 17, 2012, **Federal Register** (77 FR 23094), we requested that tribes desiring special hunting regulations in the 2012–13 hunting season submit a proposal including details on:

(a) Harvest anticipated under the requested regulations;

(b) Methods that would be employed to measure or monitor harvest (such as bag checks, mail questionnaires, etc.);

(c) Steps that would be taken to limit level of harvest, where it could be shown that failure to limit such harvest would adversely impact the migratory bird resource; and

(d) Tribal capabilities to establish and enforce migratory bird hunting regulations.

No action is required if a tribe wishes to observe the hunting regulations established by the State(s) in which an Indian reservation is located. On August 16, 2012, we published a proposed rule (77 FR 49680) that included special migratory bird hunting regulations for 30 Indian tribes, based on the input we received in response to the April 17, 2012, proposed rule. All the regulations contained in this final rule were either submitted by the tribes or approved by the tribes and follow our proposals in the August 16 proposed rule.

Although the August 16 proposed rule included generalized regulations for both early- and late-season hunting, this rulemaking addresses only the early-season proposals. Therefore, it includes information for only 21 tribes. The letter designations for the paragraphs pertaining to each tribe in this rule are discontinuous because they follow the letter designations for the 30 tribes discussed in the August 8 proposed rule, which set forth paragraphs (a) through (dd). Late-season hunting will be addressed in late September. As a general rule, early seasons begin during September each year and have a primary emphasis on such species as mourning and white-winged doves. Late seasons begin about October 1 or later each year and have a primary emphasis on waterfowl.

Population Status and Harvest

Information on the status of waterfowl and information on the status and harvest of migratory shore and upland game birds, including detailed information on methodologies and results, is available at the address indicated under **FOR FURTHER INFORMATION CONTACT** or from our Web site at *http://www.fws.gov/migratorybirds/NewsPublicationsReports.html.*

Comments and Issues Concerning Tribal Proposals

For the 2012–13 migratory bird hunting season, we proposed regulations for 30 tribes and/or Indian groups that followed the 1985 guidelines. Only 26 tribes were considered appropriate for final rulemaking because we did not receive proposals from 4 of the tribes for whom we had proposed regulations. Some of the tribal proposals had both early- and late-season elements. However, as noted earlier, only those with early-season proposals are included in this final rulemaking; 21 tribes have proposals with early seasons. The comment period for the proposed rule, published on August 16, 2012, closed on August 27, 2012. Because of the necessary brief comment period, we will respond to any comments on the proposed rule and/or these regulations postmarked by August 27, but not received prior to final action by us, in the September late-season final rule. At this time, we have received three comments.

Great Lakes Indian Fish and Wildlife Commission's (GLIFWC) Proposal

We received two comments on GLIFWC's initial proposal from the State of Wisconsin and the Mississippi Flyway Council (MFC). We also received a subsequent comment from the GLIWFC in response to our August 16 proposed rule.

The State of Wisconsin, Department of Natural Resources (WIDNR) and MFC noted the long history of working cooperatively with GLIFWC and individual tribes in the conservation of Wisconsin's waterfowl and wetland resources. However, WIDNR and MFC believed the most significant problem with the GLIFWC proposal was the request to allow tribal members to hunt with the use of electronic calls for ducks and geese within the ceded territory. WIDNR and MFC believe that, since the ceded territory covers one-third of the State of Wisconsin, one-half of the State of Michigan, significant areas of Minnesota, and significant areas of public hunting grounds and waters in those States, the use of electronic calls by tribal hunters would put any nontribal hunters in violation of the law when hunting in these areas. Thus, GLIFWC's proposal would, in effect, close public lands to hunting, increase conflicts among the hunting public, and create a safety concern and an unmanageable law enforcement environment. WIDNR and MFC also opposed the extension of shooting hours to 60 minutes past sunset and removing species restrictions from the daily bag limit because of safety and resource concerns. WIDNR and MFC also believe that GLIFWC's proposal to remove all species restrictions in hunting regulations fails to recognize the different status and regulations of each species and as such is inconsistent with established cooperative management practices. WIDNR and MFC believe that management decisions could not be honored without species-level restrictions. WIDNR and MFC believe that a tribal tundra swan hunting season in the ceded territory should not be implemented in 2012 because additional biological evaluation and harvest planning should be conducted, especially in light of the trumpeter swan issues. WIDNR asks that the same criteria of not implementing duck hunting seasons prior to September 15 because of impacts to breeding ducks in Wisconsin be applied to tribal seasons as well. WIDNR also opposes the tribes being exempt from decoy restrictions.

GLIWFC reiterated that their proposal was consistent with their underlying treaty rights and values, and that their proposals were biologically sound and culturally appropriate. More specifically, they proposed allowing the use of electronic calls for geese from September 1 to 21, and for ducks from September 4 to 21 in the 1837 and 1842 Treaty areas. They stated that the proposed revision to their initial proposal would minimize any user conflicts since waterfowl seasons in Michigan, Minnesota, and Wisconsin are closed. They also offered to conduct a post-season harvest survey on the use of and harvest associated with electronic calls.

Regarding expanded shooting hours, GLIFWC proposed to extend shooting hours from 45 minutes before sunrise to 45 minutes after sunset, a reduction of 15 minutes from their initial proposal. They stated that this proposal was consistent with other Service-approved tribal proposals (69 FR 53990; September 3, 2004) and was consistent with recent changes in Wisconsin allowing the harvest of wolves at night.

GLIWFC also proposed changes to the swan hunting proposal. They requested the establishment of an experimental season in Ashland, Bayfield, Forest, and Oneida Counties in Wisconsin with a 2-bird daily bag limit, mandatory registration, and carcass verification.

Lastly, GLIFWC proposed to correct an oversight in the initial season proposal pertaining to mergansers and woodcock seasons. They amended the proposed season opening dates in the 1836 Treaty area for both species from September 4, rather than September 15.

Service Response: The GLIFWC 2012 proposal, and subsequent proposed revisions, had several significant changes from regulations approved last season. In the 1837 and 1842 Treaty Areas, the GLIFWC proposal would allow the use of electronic calls in September; would extend shooting hours by 15 minutes in both the morning and the evening to 45 minutes before sunrise and 45 minutes after sunset; would increase the daily bag limits to 50 ducks and remove all species restrictions within the daily bag limit for ducks; would allow the first harvest of sandhill cranes and tundra swans; would open the season (other than for geese) on September 4; and would remove restrictions for decoy use in Wisconsin. In the 1836 Treaty Area, the GLIFWC proposal would remove all species restrictions within the daily bag limit for ducks.

GLIFWC states that the regulatory changes are intended to provide tribal members a harvest opportunity within the scope of rights reserved in their various treaties and increase tribal subsistence harvest opportunities, while protecting migratory bird populations. Under the GLIFWC proposed regulations, GLIFWC expects total ceded territory harvest to be approximately 1,575 ducks, 300 geese, 50 sandhill cranes, and 50 tundra swans, which is roughly similar to anticipated levels in previous years for those species for which seasons were established. GLIWFC further anticipates that tribal harvest will remain low given the small number of tribal hunters and the limited opportunity to harvest more than a small number of birds on most hunting trips.

Recent GLIFWC harvest surveys (1996–98, 2001, 2004, 2007–08, and preliminary 2011) indicate that tribal off-reservation waterfowl harvest has averaged less than 1,050 ducks and 200 geese annually. In the latest survey year for which we have specific results (2004), an estimated 53 hunters took an estimated 421 trips and harvested 645 ducks (1.5 ducks per trip) and 84 geese (0.2 geese per trip). Analysis of hunter survey data over 1996–2004 indicates a general downward trend in both harvest and hunter participation.

Many of the components of the GLIFWC proposal are acceptable to the Service and are adopted in this rule. However, a number of the components are not in the best interest of the conservation of migratory birds. More specific discussion follows below.

Allowing Electronic Calls

As we stated last year (76 FR 54676, September 1, 2011), the issue of allowing electronic calls and other electronic devices for migratory game bird hunting has been highly debated and highly controversial over the last 40 years, similar to other prohibited hunting methods such as baiting. Electronic calls, *i.e.*, the use or aid of recorded or electronic amplified bird calls or sounds, or recorded or electrically amplified imitations of bird calls or sounds to lure or attract migratory game birds to hunters, was Federally prohibited in 1957 because of its effectiveness in attracting and aiding the harvest of ducks and geese and is generally not considered a legitimate component of hunting. In 1999, after much debate, the migratory bird regulations were revised to allow the use of electronic calls for the take of light geese (lesser snow geese and Ross geese) during a light-goose-only season when all other waterfowl and crane hunting seasons, excluding falconry, were closed (64 FR 7507, February 16, 1999; 64 FR 71236, December 20, 1999; and 73 FR 65926, November 5, 2008). The regulations were subsequently changed also in 2006 to allow the use

of electronic calls for the take of resident Canada geese during Canada-goose-only September seasons when all other waterfowl and crane seasons, excluding falconry, were closed (71 FR 45964, August 10, 2006). In both instances, these changes were made in order to significantly increase the take of these species for population management due to either serious population overabundance, or depredation issues, or public health and safety issues, or both.

Available information from the use of additional hunting methods, such as electronic calls, during the special light-goose seasons indicate that total harvest increased approximately 50–69 percent. On specific days when light-goose special regulations were in effect, the mean light goose harvest increased 244 percent. One research study found that lesser snow goose flocks were 5.0 times more likely to fly within gun range (≤50 meters) in response to electronic calls than to traditional calls and the mean number of snow geese killed per hour per hunter averaged 9.1 times greater for electronic calls than for traditional calls. While these results are only directly applicable to light geese, we believe these results are applicable to most waterfowl species, and indicative of some likely adverse harvest impacts on other geese and ducks.

Removal of the electronic call prohibition would be inconsistent with our long-standing conservation concerns. Given available evidence on the effectiveness of electronic calls, and the large biological uncertainty surrounding any widespread use of electronic calls, we believe the potential for overharvest could contribute to long-term population declines. Further, migratory patterns, distribution, and localized abundance of migratory birds could be affected and it is possible that hunter participation could increase beyond GLIFWC's estimates (50 percent) and could result in additional conservation impacts, particularly on local breeding populations. Thus, we do not support allowing the use of electronic calls in the 1837 and 1842 Treaty Areas.

Additionally, given the fact that tribal waterfowl hunting covered by this proposal would occur on ceded lands that are not in the ownership of the Tribes, we believe the use of electronic calls to take waterfowl would lead to confusion on the part of the public, wildlife-management agencies, and law enforcement officials in implementing the requirements of 50 CFR part 20. Restricting the proposal to September 4–21 does not alleviate these concerns. Similar to the impacts of baiting, uncertainties concerning the zone of influence attributed to the use of electronic calls could potentially increase harvest from nontribal hunters operating within areas electronic calls are being used, or were used, thereby posing risks to the migratory patterns and distribution of migratory waterfowl.

Lastly, we remind GLIFWC that electronic calls are permitted for the take of resident Canada geese during Canada-goose-only September seasons when all other waterfowl and crane seasons are closed. In the case of GLIFWC's proposed seasons, electronic calls could only be used September 1–3 for resident Canada geese (as GLIFWC's duck and crane season begins September 4, as they proposed). This specific regulatory change was implemented in 2006 in order to significantly control resident Canada geese due to widespread population overabundance, depredation issues, and public health and safety issues..

Expanded Shooting Hours

Normally, shooting hours for migratory game birds are one-half hour before sunrise to sunset. A number of reasons and concerns have been cited for extending shooting hours past sunset. Potential impacts to some locally breeding populations (*e.g.*, wood ducks), hunter safety, difficulty of identifying birds, retrieval of downed birds, and impacts on law enforcement are some of the normal concerns raised when discussing potential expansions of shooting hours. However, despite these concerns, in 2007, we supported the expansion of shooting hours by 15 minutes after sunset in the 1837, 1842, and 1836 Treaty Areas (72 FR 58452, October 15, 2007). We had previously supported this expansion in other tribal areas and have not been made aware of any wide-scale problems. At that time, we further believed that the continuation of a specific species restriction within the daily bag limit for mallards, and the implementation of a species restriction within the daily bag limit for wood ducks, would allay potential conservation concerns for these species. We supported the increase with the understanding that we would need to closely monitor tribal harvest through either GLIFWC's own increased harvest surveys or GLIFWC's assisting the Service to survey tribal hunters.

Last year, in deference to tribal traditions and in the interest of cooperation, we approved shooting 30 minutes after sunset (an extension of 15 minutes from the then-current 15 minutes after sunset) (76 FR 54676, September 1, 2011). This was consistent with other Tribes in the general area (Fond du Lac, Leech Lake, Oneida, Sault Ste Marie, and White Earth). Extending shooting hours on both the front end and the back end of the day to 45 minutes before sunrise and 45 minutes after sunset as GLIWFC has proposed would be contrary to public safety and only heightens our previously identified concerns. It is widely considered dark 45 minutes after sunset (and 45 minutes before sunrise), and we see no viable remedies to allay our concerns. Shooting this early or late would also significantly increase the potential take of non-game birds. Thus, we cannot support increasing the shooting hours by 15 minutes in the 1837 and 1842 Treaty Areas (to 45 minutes before sunrise and 45 minutes after sunset).

Regarding GLIFWC's comments concerning our consistency with other previous tribal proposals and recent changes in Wisconsin wolf hunting regulation, we note that the referenced approval of shooting hours 45 minutes after sunset was for on-reservation hunting only at Sokaogon Chippewa Community in Cranston, Wisconsin. Ceded lands were not part of the Sokaogon's proposal or our approval. Lastly, we view the State of Wisconsin's allowance for the hunting of wolves at night as a State prerogative and not germane to the hunting of migratory birds (to improve public safety, the Wisconsin Department of Natural Resources has imposed additional restrictions for night wolf hunting to include: (1) Using bait or predator call ,which the Service prohibits for waterfowl; and (2) from a stationary position). We also note that 29.185(6)(d) (published April 16, 2012) limits wolf night hunting until after the close of the deer season for safety concerns. This new State allowance does not alleviate our previously identified concerns.

Increasing the Overall Daily Bag Limit for Ducks

Based on the proposed increased daily bag limits (from 30 to 50 ducks per day in the 1837 and 1842 Treaty Areas), GLIFWC is estimating a relatively small additional duck harvest (1,050 to 1,575 ducks). While it is possible that hunter participation and harvest could increase beyond their estimates (50 percent), we do not anticipate such an increase given their relatively small average daily harvest (2.2 ducks per day) and the GLIWFC proposals we are adopting. Further, GLIFWC reports that the largest number of ducks reportedly harvested in a single day was 20. Thus, we do not anticipate any large-scale harvest shifts or significant biological conservation impacts with GLIFWC's proposal.

However, we also note that GLIFWC's own dated harvest data indicates that present daily bag limits do not appear to be a hindrance or limiting factor for Tribal harvest, and increasing the daily bag limit to 50 ducks from the present 30-duck daily bag limit would be far in excess of anything we currently have experience with regarding tribal migratory bird hunting regulations. We further note that in 2007, in an effort to obtain the necessary information, we implemented a pilot expansion of the daily bag limit for ducks to 30 birds per day in the 1837 and 1842 Treaty Areas. We supported this change with the understanding that we would need to closely monitor tribal harvest through either GLIFWC's own increased harvest surveys or GLIFWC's assisting the Service to survey tribal hunters. We have reiterated our request over the past several years for GLIFWC to continue their current harvest survey based on our implementation of this pilot bag limit increase for ducks in the 1837 and 1842 Treaty Areas in 2007, particularly for species such as mallards, the bag limits for which were subsequently significantly increased in 2008 (from 10 to 30 per day). To date, we have not been presented with any new final reports since the 2008 harvest survey results.

Remove Restrictions on Decoy Use in Wisconsin

In Wisconsin, State law requires that decoys may not be placed more than an hour before legal shooting hours or left out more than 20 minutes after legal shooting hours. As we stated last year concerning a similar decoy restriction in Michigan (76 FR 54676, September 1, 2011), while we believe that there may be safety concerns with elimination of such a restriction, we take no position on the relative need or lack of need for such a restriction. Other than regulations on National Wildlife Refuges and other Federal lands, there are no Federal restrictions requiring the removal of unattended decoys.

Additionally, given the fact that tribal waterfowl hunting covered by this rule would occur on ceded lands that are not in the ownership of the Tribes, we believe the use of unattended decoys to ''reserve'' hunting areas in public waters (*i.e.*, those lands in the ceded territories outside of lands directly controlled by the Tribes) could lead to confusion and frustration on the part of the public, hunters, wildlife-management agencies, and law enforcement officials due to the inherent difficulties of different sets of hunting regulations for different areas and groups of hunters. However, we view this issue as a Tribal-State issue, and the Service takes no position on it in this rule.

Removal of Species Restrictions for Ducks

We have several concerns with GLIFWC's proposal to remove all species restrictions within the overall duck daily bag limits in the 1837 and 1842 Treaty Areas. We have a number of duck species that are either showing long-term downward population trends (pintails and black ducks), or other species for which an increased daily bag limit of 50 birds per day could potentially have conservation impacts (scaup, canvasbacks), particularly on locally breeding ducks (mallards and wood ducks). Overharvest of these species in localized areas due to removal of species restrictions could contribute to long-term declines. However, while we believe the proposal to eliminate all species restrictions within the daily bag limit for ducks could potentially have resource conservation impacts on locally breeding duck populations, and would prefer not to implement such a change at this time, we are willing to remove the restrictions for tribal harvest in the 1836, 1837, and 1842 ceded areas. As we stated last year regarding the removal of possession limits (76 FR 54676, September 1, 2011), we make this change with some trepidation. However, we see no significant conservation implications given the relatively small numbers of tribal hunters, and in the interest of our long-term relationship with GLIWFC and the high importance GLIWFC has placed on this issue, we would agree with this important change. We note that, should resource conservation impacts be discovered, or should a particular species'' population status warrant action, we would expect that the lack of species restrictions would be revisited and adjusted accordingly, especially if a particular species warranted a nationwide closed season (*e.g.*, canvasbacks).

Earlier Duck Season Opening Date

The Migratory Bird Treaty allows the hunting of migratory game birds beginning September 1. Generally, we have tried to guide Tribes to select an opening date for duck hunting of no earlier than September 15. This guidance is based on our concern that hunting prior to September 15 significantly increases the potential for taking ducks that have not yet fully fledged (normally the result of late-nesting or renesting hens) or species misidentification due to the fact that some species and/or sexes are not yet readily distinguishable. While these impacts primarily concern locally breeding ducks, the potential does exist for the take of molt migrants, *i.e.*, birds that have specifically migrated to an area to complete the molting process. We would prefer that GLIFWC adhere to this guidance and would prefer not to implement such a change at this time. However, we see no significant conservation implications given the relatively small numbers of tribal hunters and are willing to allow GLIFWC to begin the duck season on September 4 in the 1836, 1837, and 1842 ceded areas. We are implementing this change in the interest of our long-term relationship with GLIWFC and the understanding that if significant conservation impacts are discovered, we would adjust the duck season opening date accordingly.

Sandhill Crane Season

We have no objections to the establishment of a sandhill crane season in the 1837 and 1842 Treaty Areas. We note that at least one other Tribe currently has a sandhill crane season (see (c) Fond du Lac Band of Lake Superior Chippewa in Minnesota elsewhere in this rule) and another proposed establishing a new season this year (see (d) Grand Traverse Band of Ottawa and Chippewa in Michigan elsewhere in this rule). All cranes in these current and new hunt areas are Eastern Population (EP) sandhill cranes. EP sandhill cranes rebounded from near extirpation in the late 1800s to more than 30,000 cranes by 1996. As of last year, the current 3-year average population index for EP cranes was 51,217 cranes. As a result of this rebound and their continued range expansion, the Atlantic and Mississippi Flyway Councils developed a cooperative management plan for this population, and criteria were developed describing when hunting seasons could be opened. The State of Kentucky held its first hunting season on this population in 2011–12 and harvested 50 cranes. Further, allowance for Tribal harvest is specifically considered in the EP plan.

GLIFWC estimates that no more than 50 cranes will be harvested during the season. We note that two cranes were harvested last year in the inaugural Fond du Lac sandhill crane season. We support the establishment of GLIFWC's new sandhill crane season. However, given the need to closely monitor the harvest of this species, we requested that GLIFWC implement either a special crane harvest tag or crane harvest reporting system/survey to track crane harvest, similar to that implemented by

Fond du Lac last year, and requested of Grand Traverse this year (see (d) Grand Traverse Band of Ottawa and Chippewa Indians in Michigan elsewhere in this rule).

Tundra Swan Season

As we stated with sandhill cranes, we are not opposed to the establishment of a tundra swan season in Wisconsin. However, unlike the sandhill crane issue, the establishment of a new tundra swan season in the ceded territory areas in question involves several significant concerns and special considerations. We believe these concerns need further study and consideration before any implementation of a new tundra swan season in the ceded territories.

First, the GLIFWC proposed areas in question are also home to trumpeter swans. Many cooperators, including GLIFWC, worked together to reestablish a breeding trumpeter swan population in the Great Lakes. These efforts have been largely successful with the removal of this species from the Wisconsin endangered species list in 2009. After a 25-year recovery program, there are currently about 200 breeding pairs in Wisconsin. However, it is very difficult to distinguish between tundra and trumpeter swans unless swans vocalize in flight. We have significant concerns over the accidental harvest of trumpeter swans by tribal hunters hunting during a tundra swan season. Further, within Wisconsin, the northern ceded territory is an area of high trumpeter swan use containing over 80 percent of the breeding pairs. We believe such areas should be avoided either temporally or geographically to the extent possible. When a hunting season on tundra swans is ultimately implemented, we believe it would be best to focus hunting efforts on the primary tundra swan migration concentration areas while avoiding areas of significant trumpeter swan numbers. Unfortunately, most such areas are located outside of the ceded territories of northern Wisconsin.

In addition to the concerns about potential impacts to trumpeter swans, we believe it is imperative that any tribal tundra swan hunting proposal follow the Eastern Population of tundra swans management plan including a quota permit system and harvest reporting. The EP tundra swan management plan was cooperatively developed by the Atlantic, Central, and Mississippi Flyway Councils in 2007 and guides the management and harvest of EP tundra swans.

While we appreciate GLIFWC's proposed revisions to their initial tundra swan season proposal (area restrictions, mandatory registration, and carcass verification), we continue to believe that a tribal tundra swan hunting season in the ceded territory should not be implemented this year. Given that all these concerns can be worked through over the next year, we do not believe that implementation of a tundra swan season next season is unrealistic. We note that both the Service and the State wildlife agencies have considerable trumpeter swan information that would be helpful in conducting additional biological evaluation and harvest planning and are available to work with GLIFWC on resolution of these issues. We would prefer that all these issues be carefully considered and resolved by all involved parties to ensure that whatever action permitted for tundra swans in the future is not detrimental to trumpeter swans. We encourage GLIFWC to contact the Service early next year to cooperatively work through the issues involved with implementing a tundra swan season in the ceded territories.

Correction to Merganser and Woodcock Seasons

As we stated regarding the earlier duck season opening date, while we would prefer that GLIFWC not implement such a change at this time, we see no significant conservation implications given the relatively small numbers of tribal hunters and are willing to allow GLIFWC to begin both the merganser and woodcock seasons on September 4 in the 1836 Treaty ceded areas. We are implementing this change in the interest of our long-term relationship with GLIWFC and the understanding that if significant conservation impacts are discovered, we would adjust the season opening dates accordingly.

NEPA Consideration

NEPA considerations are covered by the programmatic document ''Final Supplemental Environmental Impact Statement: Issuance of Annual Regulations Permitting the Sport Hunting of Migratory Birds (FSES 88–14),'' filed with the Environmental Protection Agency on June 9, 1988. We published a notice of availability in the **Federal Register** on June 16, 1988 (53 FR 22582). We published our Record of Decision on August 18, 1988 (53 FR 31341). In addition, an August 1985 environmental assessment entitled ''Guidelines for Migratory Bird Hunting Regulations on Federal Indian Reservations and Ceded Lands'' is available from the address indicated under the caption **FOR FURTHER INFORMATION CONTACT**.

In a notice published in the September 8, 2005, **Federal Register** (70 FR 53376), we announced our intent to develop a new Supplemental Environmental Impact Statement (SEIS) for the migratory bird hunting program. Public scoping meetings were held in the spring of 2006, as detailed in a March 9, 2006, **Federal Register** (71 FR 12216). We released the draft SEIS on July 9, 2010 (75 FR 39577). The draft SEIS is available either by writing to the address indicated under **FOR FURTHER INFORMATION CONTACT** or by viewing our Web site at *http://www.fws.gov/migratorybirds.*

Endangered Species Act Consideration

Section 7 of the Endangered Species Act, as amended (16 U.S.C. 1531–1543; 87 Stat. 884), provides that, ''The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this Act'' (and) shall ''insure that any action authorized, funded, or carried out * * * is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat. * * *.''

Consequently, we conducted formal consultations to ensure that actions resulting from these regulations would not likely jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of their critical habitat. Findings from these consultations are included in a biological opinion, which concluded that the regulations are not likely to jeopardize the continued existence of any endangered or threatened species. Additionally, these findings may have caused modification of some regulatory measures previously proposed, and the final frameworks reflect any such modifications. Our biological opinions resulting from this section 7 consultation are public documents available for public inspection at the address indicated under **ADDRESSES**.

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rule is significant because it will have an annual effect of $100 million or more on the economy.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty,

and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

An economic analysis was prepared for the 2008–09 season. This analysis was based on data from the 2006 National Hunting and Fishing Survey, the most recent year for which data are available (see discussion in Regulatory Flexibility Act section below). This analysis estimated consumer surplus for three alternatives for duck hunting (estimates for other species are not quantified due to lack of data). The alternatives are (1) Issue restrictive regulations allowing fewer days than those issued during the 2007–08 season, (2) Issue moderate regulations allowing more days than those in alternative 1, and (3) Issue liberal regulations identical to the regulations in the 2007–08 season. For the 2008–09 season, we chose alternative 3, with an estimated consumer surplus across all flyways of $205–$270 million. We also chose alternative 3 for the 2009–10 and the 2010–11 seasons. At this time, we are proposing no changes to the season frameworks for the 2012–13 season, and as such, we will again consider these three alternatives. However, final frameworks for waterfowl will be dependent on population status information available later this year. For these reasons, we have not conducted a new economic analysis, but the 2008–09 analysis is part of the record for this rule and is available at *http://www.fws.gov/migratorybirds/NewReports Publications/SpecialTopics/Special Topics.html#HuntingRegs* or at *http://www.regulations.gov* at Docket No. FWS–R9–MB–2012–0005.

Regulatory Flexibility Act

The annual migratory bird hunting regulations have a significant economic impact on substantial numbers of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). We analyzed the economic impacts of the annual hunting regulations on small business entities in detail as part of the 1981 cost-benefit analysis. This analysis was revised annually from 1990–95. In 1995, the Service issued a Small Entity Flexibility Analysis (Analysis), which was subsequently updated in 1996, 1998, 2004, and 2008. The primary source of information about hunter expenditures for migratory game bird hunting is the National Hunting and Fishing Survey, which is conducted at 5-year intervals. The 2008 Analysis was based on the 2006 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend approximately $1.2 billion at small businesses in 2008. Copies of the Analysis are available upon request from the Division of Migratory Bird Management (see **ADDRESSES**) or from our Web site at *http://www.fws.gov/migratorybirds/NewReports Publications/SpecialTopics/SpecialTopics.html#HuntingRegs* or at *http://www.regulations.gov* at Docket No. FWS–R9–MB–2012–0005.

Small Business Regulatory Enforcement Fairness Act

This rule is a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. For the reasons outlined above, this rule will have an annual effect on the economy of $100 million or more. However, because this rule establishes hunting seasons, we are not deferring the effective date under the exemption contained in 5 U.S.C. 808(1).

Paperwork Reduction Act

We examined these regulations under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The various recordkeeping and reporting requirements imposed under regulations established in 50 CFR part 20, subpart K, are utilized in the formulation of migratory game bird hunting regulations. Specifically, OMB has approved the information collection requirements of our Migratory Bird Surveys and assigned control number 1018–0023 (expires 4/30/2014). This information is used to provide a sampling frame for voluntary national surveys to improve our harvest estimates for all migratory game birds in order to better manage these populations. A Federal agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Unfunded Mandates Reform Act

We have determined and certify, in compliance with the requirements of the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that this rulemaking will not impose a cost of $100 million or more in any given year on local or State government or private entities. Therefore, this rule is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Civil Justice Reform—Executive Order 12988

The Department, in promulgating this rule, has determined that this rule will not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of Executive Order 12988.

Takings Implication Assessment

In accordance with Executive Order 12630, this rule, authorized by the Migratory Bird Treaty Act, does not have significant takings implications and does not affect any constitutionally protected property rights. This rule will not result in the physical occupancy of property, the physical invasion of property, or the regulatory taking of any property. In fact, this rule allows hunters to exercise otherwise unavailable privileges and, therefore, reduce restrictions on the use of private and public property.

Energy Effects—Executive Order 13211

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. While this rule is a significant regulatory action under Executive Order 12866, it is not expected to adversely affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and 512 DM 2, we have evaluated possible effects on Federally-recognized Indian tribes and have determined that there are no effects on Indian trust resources. However, in the April 17 **Federal Register**, we solicited proposals for special migratory bird hunting regulations for certain Tribes on Federal Indian reservations, off-reservation trust lands, and ceded lands for the 2012–13 migratory bird hunting season. The resulting proposals were contained in a separate August 16, 2012, proposed rule (77 FR 49680). By virtue of these actions, we have consulted with Tribes affected by this rule.

Federalism Effects

Due to the migratory nature of certain species of birds, the Federal Government has been given responsibility over these species by the Migratory Bird Treaty Act. We annually prescribe frameworks from which the States make selections regarding the hunting of migratory birds, and we employ guidelines to establish special regulations on Federal Indian reservations and ceded lands. This process preserves the ability of the States and tribes to determine which seasons meet their individual needs. Any State or Indian tribe may be more restrictive than the Federal frameworks at any time. The frameworks are developed in a cooperative process with the States and the Flyway Councils. This process allows States to participate in the development of frameworks from which they will make selections, thereby having an influence on their own regulations. These rules do not have a substantial direct effect on fiscal capacity, change the roles or responsibilities of Federal or State governments, or intrude on State policy or administration. Therefore, in accordance with Executive Order 13132, these regulations do not have significant federalism effects and do not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Regulations Promulgation

The rulemaking process for migratory game bird hunting must, by its nature, operate under severe time constraints. However, we intend that the public be given the greatest possible opportunity to comment. Thus, when the preliminary proposed rulemaking was published, we established what we believed were the longest periods possible for public comment. In doing this, we recognized that when the comment period closed, time would be of the essence. That is, if there were a delay in the effective date of these regulations after this final rulemaking, States and Tribes would have insufficient time to select season dates and limits; to communicate those selections to us; and to establish and publicize the necessary regulations and procedures to implement their decisions. We therefore find that ''good cause'' exists, within the terms of 5 U.S.C. 553(d)(3) of the Administrative Procedure Act, and these seasons will, therefore, take effect less than 30 days after the date of publication.

Accordingly, with each participating Tribe having had an opportunity to participate in selecting the hunting seasons desired for its reservation or ceded territory on those species of migratory birds for which open seasons are now prescribed, and consideration having been given to all other relevant matters presented, certain sections of title 50, chapter I, subchapter B, part 20, subpart K, are hereby amended as set forth below.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Accordingly, part 20, subchapter B, chapter I of title 50 of the Code of Federal Regulations is amended as follows:

PART 20—[AMENDED]

■ 1. The authority citation for part 20 continues to read as follows:

Authority: Migratory Bird Treaty Act, 40 Stat. 755, 16 U.S.C. 703–712; Fish and Wildlife Act of 1956, 16 U.S.C. 742a–j; Pub. L. 106–108, 113 Stat. 1491, Note Following 16 U.S.C. 703.

Note: The following hunting regulations provided for by 50 CFR 20.110 will not appear in the Code of Federal Regulations because of their seasonal nature.

■ 2. Section 20.110 is revised to read as follows:

§ 20.110 Seasons, limits, and other regulations for certain Federal Indian reservations, Indian Territory, and ceded lands.

Unless specifically provided for below, all of the regulations contained in 50 CFR part 20 apply to the seasons listed herein.

(a) Colorado River Indian Tribes, Parker, Arizona (Tribal Members and Nontribal Hunters).

Doves

Season Dates: Open September 1 through 15, 2012; then open November 10 through December 24, 2012.

Daily Bag and Possession Limits: For the early season, daily bag limit is 10 mourning or white-winged doves, singly, or in the aggregate. For the late season, the daily bag limit is 10 mourning doves. Possession limits are twice the daily bag limits after the first day of the season.

General Conditions: All persons 14 years and older must be in possession of a valid Colorado River Indian Reservation hunting permit before taking any wildlife on tribal lands. Any person transporting game birds off the Colorado River Indian Reservation must have a valid transport declaration form. Other tribal regulations apply, and may be obtained at the Fish and Game Office in Parker, Arizona. The early season will be open from one-half hour before sunrise until noon. For the late season, shooting hours are from one-half hour before sunrise to sunset.

(b) Confederated Salish and Kootenai Tribes, Flathead Indian Reservation, Pablo, Montana (Tribal Hunters).

Tribal Members Only

Ducks (Including Mergansers)

Season Dates: Open September 2, 2012, through March 9, 2013.

Daily Bag and Possession Limits: The Tribe does not have specific bag and possession restrictions for Tribal members. The season on harlequin duck is closed.

Coots

Season Dates: Same as ducks.

Daily Bag and Possession Limits: Same as ducks.

Geese

Season Dates: Same as ducks.

Daily Bag and Possession Limits: Same as ducks.

General Conditions: Tribal and nontribal hunters must comply with all basic Federal migratory bird hunting regulations contained in 50 CFR part 20 regarding manner of taking. In addition, shooting hours are sunrise to sunset, and each waterfowl hunter 16 years of age or older must carry on his/her person a valid Migratory Bird Hunting and Conservation Stamp (Duck Stamp) signed in ink across the stamp face. Special regulations established by the Confederated Salish and Kootenai Tribes also apply on the reservation.

(c) Fond du Lac Band of Lake Superior Chippewa Indians, Cloquet, Minnesota (Tribal Members Only).

Ducks

1854 and 1837 Ceded Territories:

Season Dates: Begin September 15 and end November 25, 2012.

Daily Bag Limit: 18 ducks, including no more than 12 mallards (only 3 of which may be hens), 9 black ducks, 9 scaup, 9 wood ducks, 9 redheads, 9 pintails, and 9 canvasbacks.

Reservation:

Season Dates: Begin September 1 and end November 25, 2012.

Daily Bag Limit: 12 ducks, including no more than 9 mallards (only 2 of which may be hens), 6 black ducks, 6 scaup, 6 redheads, 6 pintails, 6 wood ducks, and 6 canvasbacks.

Mergansers

1854 and 1837 Ceded Territories:

Season Dates: Begin September 15 and end November 25, 2012.

Daily Bag Limit: 15 mergansers, including no more than 6 hooded mergansers.

Reservation:

Season Dates: Begin September 1 and end November 25, 2012.

Daily Bag Limit: 10 mergansers, including no more than 4 hooded mergansers.

Canada Geese: All Areas

Season Dates: Begin September 1 and end November 25, 2012.

Daily Bag Limit: 20 geese.

Coots and Common Moorhens (Common Gallinules)

1854 and 1837 Ceded Territories:

Season Dates: Begin September 15 and end November 25, 2012.

Daily Bag Limit: 20 coots and common moorhens, singly or in the aggregate.

Reservation:

Season Dates: Begin September 1 and end November 25, 2012.

Daily Bag Limit: 20 coots and common moorhens, singly or in the aggregate.

Sandhill Cranes: 1854 Ceded Territory only:

Season Dates: Begin September 1 and end November 25, 2012.

Daily Bag Limit: Two sandhill cranes. Crane carcass tags are required prior to hunting.

Sora and Virginia Rails: All Areas.

Season Dates: Begin September 1 and end November 25, 2012.

Daily Bag Limit: 25 sora and Virginia rails, singly or in the aggregate.

Common Snipe: All Areas.

Season Dates: Begin September 1 and end November 25, 2012.

Daily Bag Limit: Eight common snipe.

Woodcock: All Areas.

Season Dates: Begin September 1 and end November 25, 2012.

Daily Bag Limit: Three woodcock.

Mourning Dove: All Areas.

Season Dates: Begin September 1 and end October 30, 2012.

Daily Bag Limit: 30 mourning dove.

General Conditions:

1. While hunting waterfowl, a tribal member must carry on his/her person a valid tribal waterfowl hunting permit.

2. Except as otherwise noted, tribal members will be required to comply with tribal codes that will be no less restrictive than the provisions of Chapter 10 of the Model Off-Reservation Code. These regulations parallel Federal requirements in 50 CFR part 20 as to hunting methods, transportation, sale, exportation, and other conditions generally applicable to migratory bird hunting.

3. Band members in each zone will comply with State regulations providing for closed and restricted waterfowl hunting areas.

4. There are no possession limits on any species, unless otherwise noted above. For purposes of enforcing bag and possession limits, all migratory birds in the possession or custody of band members on ceded lands will be considered to have been taken on those lands unless tagged by a tribal or State conservation warden as having been taken on-reservation. All migratory birds that fall on reservation lands will not count as part of any off-reservation bag or possession limit.

(d) Grand Traverse Band of Ottawa and Chippewa Indians, Suttons Bay, Michigan (Tribal Members Only).

All seasons in Michigan, 1836 Treaty Zone:

Ducks

Season Dates: Open September 15, 2012, through January 15, 2013.

Daily Bag Limit: 20 ducks, which may include no more than 5 pintail, 3 canvasback, 5 black ducks, 1 hooded merganser, 5 wood ducks, 3 redheads, and 9 mallards (only 4 of which may be hens).

Canada and Snow Geese

Season Dates: Open September 1 through November 30, 2012; and open January 1, 2013, through February 8, 2013.

Daily Bag Limit: 10 geese.

Other Geese (White-fronted Geese and Brant)

Season Dates: Open September 20 through November 30, 2012.

Daily Bag Limit: Five geese.

Sora Rails, Common Snipe, and Woodcock

Season Dates: Open September 1 through November 14, 2012.

Daily Bag Limit: 10 rails, 10 snipe, and 5 woodcock.

Mourning Doves

Season Dates: Open September 1 through November 14, 2012.

Daily Bag Limit: 10 mourning doves.

Sandhill Cranes

Season Dates: Open September 1 through November 30, 2012.

Daily Bag Limit: One sandhill crane.

General Conditions: A valid Grand Traverse Band Tribal license is required and must be in possession before taking any wildlife. All other basic regulations contained in 50 CFR part 20 are valid. Other tribal regulations apply, and may be obtained at the tribal office in Suttons Bay, Michigan.

(e) Great Lakes Indian Fish and Wildlife Commission, Odanah, Wisconsin (Tribal Members Only).

The 2012–13 waterfowl hunting season regulations apply to all treaty areas (except where noted):

Ducks

Season Dates: Begin September 4 and end December 31, 2012.

Daily Bag Limit: 1837 and 1842 Ceded Territories: 50 ducks.

1836 Ceded Territory: 30 ducks.

Mergansers

Season Dates: Begin September 4 and end December 31, 2012.

Daily Bag Limit: 10 mergansers.

Geese

Season Dates: Begin September 1 and end December 31, 2012. In addition, any portion of the ceded territory that is open to State-licensed hunters for goose hunting after December 1 will also be open concurrently for tribal members.

Daily Bag Limit: 20 geese in aggregate.

Other Migratory Birds

Coots and Common Moorhens (Common Gallinules):

Season Dates: 1836 Treaty Area Season Dates: Begin September 15 and end December 31, 2012.

1837 and 1842 Treaty Area Season Dates: Begin September 4 and end December 31, 2012.

Daily Bag Limit: 20 coots and common moorhens (common gallinules), singly or in the aggregate.

Sora and Virginia Rails

Season Dates: 1836 Treaty Area Season Dates: Begin September 15 and end December 31, 2012.

1837 and 1842 Treaty Area Season Dates: Begin September 4 and end December 31, 2012.

Daily Bag and Possession Limits: 20 sora and Virginia rails, singly or in the aggregate, 25.

Common Snipe

Season Dates: 1836 Treaty Area Season Dates: Begin September 15 and end December 31, 2012.

1837 and 1842 Treaty Area Season Dates: Begin September 4 and end December 31, 2012.

Daily Bag Limit: 16 common snipe.

Woodcock

Season Dates: Begin September 4 and end December 31, 2012.

Daily Bag Limit: 10 woodcock.

Mourning Dove: 1837 and 1842 Ceded Territories.

Season Dates: Begin September 1 and end November 9, 2012.

Daily Bag Limit: 15.

Sandhill Cranes: 1837 and 1842 Ceded Territories only.

Season Dates: Begin September 4 and end December 31, 2012.

Daily Bag Limit: 1 crane.

General Conditions

A. All tribal members will be required to obtain a valid tribal waterfowl hunting permit.

B. Except as otherwise noted, tribal members will be required to comply with tribal codes that will be no less restrictive than the model ceded territory conservation codes approved by Federal courts in the *Lac Courte Oreilles* v. *State of Wisconsin (Voigt), Mille Lacs Band* v. *State of Minnesota,* and *United States* v. *Michigan* cases. Chapter 10 in each of these model codes regulates ceded territory migratory bird hunting. Both versions of Chapter 10 parallel Federal requirements as to hunting methods, transportation, sale, exportation, and other conditions generally applicable to migratory bird hunting. They also automatically incorporate by reference the Federal migratory bird regulations adopted in response to this regulation.

C. Particular regulations of note include:

1. Nontoxic shot will be required for all waterfowl hunting by tribal members.

2. Tribal members in each zone will comply with tribal regulations providing for closed and restricted waterfowl hunting areas. These regulations generally incorporate the same restrictions contained in parallel State regulations.

3. There is no possession limit. For purposes of enforcing bag limits, all migratory birds in the possession and custody of tribal members on ceded lands will be considered to have been taken on those lands unless tagged by a tribal or State conservation warden as taken on reservation lands. All migratory birds that fall on reservation lands will not count as part of any off-reservation bag or possession limit.

4. The baiting restrictions included in the respective section 10.05(2)(h) of the model ceded territory conservation codes will be amended to include language which parallels that in place for nontribal members as published at 64 FR 29799, June 3, 1999.

5. The shell limit restrictions included in the respective section 10.05(2)(b) of the model ceded territory conservation codes will be removed.

6. Hunting hours shall be from a half hour before sunrise to 30 minutes after sunset.

(f) [Reserved.]

(g) Kalispel Tribe, Kalispel Reservation, Usk, Washington (Tribal Members and Nontribal Hunters).

Nontribal Hunters on Reservation

Geese

Season Dates: Open September 1 through 13, 2012, for the early-season, and open October 1, 2012, through January 31, 2013, for the late-season. During this period, days to be hunted are specified by the Kalispel Tribe. Nontribal hunters should contact the Tribe for more detail on hunting days.

Daily Bag and Possession Limits: 5 Canada geese for the early season, and 3 light geese and 4 dark geese, for the late season. The daily bag limit is 2 brant (when the State's season is open) and is in addition to dark goose limits for the late-season. The possession limit is twice the daily bag limit.

Ducks

Season Dates: Open September 22, 2012, through January 31, 2013.

Daily Bag and Possession Limits: 7 ducks, including no more than 2 female mallards, 2 pintail, 1 canvasback, 3 scaup, and 2 redheads. The possession limit is twice the daily bag limit.

Tribal Hunters Within Kalispel Ceded Lands

Ducks

Season Dates: Open October 1, 2012, through January 31, 2013.

Daily Bag and Possession Limits: 7 ducks, including no more than 2 female mallards, 2 pintail, 1 canvasback, 3 scaup, and 2 redheads. The possession limit is twice the daily bag limit.

Geese

Season Dates: Open September 1, 2012, through January 31, 2013.

Daily Bag Limit: 6 light geese and 4 dark geese. The daily bag limit is 2 brant and is in addition to dark goose limits.

General: Tribal members must possess a validated Migratory Bird Hunting and Conservation Stamp and a tribal ceded lands permit.

(h) [Reserved.]

(i) Leech Lake Band of Ojibwe, Cass Lake, Minnesota (Tribal Members Only).

Ducks

Season Dates: Open September 15 through December 31, 2012.

Daily Bag Limits: 10 ducks, including no more than 5 pintail, 5 canvasback, and 5 black ducks.

Geese

Season Dates: Open September 1 through December 31, 2012.

Daily Bag Limits: 10 geese.

General: Possession limits are twice the daily bag limits. Shooting hours are one-half hour before sunrise to one-half hour after sunset. Nontoxic shot is required. Use of live decoys, bait, and commercial use of migratory birds are prohibited. Waterfowl may not be pursued or taken while using motorized craft.

(j) [Reserved]

(k) The Little Traverse Bay Bands of Odawa Indians, Petoskey, Michigan (Tribal Members Only).

Ducks

Season Dates: Open September 15, 2012, through January 31, 2013.

Daily Bag Limits: 20 ducks, including no more than 5 hen mallards, 5 black ducks, 5 redheads, 5 wood ducks, 5 pintail, 5 hooded merganser, 5 scaup, and 5 canvasback.

Coots and Gallinules

Season Dates: Open September 15 through December 31, 2012.

Daily Bag Limit: 20.

Canada Geese

Season Dates: Open September 1, 2012, through February 8, 2013.

Daily Bag Limit: 20.

Sora and Virginia Rails

Season Dates: Open September 1 through December 31, 2012.

Daily Bag Limit: 20.

Snipe

Season Dates: Open September 15 through December 31, 2012.

Daily Bag Limit: 16.

Mourning Doves

Season Dates: Open September 1 through November 14, 2012.

Daily Bag Limit: 15.

Woodcock

Season Dates: Open September 5 through December 1, 2012.

Daily Bag Limit: 10.

General: Possession limits are twice the daily bag limits.

(l) [Reserved.]

(m) Lower Elwha Klallam Tribe, Port Angeles, Washington (Tribal Members Only).

Ducks

Season Dates: Open September 15, 2012, through January 6, 2013.

Daily Bag and Possession Limits: Seven ducks, including no more than two hen mallards, one pintail, one canvasback, and two redheads. Possession limit is twice the daily bag limit. Bag and possession limits for harlequin ducks is one per season.

Geese

Season Dates: Open September 15, 2012, through January 6, 2013.

Daily Bag and Possession Limits: Four geese, and may include no more than three light geese. The seasons on Aleutian Canada geese and brant are closed. Possession limit is twice the daily bag limit.

Coots

Season Dates: Open September 15, 2012, through January 6, 2013.

Daily Bag and Possession Limits: 25 and 50 coots, respectively.

Mourning Doves

Season Dates: Open September 15, 2012, through January 6, 2013.

Daily Bag and Possession Limits: 10 and 20 doves, respectively.

Snipe

Season Dates: Open September 15, 2012, through January 6, 2013.

Daily Bag and Possession Limits: 8 and 16 snipe, respectively.

Band-Tailed Pigeon

Season Dates: Open September 15, 2012, through January 6, 2013.

Daily Bag and Possession Limits: 2 and 4 pigeons, respectively.

General: Tribal members must possess a tribal hunting permit from the Lower Elwha Klallam Tribe pursuant to tribal law. Hunters must observe all basic Federal migratory bird hunting regulations in 50 CFR part 20.

(n) Makah Indian Tribe, Neah Bay, Washington (Tribal Members).

Band-Tailed Pigeons

Season Dates: Open September 15 through October 28, 2012.

Daily Bag Limit: Two band-tailed pigeons.

Ducks and Coots

Season Dates: Open September 22, 2012, through January 26, 2013.

Daily Bag Limit: Seven ducks including no more than five mallards (only two of which can be a hen), one redhead, one pintail, three scaup, and one canvasback. The seasons on wood duck and harlequin are closed.

Geese

Season Dates: Open September 22, 2012, through January 26, 2013.

Daily Bag Limit: Four including no more than one brant. The seasons on Aleutian and dusky Canada geese are closed.

General

All other Federal regulations contained in 50 CFR part 20 apply. The following restrictions also apply:

(1) As per Makah Ordinance 44, only shotguns may be used to hunt any species of waterfowl. Additionally, shotguns must not be discharged within 0.25 miles of an occupied area.

(2) Hunters must be eligible, enrolled Makah tribal members and must carry their Indian Treaty Fishing and Hunting Identification Card while hunting. No tags or permits are required to hunt waterfowl.

(3) The Cape Flattery area is open to waterfowl hunting, except in designated wilderness areas, or within 1 mile of Cape Flattery Trail, or in any area that is closed to hunting by another ordinance or regulation.

(4) The use of live decoys and/or baiting to pursue any species of waterfowl is prohibited.

(5) Steel or bismuth shot only for waterfowl is allowed; the use of lead shot is prohibited.

(6) The use of dogs is permitted to hunt waterfowl.

(7) Shooting hours for all species of waterfowl are one-half hour before sunrise to one-half hour after sunset.

(8) Open hunting areas are: GMUs 601 (Hoko), a portion of the 602 (Dickey) encompassing the area north of a line between Norwegian Memorial and east to Highway 101, and 603 (Pysht).

(o) Navajo Nation, Navajo Indian Reservation, Window Rock, Arizona (Tribal Members and Nontribal Hunters).

Band-Tailed Pigeons

Season Dates: Open September 1 through 30, 2012.

Daily Bag and Possession Limits: 5 and 10 pigeons, respectively.

Mourning Doves

Season Dates: Open September 1 through 30, 2012.

Daily Bag and Possession Limits: 10 and 20 doves, respectively.

General Conditions: Tribal and nontribal hunters will comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20, regarding shooting hours and manner of taking. In addition, each waterfowl hunter 16 years of age or over must carry on his/her person a valid Migratory Bird Hunting and Conservation Stamp (Duck Stamp) signed in ink across the face. Special regulations established by the Navajo Nation also apply on the reservation.

(p) Oneida Tribe of Indians of Wisconsin, Oneida, Wisconsin (Tribal Members Only).

Ducks (including mergansers)

Season Dates: Open September 15 through November 16, 2012, and open November 26 through December 4, 2012.

Daily Bag and Possession Limits: Six, including no more than six mallards (three hen mallards), six wood ducks, one redhead, two pintail, and one hooded merganser. The possession limit is twice the daily bag limit.

Geese

Season Dates: Open September 1 through November 16, 2012; and open November 26 through December 30, 2012.

Daily Bag and Possession Limits: 5 and 10 Canada geese, respectively, from September 1 through 14, 2012; and 3 and 6 Canada geese, respectively, the remainder of the season. Hunters will be issued five tribal tags during the early season and three tribal tags during the late season for geese in order to monitor goose harvest. An additional three tags will be issued each time birds are registered. A seasonal quota of 300 birds is adopted. If the quota is reached before the season concludes, the season will be closed at that time.

Woodcock

Season Dates: Open September 1 through November 4, 2012.

Daily Bag and Possession Limits: 5 and 10 woodcock, respectively.

Dove

Season Dates: Open September 1 through November 4, 2012.

Daily Bag and Possession Limits: 10 and 20 doves, respectively.

General Conditions: Tribal member shooting hours are one-half hour before sunrise to one-half hour after sunset. Nontribal members hunting on the Reservation or on lands under the jurisdiction of the Tribe must comply with all State of Wisconsin regulations, including season dates, shooting hours, and bag limits, which differ from tribal member seasons. Tribal members and nontribal members hunting on the Reservation or on lands under the jurisdiction of the Tribe will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, with the following exceptions: Tribal members are exempt from the purchase of the Migratory Waterfowl Hunting and Conservation Stamp (Duck Stamp); and shotgun capacity is not limited to three shells.

(q) Point No Point Treaty Council, Kingston, Washington (Tribal Members Only).

Jamestown S'Klallam Tribe

Ducks

Season Dates: Open September 15, 2012, through February 1, 2013.

Daily Bag and Possession Limits: Seven ducks, including no more than two hen mallards, one pintail, one canvasback, four scoters, and two redheads. Possession limit is twice the daily bag limit. Bag and possession limits for harlequin ducks is one per season.

Geese

Season Dates: Open September 15, 2012, through March 10, 2013.

Daily Bag and Possession Limits: Four geese, and may include no more than three light geese. The seasons on Aleutian and cackling Canada geese are closed. Possession limit is twice the daily bag limit.

Brant

Season Dates: Open January 15 through January 31, 2013.

Daily Bag and Possession Limits: Two and four, respectively.

Coots

Season Dates: Open September 15, 2012, through February 1, 2013.

Daily Bag and Possession Limits: 25 and 50 coots, respectively.

Mourning Doves

Season Dates: Open September 15, 2012, through January 14, 2013.

Daily Bag and Possession Limits: 10 and 20 doves, respectively.

Snipe

Season Dates: Open September 15, 2012, through March 10, 2013.

Daily Bag and Possession Limits: 8 and 16 snipe, respectively.

Band-Tailed Pigeon

Season Dates: Open September 15, 2012, through March 10, 2013.

Daily Bag and Possession Limits: 2 and 4 pigeons, respectively.

Port Gamble S'Klallam Tribe

Ducks

Season Dates: Open September 1, 2012, through February 10, 2013.

Daily Bag and Possession Limits: Seven ducks, including no more than two hen mallards, one pintail, one canvasback, four scoters, and two redheads. Possession limit is twice the daily bag limit. Bag and possession limits for harlequin ducks is one per season.

Geese

Season Dates: Open September 15, 2012, through March 10, 2013.

Daily Bag and Possession Limits: Four geese, and may include no more than three light geese. The seasons on Aleutian and cackling Canada geese are closed. Possession limit is twice the daily bag limit.

Brant

Season Dates: Open December 1, 2012, through February 10, 2013.

Daily Bag and Possession Limits: 2 and 4, respectively.

Coots

Season Dates: Open September 1, 2012, through January 27, 2013.

Daily Bag and Possession Limits: 25 and 50 coots, respectively.

Mourning Doves

Season Dates: Open September 1, 2012, through January 27, 2013.

Daily Bag and Possession Limits: 10 and 20 doves, respectively.

Snipe

Season Dates: Open September 1, 2012, through March 10, 2013.

Daily Bag and Possession Limits: 8 and 16 snipe, respectively.

Band-Tailed Pigeon

Season Dates: Open September 1, 2012, through March 10, 2013.

Daily Bag and Possession Limits: 2 and 4 pigeons, respectively.

General: Tribal members must possess a tribal hunting permit from the Point No Point Tribal Council pursuant to tribal law. Hunting hours are from one-half hour before sunrise to sunset. Hunters must observe all other basic Federal migratory bird hunting regulations in 50 CFR part 20.

(r) Sault Ste. Marie Tribe of Chippewa Indians, Sault Ste. Marie, Michigan (Tribal Members Only).

Mourning Doves

Season Dates: Open September 1 through November 14, 2012.

Daily Bag Limit: 10 doves.

Ducks

Season Dates: Open September 15 through December 31, 2012.

Daily Bag Limits: 20, including no more than 10 mallards (only 5 of which may be hens), 5 canvasback, 5 black duck, and 5 wood duck.

Mergansers

Season Dates: Open September 15 through December 31, 2012.

Daily Bag Limit: 10.

Geese

Season Dates: Open September 1 through December 31, 2012.

Daily Bag Limit: 20 in the aggregate.

Coots and Gallinule

Season Dates: Open September 1 through December 31, 2012.

Daily Bag Limit: 20 in the aggregate.

Woodcock

Season Dates: Open September 2 through December 1, 2012.

Daily Bag Limits: 10.

Common Snipe

Season Dates: Open September 15 through December 31, 2012.

Daily Bag Limits: 16.

Sora and Virginia Rails

Season Dates: Open September 1 through December 31, 2012.

Daily Bag Limits: 20 in the aggregate.

General: Possession limits are twice the daily bag limits except for rails, of which the possession limit equals the daily bag limit (20). Tribal members must possess a tribal hunting permit from the Sault Ste. Marie Tribe pursuant to tribal law. Shooting hours are one-half hour before sunrise until one-half hour after sunset. Hunters must observe all other basic Federal migratory bird hunting regulations in 50 CFR part 20.

(s) *[Reserved.]*

(t) Skokomish Tribe, Shelton, Washington (Tribal Members Only).

Ducks

Season Dates: Open September 16, 2012, through February 28, 2013.

Daily Bag and Possession Limits: Seven ducks, including no more than two hen mallards, one pintail, one canvasback, one harlequin per season, and two redheads. Possession limit is twice the daily bag limit (except for harlequin).

Geese

Season Dates: Open September 16, 2012, through February 28, 2013.

Daily Bag and Possession Limits: Four geese, and may include no more than three light geese. The season on Aleutian Canada geese is closed. Possession limit is twice the daily bag limit.

Brant

Season Dates: Open November 1, 2012, through February 15, 2013.

Daily Bag and Possession Limits: Two and four brant, respectively.

Coots

Season Dates: Open September 16, 2012, through February 28, 2013.

Daily Bag and Possession Limits: 25 and 50 coots, respectively.

Mourning Doves

Season Dates: Open September 16, 2012, through February 28, 2013.

Daily Bag and Possession Limits: 10 and 20 doves, respectively.

Snipe

Season Dates: Open September 16, 2012, through February 28, 2013.

Daily Bag and Possession Limits: 8 and 16 snipe, respectively.

Band-Tailed Pigeon

Season Dates: Open September 16, 2012, through February 28, 2013.

Daily Bag and Possession Limits: 2 and 4 pigeons, respectively.

General Conditions: All hunters authorized to hunt migratory birds on the reservation must obtain a tribal hunting permit from the respective Tribe. Hunters are also required to adhere to a number of special regulations available at the tribal office. Hunters must observe all other basic Federal migratory bird hunting regulations in 50 CFR part 20.

(u) Spokane Tribe of Indians, Spokane Indian Reservation and Ceded Lands, Wellpinit, Washington (Tribal Members Only).

Ducks

Season Dates: Open September 2, 2012, through January 31, 2013.

Daily Bag and Possession Limits: Seven ducks, including no more than two hen mallards, two pintail, one canvasback, three scaup, and two redheads. Possession limit is twice the daily bag limit.

Geese

Season Dates: Open September 2, 2012, through January 31, 2013.

Daily Bag and Possession Limits: Four dark geese and six light geese. Possession limit is twice the daily bag limit.

General Conditions: All tribal hunters must have a valid Tribal ID card on his or her person while hunting. Shooting hours are one-half hour before sunrise to sunset, and steel shot is required for all migratory bird hunting. Hunters must observe all other basic Federal migratory bird hunting regulations in 50 CFR part 20.

(v) *[Reserved.]*

(w) Stillaguamish Tribe of Indians, Arlington, Washington (Tribal Members Only).

Band-Tailed Pigeon

Season Dates: Open September 1 through October 31, 2012.

Daily Bag and Possession Limits: Four and eight, respectively.

Mourning Dove

Season Dates: Open September 1 through October 31, 2012.

Daily Bag and Possession Limits: 10 and 20, respectively.

Tribal members hunting on lands will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, which will be enforced by the Stillaguamish Tribal Law Enforcement. Tribal members are required to use steel shot or a nontoxic shot as required by Federal regulations.

(x) *[Reserved.]*

(y) The Tulalip Tribes of Washington, Tulalip Indian Reservation, Marysville, Washington (Tribal Members and Nontribal Hunters).

Tribal Members Only

Ducks

Season Dates: Open September 7, 2012, through February 28, 2013.

Daily Bag and Possession Limits: Seven ducks, including no more than two hen mallards, two pintail, one canvasback, three scaup, and two redheads. Possession limit is twice the daily bag limit.

Geese

Season Dates: Open September 7, 2012, through February 28, 2013.

Daily Bag and Possession Limits: Seven geese. Possession limit is twice the daily bag limit.

Brant

Season Dates: Open September 7, 2012, through February 28, 2013.

Daily Bag and Possession Limits: Two and four brant, respectively.

Coots

Season Dates: Open September 7, 2012, through February 28, 2013.

Daily Bag and Possession Limits: 25 and 25 coots, respectively.

Snipe

Season Dates: Open September 7, 2012, through February 28, 2013.

Daily Bag and Possession Limits: 8 and 16 snipe, respectively.

Nontribal Hunters

Snipe

Season Dates: Open November 14, 2012, through February 28, 2013.

Daily Bag and Possession Limits: 8 and 16 snipe, respectively.

General Conditions: All tribal hunters must have a valid Tribal ID card on his or her person while hunting. All nontribal hunters must obtain and possess while hunting a valid Tulalip Tribe hunting permit and be accompanied by a Tulalip Tribal member. Shooting hours are one-half hour before sunrise to sunset, and steel shot is required for all migratory bird hunting. Hunters must observe all other basic Federal migratory bird hunting regulations in 50 CFR part 20.

(z) Upper Skagit Indian Tribe, Sedro Woolley, Washington (Tribal Members Only).

Mourning Dove

Season Dates: Open September 1 through December 31, 2012.

Daily Bag and Possession Limits: 12 and 15 mourning doves, respectively.

Tribal members must have the tribal identification and harvest report card on their person to hunt. Tribal members hunting on the Reservation will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, except shooting hours would be one-half hour before official sunrise to one-half hour after official sunset.

(aa) Wampanoag Tribe of Gay Head, Aquinnah, Massachusetts (Tribal Members Only).

Canada Geese

Season Dates: Open September 5 through 22, 2012, and open October 29, 2012, through February 23, 2013.

Daily Bag Limits: Eight Canada geese during the first period and eight during the second.

Snow Geese

Season Dates: Open September 5 through 22, 2012, and open November 26, 2012, through February 23, 2013.

Daily Bag Limits: 15 snow geese.

Sora and Virginia Rails

Season Dates: Open September 1 through November 10, 2012.

Daily Bag Limits: 5 sora and 10 Virginia Rails.

Snipe

Season Dates: Open September 1 through December 16, 2012.

Daily Bag Limits: Eight snipe.

General Conditions: Shooting hours are one-half hour before sunrise to sunset. Nontoxic shot is required. All other basic Federal migratory bird hunting regulations contained in 50 CFR part 20 will be observed.

(bb) White Earth Band of Ojibwe, White Earth, Minnesota (Tribal Members Only).

Ducks

Season Dates: Open September 15 through December 16, 2012.

Daily Bag Limit for Ducks: 10 ducks, including no more than 2 female mallards, 1 pintail, and 1 canvasback.

Mergansers

Season Dates: Open September 15 through December 16, 2012.

Daily Bag Limit for Mergansers: Five mergansers, including no more than two hooded mergansers.

Geese

Season Dates: Open September 1 through December 16, 2012.

Daily Bag Limit: Eight geese through September 21 and five thereafter.

Coots

Season Dates: Open September 1 through November 30, 2012.

Daily Bag Limit: 20 coots.

Sora and Virginia Rails

Season Dates: Open September 1 through November 30, 2012.

Daily Bag Limit: 25 sora and Virginia rails, singly or in the aggregate.

Common Snipe and Woodcock

Season Dates: Open September 1 through November 30, 2012.

Daily Bag Limit: 10 snipe and 10 woodcock.

Mourning Dove

Season Dates: Open September 1 through November 30, 2012.

Daily Bag Limit: 25 doves.

General Conditions: Shooting hours are one-half hour before sunrise to one-half hour after sunset. Nontoxic shot is required. All other basic Federal migratory bird hunting regulations contained in 50 CFR part 20 will be observed.

(cc) White Mountain Apache Tribe, Fort Apache Indian Reservation, Whiteriver, Arizona (Tribal Members and Nontribal Hunters).

Band-Tailed Pigeons (Wildlife Management Unit 10 and Areas South of Y–70 and Y–10 in Wildlife Management Unit 7, Only)

Season Dates: Open September 1 through 15, 2012.

Daily Bag and Possession Limits: Three and six pigeons, respectively.

Mourning Doves (Wildlife Management Unit 10 and Areas South of Y–70 and Y–10 in Wildlife Management Unit 7, Only)

Season Dates: Open September 1 through 15, 2012.

Daily Bag and Possession Limits: 10 and 20 doves, respectively.

General Conditions: All nontribal hunters hunting band-tailed pigeons and mourning doves on Reservation lands shall have in their possession a valid White Mountain Apache Daily or Yearly Small Game Permit. In addition to a small game permit, all nontribal hunters hunting band-tailed pigeons must have in their possession a White Mountain Special Band-tailed Pigeon Permit. Other special regulations established by the White Mountain Apache Tribe apply on the reservation. Tribal and nontribal hunters will comply with all basic Federal migratory bird hunting regulations in 50 CFR Part 20 regarding shooting hours and manner of taking.

(dd) [Reserved.]

Dated: August 30, 2012.

Rachel Jacobson,

Principal Assistant Deputy Secretary for Fish and Wildlife and Parks.

[FR Doc. 2012–21969 Filed 8–31–12; 4:15 pm]

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Proposed Rules

Federal Register

Vol. 77, No. 172

Wednesday, September 5, 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.

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230 and 239

[Release No. 33–9354; File No. S7–07–12]

RIN 3235–AL34

Eliminating the Prohibition Against General Solicitation and General Advertising in Rule 506 and Rule 144A Offerings

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: We are proposing amendments to Rule 506 of Regulation D and Rule 144A under the Securities Act of 1933 to implement Section 201(a) of the Jumpstart Our Business Startups Act. The proposed amendment to Rule 506 would provide that the prohibition against general solicitation and general advertising contained in Rule 502(c) of Regulation D would not apply to offers and sales of securities made pursuant to Rule 506, provided that all purchasers of the securities are accredited investors. The proposed amendment to Rule 506 would also require that, in Rule 506 offerings that use general solicitation or general advertising, the issuer take reasonable steps to verify that purchasers of the securities are accredited investors. The proposed amendment to Rule 144A(d)(1) would provide that securities may be offered pursuant to Rule 144A to persons other than qualified institutional buyers, provided that the securities are sold only to persons that the seller and any person acting on behalf of the seller reasonably believe are qualified institutional buyers. We are also proposing to revise Form D to add a separate check box for issuers to indicate whether they are using general solicitation or general advertising in a Rule 506 offering.

DATES: Comments should be received on or before October 5, 2012.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/proposed.shtml*);
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–07–12 on the subject line; or
- Use the Federal eRulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–07–12. This file number should be included on the subject line if email is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/proposed.shtml*). Comments are also available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090 on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Charles Kwon, Special Counsel, or Ted Yu, Senior Special Counsel, Office of Chief Counsel, Division of Corporation Finance, at (202) 551–3500, or, with respect to privately offered funds, Holly Hunter-Ceci, Senior Counsel, Office of Chief Counsel, or Alpa Patel, Attorney-Adviser, Private Funds Branch, Office of Investment Adviser Regulation, Division of Investment Management, at (202) 551–6825 or (202) 551–6787, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

SUPPLEMENTARY INFORMATION: We are proposing amendments to Rule 144A,[1] Form D,[2] and Rules 500,[3] 501,[4] 502[5] and 506[6] of Regulation D[7] under the Securities Act of 1933.[8]

Table of Contents

I. Introduction
II. Proposed Amendments to Rule 506 and Form D
  A. Eliminating the Prohibition Against General Solicitation
  B. Reasonable Steps to Verify Accredited Investor Status
  C. Reasonable Belief that All Purchasers Are Accredited Investors
  D. Form D Check Box for Rule 506(c) Offerings
  E. Specific Issues for Privately Offered Funds
  F. Technical and Conforming Amendments
  G. Request for Comment
III. Proposed Amendment to Rule 144A
  A. Offers to Persons Other Than Qualified Institutional Buyers
  B. Request for Comment
IV. Integration With Offshore Offerings
V. General Request for Comment
VI. Paperwork Reduction Act
VII. Economic Analysis
  A. Background and Summary of Proposed Rule and Form Amendments
  B. Baseline
  C. Eliminating the Prohibition Against General Solicitation in Rule 506 Offerings and Rule 144A Offerings
  D. Verifying Accredited Investor Status in Rule 506(c) Offerings
  E. Form D Check Box for Rule 506(c) Offerings
  F. Request for Comment
VIII. Small Business Regulatory Enforcement Fairness Act
IX. Initial Regulatory Flexibility Analysis
  A. Reasons for, and Objectives of, the Action
  B. Small Entities Subject to the Proposed Rule and Form Amendments
  C. Projected Reporting, Recordkeeping and Other Compliance Requirements
  D. Duplicative, Overlapping or Conflicting Federal Rules
  E. Significant Alternatives
  F. General Request for Comment
X. Statutory Authority and Text of Proposed Rule and Form Amendments

I. Introduction

The Jumpstart Our Business Startups Act (the ''JOBS Act'') was enacted on April 5, 2012.[9] Section 201(a)(1) of the JOBS Act directs the Commission, not

[1] 17 CFR 230.144A.

[2] 17 CFR 239.500.

[3] 17 CFR 230.500.

[4] 17 CFR 230.501.

[5] 17 CFR 230.502.

[6] 17 CFR 230.506.

[7] 17 CFR 230.500 through 230.508.

[8] 15 U.S.C. 77a *et seq.*

[9] Public Law 112–106, 126 Stat. 306.

later than 90 days after the date of enactment, to amend Rule 506 of Regulation D [10] under the Securities Act of 1933 (the ''Securities Act'') to permit general solicitation or general advertising in offerings made under Rule 506, provided that all purchasers of the securities are accredited investors. Section 201(a)(1) also states that ''[s]uch rules shall require the issuer to take reasonable steps to verify that purchasers of the securities are accredited investors, using such methods as determined by the Commission.'' Section 201(a)(2) of the JOBS Act directs the Commission, not later than 90 days after the date of enactment, to revise Rule 144A(d)(1) [11] under the Securities Act to permit offers of securities pursuant to Rule 144A to persons other than qualified institutional buyers (''QIBs''),[12] including by means of general solicitation or general advertising, provided that the securities are sold only to persons that the seller and any person acting on behalf of the seller reasonably believe are QIBs.

Rule 506 is a non-exclusive safe harbor under Section 4(a)(2) (formerly Section 4(2)) of the Securities Act,[13] which exempts transactions by an issuer ''not involving any public offering'' from the registration requirements of Section 5 of the Securities Act.[14] Under existing Rule 506, an issuer may offer and sell securities, without any limitation on the offering amount, to an unlimited number of ''accredited investors,'' as defined in Rule 501(a) of Regulation D,[15] and to no more than 35 non-accredited investors who meet certain ''sophistication'' requirements.[16] The availability of the Rule 506 safe harbor is subject to a number of requirements [17] and is currently conditioned on the issuer, or any person acting on its behalf, not offering or selling securities through any form of ''general solicitation or general advertising.'' [18] Although the terms ''general solicitation'' and ''general advertising'' are not defined in Regulation D, Rule 502(c) does provide examples of general solicitation and general advertising, including advertisements published in newspapers and magazines, communications broadcast over television and radio, and seminars whose attendees have been invited by general solicitation or general advertising.[19] By interpretation, the Commission has confirmed that other uses of publicly available media, such as unrestricted Web sites, also constitute general solicitation and general advertising.[20] In this release, we will refer to both general solicitation and general advertising as ''general solicitation.''

Rule 144A is a non-exclusive safe harbor exemption from the registration requirements of the Securities Act for resales of certain ''restricted securities'' [21] to QIBs. Resales to QIBs in accordance with the conditions of Rule 144A [22] are exempt from registration pursuant to Section 4(a)(1) (formerly Section 4(1)) of the Securities Act,[23] which exempts transactions by any person ''other than an issuer, underwriter, or dealer.'' Although Rule 144A does not include an express prohibition against general solicitation, offers of securities under Rule 144A currently must be limited to QIBs, which has the same practical effect. By its terms, Rule 144A is available solely for resale transactions; however, since its adoption by the Commission in 1990, market participants have used Rule 144A to facilitate capital-raising by issuers. The term ''Rule 144A offering'' in this release refers to a primary offering of securities by an issuer to one or more financial intermediaries—commonly known as the ''initial purchasers''—in a transaction that is exempt from registration pursuant to Section 4(a)(2) or Regulation S,[24] followed by the immediate resale of those securities by the initial purchasers to QIBs in reliance on Rule 144A.

Rule 506 offerings and Rule 144A offerings are widely used by U.S. and foreign issuers to raise capital. In 2011, the estimated amount of capital (including both equity and debt) raised in Rule 506 offerings and Rule 144A offerings was $895 billion and $168 billion, respectively, compared to $984 billion raised in registered offerings. In 2010, the estimated amount of capital (including both equity and debt) raised in Rule 506 offerings and Rule 144A offerings was $902 billion and $233 billion, respectively, compared to $1.07 trillion raised in registered offerings.[25]

[10] The Commission adopted Regulation D in 1982 as a result of the Commission's evaluation of the impact of its rules on the ability of small businesses to raise capital. *See Revision of Certain Exemptions From Registration for Transactions Involving Limited Offers and Sales,* Release No. 33–6389 (Mar. 8, 1982) [47 FR 11251]. Over the years, the Commission has revised various provisions of Regulation D in order to address, among other things, specific concerns relating to facilitating capital-raising as well as abuses that have arisen under Regulation D. *See, e.g., Additional Small Business Initiatives,* Release No. 33–6996 (Apr. 28, 1993) [58 FR 26509] and *Revision of Rule 504 of Regulation D, the ''Seed Capital'' Exemption,* Release No. 33–7644 (Feb. 25, 1999) [64 FR 11090].

[11] 17 CFR 230.144A(d)(1).

[12] The term ''qualified institutional buyer'' is defined in Rule 144A(a)(1) [17 CFR 230.144A(a)(1)] and includes specified institutions that, in the aggregate, own and invest on a discretionary basis at least $100 million in securities of issuers that are not affiliated with such institutions. Banks and other specified financial institutions must also have a net worth of at least $25 million. A registered broker-dealer qualifies as a QIB if it, in the aggregate, owns and invests on a discretionary basis at least $10 million in securities of issuers that are not affiliated with the broker-dealer.

[13] 15 U.S.C. 77d(a)(2).

[14] 15 U.S.C. 77e.

[15] The definition of the term ''accredited investor'' is set forth in Rule 501(a) of Regulation D [17 CFR 230.501(a)] and includes any person who comes within one of the definition's enumerated categories of persons, or whom the issuer ''reasonably believes'' comes within any of the enumerated categories, at the time of the sale of the securities to that person.

[16] Under Rule 506(b)(2)(ii) [17 CFR 230.506(b)(2)(ii)], each purchaser in a Rule 506 offering who is not an accredited investor must possess, or the issuer must reasonably believe immediately before the sale that such purchaser possesses, either alone or with his or her purchaser representative, ''such knowledge and experience in financial and business matters that he [or she] is capable of evaluating the merits and risks of the prospective investment.''

[17] Offerings under Rule 506 are subject to all the terms and conditions of Rules 501 and 502. If securities are sold to any non-accredited investors, specified information requirements apply. *See* Rule 502(b) [17 CFR 230.502(b)].

[18] Rule 502(c) of Regulation D [17 CFR 230.502(c)].

[19] *Id.*

[20] *See Use of Electronic Media for Delivery Purposes,* Release No. 33–7233 (Oct. 6, 1995) [60 FR 53458] at Ex. 20; *Use of Electronic Media,* Release No. 33–7856 (Apr. 28, 2000) [65 FR 25843] at footnotes 79–80 and accompanying text.

[21] ''Restricted securities'' are defined in Securities Act Rule 144(a)(3) [17 CFR 230.144(a)(3)] to include, in part, ''[s]ecurities acquired directly or indirectly from the issuer, or from an affiliate of the issuer, in a chain of transactions not involving a public offering.''

[22] In order for a transaction to come within existing Rule 144A, a seller must have a reasonable basis for believing that the offeree or purchaser is a QIB and must take reasonable steps to ensure that the purchaser is aware that the seller may rely on Rule 144A. Further, only securities that were not, when issued, of the same class as securities listed on a U.S. securities exchange or quoted on a U.S. automated interdealer quotation system are eligible for resale under Rule 144A. Also, the seller and a prospective purchaser designated by the seller must have the right to obtain from the issuer, upon request, certain information on the issuer, unless the issuer falls within specified categories as to which this condition does not apply.

[23] 15 U.S.C. 77d(a)(1).

[24] Regulation S under the Securities Act [17 CFR 230.901 through 230.905] was adopted in 1990 as a safe harbor from the registration requirements of the Securities Act for any offer or sale of securities made outside the United States. It provides that any ''offer,'' ''offer to sell,'' ''sell,'' ''sale'' or ''offer to buy'' that occurs outside the United States is not subject to the registration requirements of Section 5. Regulation S does not limit the scope or availability of the antifraud or other provisions of the Securities Act to offers and sales made in reliance on Regulation S.

[25] These statistics are based on a review of Form D electronic filings with the Commission—specifically, the ''total amount sold'' as reported in Form D—and data regarding other types of offerings (*e.g.,* public debt offerings and Rule 144A offerings) from Securities Data Corporation's New Issues

Continued

These data points underscore the importance of the Rule 506 and Rule 144A exemptions for issuers seeking access to the U.S. capital markets.

To implement Section 201(a) of the JOBS Act, we are proposing to amend Rule 506 to provide that the prohibition against general solicitation contained in Rule 502(c) shall not apply to offers and sales of securities made pursuant to Rule 506, as amended, provided that all purchasers of the securities are accredited investors and the issuer takes reasonable steps to verify that the purchasers are accredited investors. In addition, we are proposing to amend Form D, which is a notice required to be filed with the Commission by each issuer claiming a Regulation D exemption, to add a check box to indicate whether an offering is being conducted pursuant to the proposed amendment to Rule 506 that would permit general solicitation. We are also proposing to amend Rule 144A to provide that securities sold pursuant to Rule 144A may be offered to persons other than QIBs, including by means of general solicitation, provided that the securities are sold only to persons that the seller and any person acting on behalf of the seller reasonably believe are QIBs.

We have considered comment letters received to date on Section 201(a) of the JOBS Act, and we are requesting comment on various issues relating specifically to the proposed amendments described above.[26] In this release, we are proposing only those rule and form amendments that are, in our view, necessary to implement the mandate in Section 201(a). We recognize that commentators have urged us to consider and propose other amendments to Regulation D or to Form D that they believe are appropriate in connection with implementation of the rule and form amendments proposed here. For example, several commentators have recommended that the Commission also amend the definition of ''accredited investor'' as it relates to natural persons.[27] Other commentators have suggested that we amend the Form D filing requirement, including conditioning the availability of the proposed Rule 506 exemption on the filing of Form D,[28] requiring the Form D to be filed in advance of any general solicitation,[29] and adding to the information requirements of Form D.[30] Other commentators have suggested that we propose rules governing the content and manner of advertising and solicitations used in offerings conducted under the proposed Rule 506 exemption,[31] particularly with respect to privately offered funds.[32]

We appreciate the suggestions made by these commentators; however, at this time, we are not proposing these or any other amendments to Regulation D or to Form D.

II. Proposed Amendments to Rule 506 and Form D

A. Eliminating the Prohibition Against General Solicitation

Section 4(a)(2) exempts transactions by an issuer ''not involving any public offering.'' An issuer relying on Section 4(a)(2) is restricted in its ability to make public communications to attract investors for its offering because public advertising is incompatible with a claim of exemption under Section 4(a)(2).[33] As noted above, Rule 506 currently conditions the availability of the safe harbor under Section 4(a)(2) on the issuer, or any person acting on its behalf, not offering or selling securities through any form of general solicitation.[34] Section 201(a)(1) of the JOBS Act directs the Commission to amend Rule 506 to provide that the prohibition against general solicitation contained in Rule 502(c) shall not apply to offers and sales of securities made pursuant to Rule 506, as so amended, provided that purchasers of the securities are accredited investors. This mandate affects only the Rule 506 safe harbor, and not Section 4(a)(2) offerings in general.[35]

database (Thomson Financial). *See* Vlad Ivanov and Scott Bauguess, *Capital Raising in the U.S.: The Significance of Unregistered Offerings Using the Regulation D Exemption* (Feb. 2012) (the ''Ivanov/Bauguess Study''), available at: *http://www.sec.gov/info/smallbus/acsec/acsec103111_analysis-reg-d-offering.pdf.* The amount of capital raised through offerings under Regulation D may be considerably larger than what is reported on Form D because, although the filing of a Form D is a requirement of Rule 503(a) of Regulation D [17 CFR 230.503(a)], it is not a condition to the availability of the exemptions under Regulation D. Further, once a Form D is filed, the issuer is not required to file an amendment to the notice to reflect a change that occurs after the offering terminates or a change that occurs solely with respect to certain information, such as the amount sold in the offering. For example, if the amount sold does not exceed the offer size by more than 10% or the offer closes within a year, the filing of an amendment to the initial Form D is not required. Therefore, a Form D filed for a particular offering may not reflect the total amount of securities sold in the offering in reliance on the exemption.

[26] To facilitate public input on JOBS Act rulemaking before the issuance of rule proposals, the Commission has invited members of the public to make their views known on various JOBS Act initiatives in advance of any rulemaking by submitting comment letters to the Commission's Web site at *http://www.sec.gov/spotlight/jobsactcomments.shtml.* Comment letters received to date on Section 201(a) of the JOBS Act are available at *http://www.sec.gov/comments/jobs-title-ii/jobs-title-ii.shtml,* and we cite to many of them in this release. Comment letters on this release should be submitted as directed in ''Addresses'' above.

[27] *See* letters from Cambridge Innovation Center (suggesting that the Commission consider offering investor education classes whereby investors who meet a lower financial threshold but pass a qualifying test could be granted accredited investor status); Fund Democracy, Consumer Federation of America, Consumer Action, AFL–CIO, and Americans for Financial Reform (''Fund Democracy'') (recommending higher financial thresholds for natural persons claiming to be accredited investors); Investment Company Institute (''ICI'') (May 21, 2012) (recommending increased income and net worth thresholds in the accredited investor definition and inclusion of a new category of ''accredited natural persons'' in the accredited investor definition); Managed Funds Association (''MFA'') (May 4, 2012) (recommending adding ''knowledgeable employee'' under the Investment Company Act to the definition of ''accredited investor''); Public Citizen (recommending higher income and net worth thresholds in the accredited investor definition); Office of the Secretary of the Commonwealth of Massachusetts Securities Division (''Massachusetts Securities Division'') (same); Ilan Moscovitz and John Maxfield (''Moscovitz and Maxfield'') (same); Ohio Division of Securities (''Ohio Division'') (same). One commentator opposed increasing the thresholds for accredited investor status. *See* letter from National Small Business Association (''NSBA'') (June 12, 2012).

[28] *See* letters from Massachusetts Securities Division (''The filing of a Form D should be a condition of the availability of the new Rule 506 exemption.''); North American Securities Administrators Association, Inc. (''NASAA'') (July 3, 2012) (recommending that the failure to file a Form D prior to the use of general solicitation must result in the loss of the exemption and warning that without such a filing requirement, regulators would ''have no way of knowing whether a promoter is legitimately trying to comply with Rule 506, so a fraudulent offering will be allowed to continue until the regulators have gathered sufficient evidence to prove fraud has already occurred'').

[29] *See* letters from Fund Democracy; NASAA (July 3, 2012); Public Citizen.

[30] *See, e.g.,* letters from NASAA (July 3, 2012) (listing a number of recommended amendments to Form D, such as the disclosure of the issuer's Web site address); Ohio Division (recommending that Form D provide more background information to allow broker-dealers, regulators, and investors to assess whether an issuer has been disqualified from using Rule 506).

[31] Letters from NASAA (July 3, 2012) (stating that advertising materials used in Rule 506 offerings should include a ''balanced presentation of risks and rewards'' and be subject to a requirement that statements in the advertising materials are consistent with representations in the offering documents); Ohio Division (recommending that, among other things, the Commission adopt a uniform set of required disclosures and content restrictions for general solicitation materials, such as a mandatory legend disclosing those jurisdictions where the offering is being made (and disclaiming sales in any others) and a prohibition on financial projections or statements of future performance).

[32] *See, e.g.,* letters from ICI (May 21, 2012); Moscovitz and Maxfield; and Fund Democracy (Aug. 16, 2012).

[33] *See Non-Public Offering Exemption,* Release No. 33–4552 (Nov. 6, 1962) [27 FR 11316].

[34] *See* Rule 502(c) and Rule 506(b)(1) of Regulation D [17 CFR 230.506(b)(1)].

[35] In this regard, we note that bills that would have amended Section 4(a)(2) itself to permit the use of general solicitation were introduced and considered by Congress but not enacted. *See* Access

To implement the mandated rule change, we are proposing new Rule 506(c), which would permit the use of general solicitation to offer and sell securities under Rule 506, provided that certain conditions are satisfied.[36] These conditions are:

- The issuer must take reasonable steps to verify that the purchasers of the securities are accredited investors;
- All purchasers of securities must be accredited investors, either because they come within one of the enumerated categories of persons that qualify as accredited investors or the issuer reasonably believes that they do, at the time of the sale of the securities; [37] and
- All terms and conditions of Rule 501 and Rules 502(a) and 502(d) must be satisfied.[38]

Offerings under proposed Rule 506(c) would not be subject to the requirement to comply with Rule 502(c), which contains the prohibition against general solicitation.[39]

While we are proposing Rule 506(c) to allow for Rule 506 offerings that use general solicitation, we are preserving, under existing Rule 506(b), the existing ability of issuers to conduct Rule 506 offerings without the use of general solicitation. We recognize that offerings under existing Rule 506 represent an important source of capital for issuers of all sizes and believe that the continued availability of existing Rule 506 will be important for those issuers that either do not wish to engage in general solicitation in their Rule 506 offerings (and become subject to the new requirement to take reasonable steps to verify the accredited investor status of purchasers) or wish to sell privately to non-accredited investors who meet Rule 506(b)'s sophistication requirements. Retaining the safe harbor under existing Rule 506 may also be beneficial to investors with whom an issuer has a pre-existing substantive relationship.[40] In this regard, we do not believe that Section 201(a) requires the Commission to modify Rule 506 to impose any new requirements on offers and sales of securities that do not involve general solicitation. Therefore, the amendments to Rule 506 we are proposing today would not amend or modify the requirements relating to existing Rule 506.

B. Reasonable Steps to Verify Accredited Investor Status

While Section 201(a)(1) of the JOBS Act mandates that our amendments to Rule 506 require issuers using general solicitation in Rule 506 offerings ''to take reasonable steps to verify that purchasers of the securities are accredited investors,'' it does not specify the methods necessary to satisfy this requirement and instead requires issuers to use ''such methods as determined by the Commission.'' We believe that the purpose of the verification mandate is to address concerns, and reduce the risk, that the use of general solicitation under Rule 506 may result in sales to investors who are not, in fact, accredited investors.[41] We also recognize, however, that it would be necessary that our proposed amendment to Rule 506 provide sufficient flexibility to accommodate the different types of issuers that would conduct offerings under proposed Rule 506(c) and the different types of accredited investors (such as natural persons, public and private for-profit and not-for-profit corporations, general and limited partnerships, business and other types of trusts, and funds and other types of collective investment vehicles) that may purchase securities in these offerings.

We are proposing a requirement in Rule 506(c) that issuers using general solicitation ''take reasonable steps to verify'' that the purchasers of the offered securities are accredited investors. Whether the steps taken are ''reasonable'' would be an objective determination, based on the particular facts and circumstances of each transaction.

Under this proposed approach, issuers would consider a number of factors when determining the reasonableness of the steps to verify that a purchaser is an accredited investor. Some examples of these factors include:

- The nature of the purchaser and the type of accredited investor that the purchaser claims to be;
- The amount and type of information that the issuer has about the purchaser; and
- The nature of the offering, such as the manner in which the purchaser was solicited to participate in the offering, and the terms of the offering, such as a minimum investment amount.

We discuss each of these factors in greater detail below.

Nature of the Purchaser. The definition of ''accredited investor'' in Rule 501(a) includes natural persons and entities that come within any of eight enumerated categories in the rule, or that the issuer reasonably believes come within one of those categories, at the time of the sale of securities to that natural person or entity. Some purchasers may be accredited investors based on their status, such as:

- A broker or dealer registered pursuant to Section 15 of the Securities Exchange Act of 1934 (the ''Exchange Act''); [42] or
- An investment company registered under the Investment Company Act of 1940 (the ''Investment Company Act'') or a business development company as defined in Section 2(a)(48) of that Act.[43]

Some purchasers may be accredited investors based on a combination of

to Capital for Job Creators, H.R. 2940, 112th Cong. (2011) (proposing to amend Section 4(a)(2) by adding the phrase ''whether or not such transactions involve general solicitation or general advertising''); Access to Capital for Job Creators, S.1831, 112th Cong. (2011) (same).

[36] We note that broker-dealers participating in offerings in conjunction with issuers relying on proposed Rule 506(c) would continue to be subject to the rules of the Financial Industry Regulatory Authority (''FINRA'') regarding communications with the public. *See* FINRA Rule 2210.

[37] Rule 501(a) of Regulation D.

[38] Securities acquired under proposed Rule 506(c) would be subject to the resale limitations under Rule 502(d) [17 CFR 230.502(d)] and therefore would be ''restricted securities'' as defined in Rule 144(a)(3)(ii) [17 CFR 230.144(a)(3)(ii)]. Further, Section 201(b) of the JOBS Act added Section 4(b) of the Securities Act, which provides that ''[o]ffers and sales exempt under [Rule 506 as amended pursuant to Section 201 of the JOBS Act] shall not be deemed public offerings under the Federal securities laws as a result of general advertising or general solicitation.'' Thus, securities acquired under proposed Rule 506(c) would also meet the definition of ''restricted securities'' under Rule 144(a)(3)(i) [17 CFR 230.144(a)(3)(i)] (''[s]ecurities acquired directly or indirectly from the issuer, or from an affiliate of the issuer, in a transaction or chain of transactions not involving any public offering'').

[39] Offerings under proposed Rule 506(c) would also not be subject to the information requirements in Rule 502(b), because all purchasers in proposed Rule 506(c) offerings would be accredited investors.

[40] In a series of no-action and interpretive letters, the Commission staff has indicated that an issuer would not contravene Rule 502(c)'s prohibition against general solicitation if the issuer has a pre-existing substantive relationship with the offerees. *See, e.g., Mineral Lands Research and Marketing Corp.* (Nov. 3, 1985). The Commission staff has also addressed how an intermediary, such as a broker-dealer acting as a placement agent, can establish a sufficient pre-existing substantive relationship with its customers such that there would be no general solicitation when an issuer engages that intermediary to offer securities to the intermediary's customers. *See, e.g., E.F. Hutton & Co.* (Dec. 3, 1985). The framework set forth by this staff guidance on pre-existing substantive relationships has also provided flexibility in the use of the Internet in Regulation D offerings. *See, e.g., IPONET* (July 26, 1996); *Lamp Technologies, Inc.* (May 29, 1998).

[41] *See, e.g., Markup of H.R. 2940, Access to Capital for Job Creators Act,* Subcommittee on Capital Markets and Government Sponsored Enterprises, House Financial Services Committee, 112th Cong. (Oct. 5, 2011) (remarks of Representative Waters, explaining that she is introducing the amendment that requires issuers to take reasonable steps to verify accredited investor status because ''we must take steps to ensure that those folks are indeed sophisticated''); 157 Cong. Rec. H7291 (daily ed. Nov. 3, 2011) (remarks of Representative Maloney (same)); 157 Cong. Rec. H7294 (daily ed. Nov. 3, 2011) (remarks of Representative Lee (same)).

[42] *See* 17 CFR 230.501(a)(1).

[43] *See id.*

their status and the amount of their total assets, such as:

- A plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of $5 million;[44] or
- An Internal Revenue Code (''IRC'') Section 501(c)(3) organization, corporation, Massachusetts or similar business trust, or partnership, not formed for the specific purpose of acquiring the securities offered, with total assets in excess of $5 million.[45]

Natural persons may be accredited investors based on either their net worth or their annual income, as follows:

- A natural person whose individual net worth, or joint net worth with that person's spouse, exceeds $1 million, excluding the value of the person's primary residence (the ''net worth test'');[46] or
- A natural person who had an individual income in excess of $200,000 in each of the two most recent years, or joint income with that person's spouse in excess of $300,000 in each of those years, and has a reasonable expectation of reaching the same income level in the current year (the ''income test'').[47]

As Rule 501(a) sets forth different categories of accredited investors, we expect the steps that would be reasonable for an issuer to take to verify whether a purchaser is an accredited investor under proposed Rule 506(c) would likely vary depending on the type of accredited investor that the purchaser claims to be. For example, the steps that may be reasonable to verify that an entity is an accredited investor by virtue of being a registered broker-dealer—such as by going to FINRA's BrokerCheck Web site[48]—would necessarily differ from the steps that would be reasonable to verify whether a natural person is an accredited investor.

We recognize that taking reasonable steps to verify the accredited investor status of natural persons poses greater practical difficulties as compared to other categories of accredited investors, and these practical difficulties likely would be exacerbated by natural persons' privacy concerns about the disclosure of personal financial information.[49] As between the net worth test and the income test for natural persons, we recognize that commentators have suggested that it might be more difficult for an issuer to obtain information about a person's assets and liabilities than it would be to obtain information about a person's annual income,[50] although there could be privacy concerns with respect to either test. The question of what type of information would be sufficient to constitute reasonable steps to verify accredited investor status under the particular facts and circumstances of each purchaser would also depend on other factors, as described below.

Information about the Purchaser. The amount and type of information that an issuer has about a purchaser would be a significant factor in determining what additional steps would be reasonable to verify the purchaser's accredited investor status. The more information an issuer has indicating that a prospective purchaser is an accredited investor, the fewer steps it would have to take, and vice versa.[51] Examples of the types of information that issuers could review or rely upon—any of which might, depending on the circumstances, in and of themselves constitute reasonable steps to verify a purchaser's accredited investor status—include, without limitation:

- Publicly available information in filings with a federal, state or local regulatory body—for example, without limitation:
  - The purchaser is a named executive officer of an Exchange Act registrant, and the registrant's proxy statement discloses the purchaser's compensation for the last three completed fiscal years; or
  - The purchaser claims to be an IRC Section 501(c)(3) organization with $5 million in assets, and the organization's Form 990 series return filed with the Internal Revenue Service discloses the organization's total assets;[52]
- Third-party information that provides reasonably reliable evidence that a person falls within one of the enumerated categories in the accredited investor definition—for example, without limitation:
  - The purchaser is a natural person and provides copies of Forms W–2; or
  - The purchaser works in a field where industry or trade publications disclose average annual compensation for certain levels of employees or partners, and specific information about the average compensation earned at the purchaser's workplace by persons at the level of the purchaser's seniority is publicly available; or
- Verification of a person's status as an accredited investor by a third party, such as a broker-dealer, attorney or accountant, provided that the issuer has a reasonable basis to rely on such third-party verification.[53]

[44] *See id.*

[45] *See* 17 CFR 230.501(a)(3).

[46] *See* 17 CFR 230.501(a)(5).

[47] *See* 17 CFR 230.501(a)(6).

[48] This Web site is available at *http://www.finra.org/Investors/ToolsCalculators/BrokerCheck/.*

[49] *See, e.g.,* letters from BrokerBank Securities, Inc. (''BrokerBank'') (''By the time most people accumulate a net worth of $1,000,000+ not counting their principal residence, they usually really want to keep their financial information very close to the vest.''); Federal Regulation of Securities Committee of the Business Law Section of the American Bar Association (''ABA'') (stating that ''the Commission should be sensitive to the legitimate privacy concerns of purchasers'' when considering the steps that issuers should take to verify accredited investor status); SecondMarket Holdings, Inc. (''SecondMarket'') (''In addition, legitimate privacy concerns may result in potential investors being unwilling to provide highly sensitive personal information outside of a clearly protective framework, which may cause such investors to avoid participating in Rule 506 offerings.'').

[50] *See* letters from NASAA (July 3, 2012) (''Verification of net worth is more challenging because an individual could provide proof of assets but not liabilities.''); SecondMarket (indicating that, in its experience, the majority of natural persons who indicated that they were accredited investors did so based on the income test of Rule 501(a)(6), which can be verified through tax returns, Form W–2, Form 1099, or other income documentation, in addition to a pay stub from the current year, whereas verifying that a purchaser satisfies the net worth test may be very difficult; therefore, this commentator recommended that a ''substantial minimum investment requirement,'' coupled with representations by the purchaser, should be deemed sufficient evidence to presume that a purchaser satisfies the net worth test without requiring additional verification of that purchaser's accredited investor status).

[51] If an issuer has actual knowledge that the purchaser is an accredited investor, then the issuer would not have to take any steps at all.

[52] Such an organization is required to make the Form 990 series returns available for public inspection. *See* Internal Revenue Service, *Public Disclosure and Availability of Exempt Organizations Returns and Applications: Documents Subject to Public Disclosure, http://www.irs.gov/charities/article/0,,id=135008,00.html* (last updated Sept. 21, 2011).

[53] For example, in the future, services may develop that verify a person's accredited investor status for purposes of proposed Rule 506(c) and permit issuers to check the accredited investor status of possible investors, particularly for web-based Rule 506 offering portals that include offerings for multiple issuers. This third-party service, as opposed to the issuer itself, could obtain appropriate documentation or otherwise verify accredited investor status. Several commentators, in fact, have recommended that the Commission take action to facilitate the ability of issuers to rely on third parties to perform the necessary verification. *See* letters from NASAA (July 3, 2012) (recommending that the Commission allow an issuer to obtain the necessary verification through registered broker-dealers, provided that there are independent liability provisions for failure to adequately perform the verification); Massachusetts Securities Division (urging the Commission to adopt as a safe harbor or best practice the use of an independent party, such as a broker-dealer, bank, or other financial institution, that would verify the accredited investor status of potential purchasers). One commentator, however, expressed

Nature and Terms of the Offering. The nature of the offering—such as the means through which the issuer publicly solicits purchasers—may be relevant in determining the reasonableness of the steps taken to verify accredited investor status. An issuer that solicits new investors through a Web site accessible to the general public or through a widely disseminated email or social media solicitation would likely be obligated to take greater measures to verify accredited investor status than an issuer that solicits new investors from a database of pre-screened accredited investors created and maintained by a reasonably reliable third party, such as a registered broker-dealer. In the case of the former, we do not believe that an issuer would have taken reasonable steps to verify accredited investor status if it required only that a person check a box in a questionnaire or sign a form, absent other information about the purchaser indicating accredited investor status. In the case of the latter, we believe an issuer would be entitled to rely on a third party that has verified a person's status as an accredited investor, provided that the issuer has a reasonable basis to rely on such third-party verification.

The terms of the offering would also affect whether the verification methods used by the issuer are reasonable. Some commentators have expressed the view that a purchaser's ability to meet a high minimum investment amount could be relevant to the issuer's evaluation of the types of steps that would be reasonable to take in order to verify that purchaser's status as an accredited investor.[54] We believe that there is merit to this view. By way of example, the ability of a purchaser to satisfy a minimum investment amount requirement that is sufficiently high such that only accredited investors could reasonably be expected to meet it, with a direct cash investment that is not financed by the issuer or by any other third party, could be taken into consideration in verifying accredited investor status.

These factors are interconnected, and the information gained by looking at these factors would help an issuer assess the reasonable likelihood that a potential purchaser is an accredited investor, which would, in turn, affect the types of steps that would be reasonable to take to verify a purchaser's accredited investor status. After consideration of the facts and circumstances of the purchaser and of the transaction, if it appears likely that a person qualifies as an accredited investor, the issuer would have to take fewer steps to verify accredited investor status, and vice versa. For example, if an issuer knows little about the potential purchaser who seeks to qualify under the natural person tests for accredited investor status, but the terms of the offering require a high minimum investment amount, then it may be reasonable for the issuer to take no steps to verify accredited investor status other than to confirm that the purchaser's cash investment is not being financed by the issuer or by a third party, absent any facts that may indicate that the purchaser is not an accredited investor.

Regardless of the particular steps taken, it would be important for issuers to retain adequate records that document the steps taken to verify that a purchaser was an accredited investor. Any issuer claiming an exemption from the registration requirements of Section 5 has the burden of showing that it is entitled to that exemption.[55]

We are mindful of the differing views expressed by commentators to date on how the Commission should implement the verification mandate of Section 201(a). A number of commentators have cautioned that unduly prescriptive or burdensome rules for verifying a purchaser's accredited investor status would have the potential to result in significant economic harm, could lead to reluctance on the part of issuers to access the relevant capital markets, or would contravene the purposes of the JOBS Act.[56] Some commentators recommended approaches based on current practices or standards.[57] One commentator, for example, stated that whether a purchaser is an accredited investor depends on the particular facts and circumstances, that the current practices already take these considerations into account, and that the Commission should therefore refrain from imposing any additional burdens on issuers or purchasers.[58] Another commentator expressed similar views, recommending that the Commission adopt a principles-based non-exclusive safe harbor that would be flexible enough to accommodate new offering techniques and that would build on existing practices (such as broker-

concerns that some of the Web sites that currently offer lists of accredited investors could be used to facilitate fraud, noting that some offer lists based on ''ethnicity, gender, and lifestyle—presumably to make [it] easier for scammers to relate to marks—and ominously, 'seniors.' '' Letter from Moscovitz and Maxfield.

[54] *See, e.g.,* letters from MFA (May 4, 2012) (stating that many hedge funds managed by its members obtain further assurance that investors meet the qualification standards in the Investment Company Act or the Investment Advisers Act of 1940, as applicable, through minimum investment thresholds that meet or exceed the net worth test of the accredited investor definition); NASAA (July 3, 2012) (''For example, if an investor makes an investment of $1 million in the issuer's securities, it would be reasonable for the issuer to assume that the investor has $1 million in net worth, even though it is not necessarily a certainty. NASAA would not oppose the creation of this type of specific safe harbor, provided the factors used to demonstrate the requisite net worth are set sufficiently high.''); SecondMarket (recommending that a ''substantial minimum investment requirement,'' coupled with representations by the purchaser, should be deemed sufficient evidence to presume that a purchaser satisfies the net worth test without requiring additional verification of that purchaser's accredited investor status). One commentator, however, disagreed with this approach, noting that ''[w]hile a large investment amount may indicate that the investor is wealthy, it also might indicate that a non-wealthy investor is over-concentrated in the investment.'' Letter from Massachusetts Securities Division.

[55] *SEC* v. *Ralston Purina,* 346 U.S. 119, 126 (1953) (''Keeping in mind the broadly remedial purposes of federal securities legislation, imposition of the burden of proof on an issuer who would plead the exemption seems to us fair and reasonable.'').

[56] *See, e.g.,* letters from Committee on Securities Regulation of the New York City Bar Association (''NYC Bar Association'') (stating that unduly detailed or prescriptive verification rules would ''have the potential to result in significant economic harm''); SecondMarket (asserting that ''[p]lacing too heavy a burden on issuers and investors could have the undesired effect of inhibiting private capital formation'' and that ''issuers are likely to be unwilling or unable to assume the liability and cost that would arise from a significant documentary verification requirement''); NSBA (Aug. 2, 2012) (stating that ''imposing additional burdens on Rule 506 issuers who engage in general solicitation or general advertising would make it more difficult for small firms to raise capital''); Small Biotechnology Business Coalition (''SBBC'') (stating that additional burdens on issuers seeking to utilize Rule 506 would make it more difficult for small firms to raise capital, and make it less likely that investors will invest in small firms); ABA (asserting that a verification requirement that imposes additional burdens on issuers or purchasers ''would contravene the fundamental impetus for the JOBS Act''); MFA (June 26, 2012) (stating that ''overly restrictive procedures * * * would have the effect of thwarting the purposes of Title II of the JOBS Act'').

[57] *See, e.g.,* letters from BrokerBank (noting that self-certification of accredited investor status has been the ''procedure that has been followed by the industry for decades'' and urging the Commission to continue to allow self-certification of accredited status of individuals wishing to participate in Rule 506 offerings that utilize general solicitation); Phillip Goldstein, Bulldog Investors (''Goldstein'') (July 18, 2012) (urging that the Commission ''promptly create a simple form that an issuer can provide to an investor to certify that he or she is accredited''); MFA (May 4, 2012) (stating that methods similar to those currently used by hedge fund managers, which include the identification by the purchaser of the qualification standards that it meets and minimum investment thresholds, would achieve the objectives of Section 201(a)); Securities Industry and Financial Markets Association (''SIFMA'') (urging that the requirement to take reasonable steps to verify should not impose a higher burden than the ''reasonable belief'' standard currently applicable to Rule 506 offerings and that an issuer should be deemed to have taken reasonable steps to verify if it has reasonable belief that the offeree is an eligible offeree).

[58] Letter from ABA.

dealers' account-opening and suitability procedures).[59]

Other commentators stated that the verification mandate of Section 201(a) requires the Commission to enhance the current standard under which issuers determine that purchasers are accredited investors.[60] In their view, the verification mandate of Section 201(a) calls for a standard that is higher than the current reasonable belief standard in the Rule 501(a) definition of accredited investor and such higher standard is needed in light of the greater likelihood of fraudulent activities resulting from the removal of the prohibition against general solicitation. Therefore, these commentators believe that the Commission must mandate the specific steps that issuers must take in order to form a reasonable belief that a purchaser is an accredited investor.[61]

We also received a number of comments on specific methods that should or should not be viewed as reasonable steps for verifying accredited investor status. For example, some viewed a representation from the purchaser that it is an accredited investor as sufficient,[62] while others asserted that such a representation alone would not be enough.[63] Several commentators stated that the verification of accredited investor status should require the production of documentary evidence.[64] One commentator recommended that only registered broker-dealers, and not other intermediaries, be permitted to verify accredited investor status on behalf of issuers because registered broker-dealers are subject to existing regulatory schemes, including Commission oversight.[65] Other commentators recommended allowing issuers to rely on third-party firms to verify accredited investor status.[66] Some commentators suggested that purchasers be required to submit a letter from a third party with knowledge of the purchaser's financial status (such as a certified public accountant or attorney) indicating that the purchaser is an accredited investor,[67] while another commentator suggested that, in combination with an independent professional's certification as to the purchaser's accredited investor status, the purchaser be required to certify his or her accredited investor status under penalty of perjury.[68] Another commentator stated that issuers should be allowed to rely on basic information about a purchaser that they may already have (for example, that the purchaser is an officer of a Fortune 500 company).[69] One commentator suggested that the Commission adopt an approach under which a minimum investment of 50% of the net worth or total assets requirement under the applicable category of accredited investor, coupled with a certification by the investor, would be deemed to constitute ''reasonable steps'' to verify accredited investor status.[70] Another commentator suggested that investors be permitted to self-certify their accredited investor status so long as at least 30 days have passed between the first date of public solicitation and the date of investment.[71]

We believe that the approach we are proposing appropriately addresses these concerns by obligating issuers to take reasonable steps to verify that the purchasers are accredited investors, as mandated by Section 201(a), but not requiring them to follow uniform verification methods that may be ill-suited or unnecessary to a particular offering or purchaser, given the facts and circumstances. We also expect that such an approach would give issuers and market participants the flexibility to adopt different approaches to verification depending on the circumstances, to adapt to changing market practices, and to implement innovative approaches to meeting the verification requirement, such as the development of third-party databases of accredited investors. In addition, we anticipate that many practices currently used by issuers in connection with existing Rule 506 offerings would satisfy the verification requirement proposed for offerings pursuant to Rule 506(c).

We considered but have decided not to propose requiring issuers to use specified methods of verification. We believe that, at present, proposing to require issuers to use specified methods of verification would be impractical and potentially ineffective in light of the numerous ways in which a purchaser can qualify as an accredited investor, as well as the potentially wide range of verification issues that may arise, depending on the nature of the purchaser and the facts and circumstances of a particular Rule 506(c) offering. We are also concerned that a prescriptive rule that specifies required verification methods could be overly burdensome in some cases, by requiring issuers to follow the same steps, regardless of their particular circumstances, and ineffective in others, by requiring steps that, in the particular

[59] Letter from NYC Bar Association. For example, in connection with complying with anti-money laundering requirements, broker-dealers already obtain certain identifying information about their customers.

[60] *See* letters from Fund Democracy; Moscovitz and Maxfield; NASAA (July 3, 2012); Ohio Division; Public Citizen.

[61] *Id.*

[62] Letters from Goldstein (June 3, 2012); Mona Shah & Associates; SIFMA; JC Williams II, Tucson Business Development Group (''Williams'').

[63] Letters from Fund Democracy (stating that a representation from the purchaser that it is an accredited investor would not satisfy the statutory mandate that the issuer take steps to verify accredited investor status); John C. Nimmer (''Nimmer''); Ohio Division (''A 'check-the-box' approach to investor self-verification of accredited status will not suffice because the Title II issuer must have more than a belief that a prospective purchaser is accredited.'').

[64] *See* letters from Massachusetts Securities Division (stating that verification should require issuers to determine whether investors are accredited based on documentary evidence, rather than just representations from potential investors); NASAA (July 3, 2012) (recommending that the Commission require issuers to obtain documents such as tax returns, recent pay stubs, brokerage statements, tax assessment valuations, appraisals, list of liabilities (including a sworn statement that all material liabilities have been disclosed), organizational documents, balance sheets, and quarterly statements); Ohio Division (recommending that the issuer should ''review financial statements and/or tax returns evidencing actual satisfaction of accredited investor thresholds'' and, with respect to entities claiming to be accredited investors, should review ''regulatory letters or certificates approving or confirming the entity's status as a bank, insurance company, registered investment company, business development company, or small business investment company'').

[65] Letter from SecondMarket (also suggesting that the Commission establish specific guidelines that registered broker-dealers must follow with respect to the verification process in order to be an approved ''accreditation verification provider'').

[66] *See* letters from National Investment Banking Association (''NIBA'') (recommending that if a FINRA member firm is not involved in the offering, then the issuer could satisfy the verification mandate by relying on a third-party report obtained from an investigatory firm indicating that a purchaser is an accredited investor; if a broker-dealer is involved in the offering as a placement agent, the issuer could satisfy the verification mandate by obtaining and reviewing a form from the broker-dealer that describes the process undertaken by the broker-dealer to establish accredited investor status for a purchaser); NSBA (Aug. 2, 2012) (stating that ''[r]equiring investors to provide to issuers an independent professional's certification as to the investor's accredited investor status and requiring the investor to certify his or her own status under penalty of perjury would provide a high degree of protection against non-accredited investors asserting accredited investor status in Regulation D offerings''); Sigelman Law Corporation (asserting that third-party verification of accredited investor status should not be limited to broker-dealers but that independent third-party professional intermediaries ''registered with the Commission and sworn to follow the protocol rules'' should be allowed to provide such services).

[67] *See* letters from Frank Nagy; Williams.

[68] Letter from NSBA (Aug. 2, 2012) (stating that Section 1746 of Title 28 of the United States Code authorizes this approach). One commentator stated that self-certification under penalty of perjury, in and of itself, should be sufficient. Letter from Nimmer.

[69] Letter from AngelList.

[70] Letter from MFA (June 26, 2012).

[71] Letter from SBBC (noting that such a ''cooling off'' period will help discourage impulse investments and will permit the issuer and the investor to assess one another).

circumstances, would not actually verify accredited investor status.

For similar reasons, we considered but have decided not to propose providing a non-exclusive list of specified methods for satisfying the verification requirement.[72] We are concerned that, in designating such a list—for example, by setting forth particular types of information that issuers may rely upon as conclusive means of verifying accredited investor status—there may be circumstances where such information would not actually verify accredited investor status or where issuers may unreasonably overlook or disregard other information indicating that a purchaser is not, in fact, an accredited investor. Indeed, a method that is reasonable under one set of circumstances may not be reasonable under a different set of circumstances. In addition, we are concerned that a non-exclusive list of specified verification methods could be viewed by market participants as the required verification methods, in which compliance with at least one of the enumerated methods could be viewed, in the practical application of the verification requirement, as necessary in all circumstances to demonstrate that the verification requirement has been satisfied, thereby eliminating the flexibility that proposed Rule 506(c) is intended to provide. Such flexibility is likely to mitigate the cost to issuers of complying with proposed Rule 506(c) because it would allow them to select the most cost-effective verification method for each offering, based on the particular facts and circumstances of the offering and of the investors.

We are soliciting comment on a variety of possible approaches to verification. In addition, following the completion of this rulemaking, we intend to monitor and study the development of verification practices by issuers, securities intermediaries and others as well as the impact of compliance with this requirement on investor protection and capital formation.

C. Reasonable Belief That All Purchasers Are Accredited Investors

A number of commentators have raised concerns that the language of Section 201(a) could be interpreted as precluding the use of the ''reasonable belief'' standard in Rule 501(a) in determining whether a purchaser is an accredited investor, such that an issuer's determination as to whether a purchaser is an accredited investor is subject to an absolute, rather than a ''reasonable belief,'' standard.[73] Section 201(a)(2) of the JOBS Act, which calls for amendments to Rule 144A, specifically refers to a ''reasonable belief'' standard as to whether a purchaser is a QIB, whereas Section 201(a)(1) does not mention a similar ''reasonable belief'' standard with respect to the amendments to Rule 506.[74] From this, some commentators have requested that our proposed rule amendments ''confirm'' that the reasonable belief standard for accredited investor status in Rule 501(a) continues to apply.[75] In their view, issuers may be more reluctant to use general solicitation in Rule 506 offerings if their determinations as to whether a purchaser is an accredited investor are subject to an absolute standard. One commentator added that the Commission should adopt a safe harbor under which an issuer or broker-dealer would not be penalized if it took the steps required by the Commission to verify a purchaser's accredited investor status, but later learned that the purchaser was not, in fact, an accredited investor.[76] Other commentators have interpreted this omission as indicating Congress's intent that the Commission ''raise the 'reasonable belief' standard for Rule 506 offerings. * * * ''[77]

Both Rule 506 and Rule 144A currently provide for a reasonable belief standard regarding the eligibility of an investor to participate in an offering under the respective rules, but they reach that result in different ways. For Rule 506, the Commission chose to include the reasonable belief standard within the Rule 501(a) definition of ''accredited investor''; for Rule 144A, the Commission chose to include the standard as a condition, in paragraph (d)(1), to the use of the exemption.[78] The definition of accredited investor remains unchanged with the enactment of the JOBS Act and includes persons that come within any of the listed categories of accredited investors, as well as persons that the issuer reasonably believes come within any such category. In our view, the difference in the language between Section 201(a)(1) and Section 201(a)(2) reflects only the differing manner in which the reasonable belief standard was included in the respective rules at the time they were adopted, and does not represent a Congressional intent to eliminate the existing reasonable belief standard in Rule 501(a) or for Rule 506 offerings.

We recognize that a person could provide false information or documentation to an issuer in order to purchase securities in an offering made under proposed Rule 506(c). Thus, even if an issuer has taken reasonable steps to verify that a purchaser is an accredited investor, it is possible that a person nevertheless could circumvent those measures.[79] If a person who does not meet the criteria for any category of accredited investor purchases securities in a Rule 506(c) offering, we believe that the issuer would not lose the ability to rely on the proposed Rule 506(c) exemption for that offering, so long as the issuer took reasonable steps to verify that the purchaser was an accredited

[72] *See* letters from MFA (June 26, 2012) (suggesting that the Commission publish a non-exclusive list of the types of third-party evidence that an investor could provide to establish accredited investor status, in conjunction with certifying that he or she is an accredited investor); NASAA (July 3, 2012) (recommending that the Commission set forth non-exclusive safe harbors to specify the types of actions that would be deemed ''reasonable steps to verify'' for three types of accredited investors: natural persons who purport to satisfy the income test; natural persons who purport to satisfy the net worth test; and entities who purport to meet one of the other tests set forth in Rule 501(a)).

[73] *See, e.g.,* letters from ABA; BlackRock, Inc. (''BlackRock''); NYC Bar Association; William K. Sjostrom, Jr.

[74] *See, e.g.,* letters from ABA; Fund Democracy; NYC Bar Association.

[75] *See, e.g.,* letter from ABA.

[76] Letter from NIBA. To facilitate third-party verification of accredited investor status, another commentator requested clarification that a third party providing verification services for issuers would not incur any liability as long as it had a reasonable belief that a purchaser was an accredited investor, based on its knowledge of the investor. Letter from AngelList.

[77] Letter from Fund Democracy. *See also* letter from Massachusetts Securities Division.

[78] Regulation S also has a reasonable belief standard with respect to the requirement that the offer or sale be made to a person outside the United States. *See* Rule 902(h)(1)(ii)(A) [17 CFR 230.902(h)(1)(ii)(A)] (''At the time the buy order is originated, the buyer is outside the United States, or the seller and any person acting on its behalf reasonably believe that the buyer is outside the United States.'').

[79] We note that several federal courts have been unsympathetic to attempts by investors who represented that they were accredited investors at the time of the sale of securities to subsequently disavow those representations in order to pursue a cause of action under the federal securities laws. *See, e.g., Wright* v. *Nat'l Warranty Co.,* 953 F.2d 256 (6th Cir. 1991) (rejecting the plaintiffs' argument that Rule 505 was unavailable because the plaintiffs ''specifically warranted and represented in the subscription agreement * * * that they were accredited investors''); *Goodwin Properties, LLC* v. *Acadia Group, Inc.,* 2001 U.S. Dist. LEXIS 9975 (D. Me. 2001) (noting that the plaintiffs ''provided the defendants with reason to believe that they were accredited investors as defined by 17 C.F.R. § 230.501(a)'' and stating that therefore ''[t]hey cannot now disavow those representations in order to support their claims against the defendants''); *Faye L. Roth Revocable Trust* v. *UBS Painewebber Inc.,* 323 F. Supp. 2d 1279 (S.D. Fla. 2004) (stating that the plaintiffs ''cannot disavow their representations that they were accredited investors'' and concluding that there was no material dispute that the offering complied with Regulation D).

investor and had a reasonable belief that such purchaser was an accredited investor.[80]

D. Form D Check Box for Rule 506(c) Offerings

Form D is the notice of an offering of securities made without registration under the Securities Act in reliance on an exemption provided by Regulation D.[81] Under Rule 503 of Regulation D, an issuer offering or selling securities in reliance on Rule 504, 505 or 506 must file a notice of sales on Form D with the Commission for each new offering of securities no later than 15 calendar days after the first sale of securities in the offering. Form D is currently organized around 16 numbered ''items'' or categories of information. The information required to be provided in a Form D filing includes basic identifying information, such as the name of the issuer of the securities and the issuer's year and place of incorporation or organization; information about related persons (executive officers, directors, and promoters); identification of the exemption or exemptions being claimed for the offering; and factual information about the offering, such as the duration of the offering, the type of securities offered, and the total offering amount.

We are proposing a revision to Form D to add a separate field or check box for issuers to indicate whether they are claiming an exemption under Rule 506(c). Item 6 of Form D currently requires the issuer to identify the claimed exemption or exemptions for the offering from among Rule 504's paragraphs and subparagraphs, Rule 505, Rule 506 and Section 4(5), as applicable. A new check box in Item 6 of Form D would require issuers to indicate specifically whether they are relying on the proposed Rule 506(c) exemption. In addition, the current check box for ''Rule 506'' would be renamed ''Rule 506(b),'' and the current check box for ''Section 4(5)'' would be renamed ''Section 4(a)(5)'' to update the reference to former Section 4(5) of the Securities Act.

We are proposing to require this additional information in order to assist our efforts to monitor the use of general solicitation in Rule 506(c) offerings and the size of this offering market. This information would also help us to look into the practices that would develop to satisfy the verification requirement, which would help us assess the effectiveness of various verification practices in identifying and excluding non-accredited investors from participation in proposed Rule 506(c) offerings.

E. Specific Issues for Privately Offered Funds

Privately offered funds, such as hedge funds, venture capital funds and private equity funds, typically rely on Section 4(a)(2) and the Rule 506 safe harbor to offer and sell their interests without registration under the Securities Act.[82] In addition, privately offered funds generally rely on one of two exclusions from the definition of ''investment company'' under the Investment Company Act, which enables them to be excluded from the regulatory provisions of that Act. Privately offered funds are precluded from relying on either of the two exclusions set forth in Section 3(c)(1)[83] and Section 3(c)(7)[84] of the Investment Company Act if they make a public offering of their securities.[85] Section 3(c)(1) excludes from the definition of ''investment company''any issuer whose outstanding securities (other than short-term paper) are beneficially owned by not more than 100 beneficial owners,[86] and which is not making and does not presently propose to make a public offering of its securities. Section 3(c)(7) excludes from the definition of ''investment company'' any issuer whose outstanding securities are owned exclusively by persons who, at the time of acquisition of such securities, are ''qualified purchasers,''[87] and which is not making and does not at that time propose to make a public offering of its securities.

The JOBS Act directs the Commission to eliminate the prohibition against general solicitation for a new subset of Rule 506 offerings, and makes no specific reference to privately offered funds. Section 201(b) of the JOBS Act also provides that ''[o]ffers and sales exempt under [Rule 506, as revised pursuant to Section 201(a)] shall not be deemed public offerings under the Federal securities laws as a result of general advertising or general solicitation.'' We historically have regarded Rule 506 transactions as non-public offerings for purposes of Sections 3(c)(1) and 3(c)(7).[88] We believe the effect of Section 201(b) is to permit privately offered funds to make a general solicitation under amended Rule 506 without losing either of the exclusions under the Investment Company Act.

F. Technical and Conforming Amendments

We are proposing a number of technical and conforming amendments to Rules 502 and 506 of Regulation D. We are proposing amendments to various provisions in Rule 502(b) to clarify that the references to sales to non-accredited investors under Rule 506, and the corresponding informational requirements, would be applicable to offerings under Rule 506(b) and not to offerings under proposed Rule 506(c). We are also proposing an amendment to Rule 502(c) to clarify that Rule 502(c)'s prohibition against general solicitation would not apply to offerings under proposed Rule 506(c).

[80] Our views regarding an issuer's ability to maintain the exemption for a proposed Rule 506(c) offering notwithstanding the fact that not all purchasers are accredited investors are consistent with our views regarding the effect of attempts by prospective investors to circumvent the requirement in Regulation S that offers and sales be made only to non-U.S. persons. *See Statement of the Commission Regarding Use of Internet Web Sites to Offer Securities, Solicit Securities Transactions or Advertise Investment Services Offshore,* Release No. 33–7516 (Mar. 23, 1998) [63 FR 14806] (''In our view, if a U.S. person purchases securities or investment services notwithstanding adequate procedures reasonably designed to prevent the purchase, we would not view the Internet offer after the fact as having been targeted at the United States, absent indications that would put the issuer on notice that the purchaser was a U.S. person.'').

[81] Form D also applies to offerings conducted using the Section 4(a)(5) exemption. The Commission adopted Form D when it adopted Regulation D in 1982. Release No. 33–6389 (adopting Form D as a replacement for Forms 4(6), 146, 240 and 242).

[82] *See, e.g., Implications of the Growth of Hedge Funds, Staff Report to the Securities and Exchange Commission* (Sept. 2003), available at: *http://www.sec.gov/news/studies/hedgefunds0903.pdf.*

[83] 15 U.S.C. 80a–3(c)(1).

[84] 15 U.S.C. 80a–3(c)(7).

[85] *See also* Section 202(a)(29) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–2(a)(29)] (defining a ''private fund'' as an issuer that would be an investment company under the Investment Company Act, but for Sections 3(c)(1) and 3(c)(7) of that Act). Many issuers of asset-backed securities (''ABS'') also rely on the exclusions contained in Sections 3(c)(1) and 3(c)(7) of the Investment Company Act. These ABS issuers frequently participate in Rule 144A offerings.

[86] *See also* Rule 3c–5 under the Investment Company Act [17 CFR 270.3c–5] (providing that the section's limit of 100 beneficial owners does not include ''knowledgeable employees,'' as defined in the rule).

[87] *See* Section 2(a)(51) of the Investment Company Act [15 U.S.C. 80a–2(a)(51)] and the rules thereunder. *See also* Rule 3c–5 under the Investment Company Act (excluding ''knowledgeable employees'' from the determination of whether all of the outstanding securities of the Section 3(c)(7) fund are owned exclusively by qualified purchasers).

[88] *See* Release No. 33–6389 (noting that the ''Commission regards rule 506 transactions as non-public offerings for purposes of the definition of 'investment company' in section 3(c)(1) of the Investment Company Act''); *Privately Offered Investment Companies,* Release No. IC–22597 (Apr. 3, 1997) [62 FR 17512], at n.5 (noting that the ''Commission believes that section 3(c)(7)'s public offering limitation should be interpreted in the same manner as the limitation in section 3(c)(1)'').

As Section 201(c) of the JOBS Act renumbered Section 4 of the Securities Act, we are also proposing amendments to Regulation D and Rule 144A to update the references to Section 4. We are also proposing to update references to Section 2 of the Securities Act in these rules as some of the references have not been updated to reflect the current numbering scheme in Section 2.

G. Request for Comment

1. Will the Commission's proposed approach to implementing the verification mandate of Section 201(a) be effective in limiting issuers' sales to only accredited investors in Rule 506 offerings that use general solicitation? Should the Commission adopt a rule that specifies the methods that issuers must use or could use to verify accredited investor status? Would such an approach provide greater certainty for issuers than the approach that we are proposing? Would the inclusion of a specified list result in an assumption or practice that the listed methods are ''de facto'' requirements, thereby inappropriately reducing flexibility and effectiveness of the new rule? What are the benefits and costs of each approach? In the case of the latter, if the Commission were to adopt such a rule, should it be in the form of a safe harbor for compliance with the verification requirement? What would be examples of the types of methods that issuers could use to verify accredited investor status, and what would be the merits of each such method?

2. Some commentators have recommended that the Commission look to current market practices in determining the methods that should be required or permitted for verifying accredited investor status. As noted above, we anticipate that many practices currently used by issuers in connection with existing Rule 506 offerings would satisfy the verification requirement proposed for offerings pursuant to Rule 506(c). How effective have these practices been in assessing the eligibility of purchasers to participate in an offering made under Regulation D? Are certain practices more effective than others? If so, please describe these practices with specificity. What are the costs and benefits of these practices (to issuers, investors and other market participants)?

3. Under what circumstances, if any, should an issuer be deemed to have taken ''reasonable steps to verify'' if the only action taken by the issuer is to request a representation from a purchaser that it is an accredited investor, as some have suggested? [89] Should the Commission provide that an issuer is deemed to have taken ''reasonable steps to verify'' if the issuer ''reasonably believes'' that such a purchaser is an accredited investor, as some have suggested? [90] What are the potential benefits and potential harms of such an approach?

4. As we noted above, depending on the facts and circumstances, we believe there is merit to the view that the ability of a purchaser to satisfy the high minimum investment amount required to participate in an offering may be a relevant factor in determining whether that purchaser is an accredited investor. At the same time, we also believe that issuers must be mindful of any indications that the purchaser, despite the ability to provide the funds needed to satisfy a high minimum investment amount requirement, may not actually be an accredited investor. We have noted that the financing of a purchaser's cash investment by the issuer or a third party is a factor that an issuer should consider. Are there other factors? In light of these considerations, should the Commission specifically provide that a high minimum investment amount is sufficient, in and of itself, to satisfy the requirement that the issuer has taken reasonable steps to verify a purchaser's accredited investor status, provided that the high minimum investment amount is not being financed by the issuer or any third party? If so, should the rule specify an amount, and, if so, what amount would be appropriate?

5. Are there certain types of issuers (*e.g.,* shell companies, blank check companies or issuers of penny stock, as defined by Exchange Act Rule 3a51–1 [91]) that would present heightened investor protection concerns as a result of the removal of the prohibition against general solicitation? If so, what actions should the Commission take to address these concerns? Should these issuers be subject to a different verification standard for offerings made under proposed Rule 506(c)?

6. Verification methods could include obtaining information from prospective purchasers, such as Forms W–2, personal bank and brokerage account statements and similar documentation. We are cognizant that prospective purchasers may have privacy concerns when undergoing a verification process by issuers.[92] Do any other concerns in addition to privacy concerns arise from a requirement to provide such information? How, if at all, could the Commission address these concerns? [93] What other documentation could be used to verify accredited investor status while minimizing privacy concerns? Does use of a reasonably reliable third party to provide this information respond to those concerns?

7. Currently, Rule 508 of Regulation D [94] provides that the exemption in Rule 506 will not be lost due to an ''insignificant'' deviation from a term, condition, or requirement of Regulation D. Should Rule 508 be amended to include any additional provisions specifically related to proposed Rule 506(c)?

8. Should the Commission amend Form D to include a check box for issuers to indicate whether they are claiming an exemption under Rule 506(c), as proposed? If not, why not?

9. Are there any other rule amendments necessary or appropriate to implement the statutory mandate of Section 201(a) of the JOBS Act? Are there any other measures that the Commission should consider taking in connection with the removal of the prohibition against general solicitation?

III. Proposed Amendment to Rule 144A

A. Offers to Persons Other Than Qualified Institutional Buyers

Section 201(a)(2) of the JOBS Act directs the Commission to revise Rule 144A(d)(1) under the Securities Act to provide that securities sold pursuant to Rule 144A may be offered to persons other than QIBs, including by means of general solicitation, provided that securities are sold only to persons that the seller and any person acting on behalf of the seller reasonably believe is a QIB. In the amendment to Rule 144A that we are proposing, we would amend Rule 144A(d)(1) to eliminate the references to ''offer'' and ''offeree.'' As amended, the rule would require only that the securities are sold to a QIB or to a purchaser that the seller and any person acting on behalf of the seller reasonably believe is a QIB.[95] Under this proposed amendment, resales of securities pursuant to Rule 144A could be conducted using general solicitation, so long as the purchasers are limited in this manner.

B. Request for Comment

10. Rule 144A currently provides a list of non-exclusive methods of

[89] *See, e.g.,* letter from SIFMA.

[90] *See id.*

[91] 17 CFR 240.3a51–1.

[92] *See, e.g.,* letter from ABA.

[93] *See, e.g.,* letter from NASAA (July 3, 2012) (recommending that the Commission require issuers to maintain the confidentiality of any information received for the purpose of verifying accredited investors status).

[94] 17 CFR 230.508.

[95] Proposed Rule 144A(d)(1).

establishing a prospective purchaser's ownership and discretionary investments of securities for purposes of determining whether the prospective purchaser is a QIB.[96] How has this non-exclusive list worked in practice? Do issuers favor a non-exclusive list? Why or why not? Has the non-exclusive list resulted in an assumption or practice that the listed methods are ''de facto'' requirements?

IV. Integration with Offshore Offerings

Regulation S provides a safe harbor for offers and sales of securities outside the United States and includes an issuer and a resale safe harbor. Two general conditions apply to both safe harbors: (1) The securities must be sold in an offshore transaction and (2) there can be no directed selling efforts[97] in the United States.[98] The safe harbors are important when U.S. and foreign companies engage in global offerings of securities in which the U.S. portion of the offering is conducted in accordance with Rule 144A or Rule 506 and the offshore portion is conducted in reliance on Regulation S.

The mandate in Section 201(a) that the Commission amend Rule 506 and Rule 144A to permit the use of general solicitation in transactions under those rules has raised questions from some commentators regarding the impact of the use of general solicitation on the availability of the Regulation S safe harbors for concurrent unregistered offerings inside and outside the United States.[99] One commentator recommended that the Commission reexamine the directed selling efforts concept in light of the terms and policy objectives of Section 201 of the JOBS Act, as well as evolving technology and offering techniques.[100] Another recommended that, although the JOBS Act does not explicitly address Section 4(a)(2) or the definition of directed selling efforts in Regulation S, there is no policy reason for distinguishing between the various exemptions and maintaining a prohibition against general solicitation in some but not others.[101] We also received requests that the Commission confirm that the use of general solicitation in offerings conducted pursuant to Rule 506 or Rule 144A, as amended, would not be deemed to constitute directed selling efforts by that issuer in connection with a contemporaneous offering under Regulation S.[102] One commentator asked for clarification that the limitations in Securities Act Rule 135c[103] do not apply to offerings pursuant to Rule 506 or Rule 144A where general solicitation is permitted,[104] while another commentator suggested that the information on Regulation S offerings that is permitted to be communicated in the United States continue to be limited to the information permitted under Rule 135c, but regardless of whether the issuer meets the eligibility criteria in Rule 135c.[105]

In the adopting release for Regulation S, the Commission stated that ''[o]ffshore transactions made in compliance with Regulation S will not be integrated with registered domestic offerings or domestic offerings that satisfy the requirements for an exemption from registration under the Securities Act.''[106] We believe that this approach continues to apply. Consistent with the historical treatment of concurrent Regulation S and Rule 144A/Rule 506 offerings, concurrent offshore offerings that are conducted in compliance with Regulation S would not be integrated with domestic unregistered offerings that are conducted in compliance with Rule 506 or Rule 144A, as proposed to be amended.

V. General Request for Comment

We request and encourage any interested person to submit comments regarding the proposed rule and form amendments, specific issues discussed in this release, and other matters that may have an effect on the proposed rules. We request comment from the point of view of issuers, investors and other market participants. With regard to any comments, we note that such comments are of particular assistance to us if accompanied by supporting data and analysis of the issues addressed in those comments. Commentators are urged to be as specific as possible.

VI. Paperwork Reduction Act

The proposed amendment to Form D contains a ''collection of information'' requirement within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[107] The title of this requirement is: ''Form D'' (OMB Control No. 3235–0076).[108] We adopted Regulation D and Form D as part of the establishment of a series of exemptions for offerings and sales of securities under the Securities Act. We are submitting this requirement to the Office of Management and Budget (''OMB'') for review and approval in accordance with the PRA and its implementing regulations.[109]

The information collection requirements related to the filing of Form D with the Commission are mandatory to the extent that an issuer elects to make an offering of securities in reliance on the relevant exemption. Responses are not confidential. The hours and costs associated with preparing and filing forms and retaining records constitute reporting and cost burdens imposed by the collection of information requirements. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information requirement unless it displays a currently valid OMB control number.

The Form D filing is required to be made by issuers as a notice of sales without registration under the Securities Act based on a claim of exemption under Regulation D or Section 4(a)(5) of the Securities Act. The Form D is required to include basic information about the issuer, certain related persons, and the offering. This information is needed for implementing the exemptions and monitoring their use.

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[96] Rule 144A(d)(1).

[97] Rule 902(c)(1) [17 CFR 230.902(c)(1)] broadly defines ''directed selling efforts'' as: any activity undertaken for the purpose of, or that could reasonably be expected to have the effect of, conditioning the market in the United States for any of the securities offered in reliance on Regulation S. Such activity includes placing an advertisement in a publication ''with a general circulation in the United States'' that refers to the offering of securities being made in reliance upon Regulation S.

[98] *See* Rules 903 [17 CFR 230.903] and 904 [17 CFR 230.904] under the Securities Act.

[99] *See, e.g.,* letters from ABA; Lee D. Neumann (''Neumann''); NYC Bar Association; SecuritiesLawUSA, PC (''SecuritiesLawUSA''); SIFMA.

[100] Letter from NYC Bar Association.

[101] Letter from SIFMA.

[102] Letters from ABA; SecuritiesLawUSA.

[103] 17 CFR 230.135c.

[104] Letter from SecuritiesLawUSA.

[105] Letter from Neumann.

[106] *See Offshore Offers and Sales,* Release 33–6863 (Apr. 24, 1990) [55 FR 18306], at Section III.C.1. In addressing the offshore transaction component of the Regulation S safe harbor, the Commission stated, ''Offers made in the United States in connection with contemporaneous registered offerings or offerings exempt from registration will not preclude reliance on the safe harbors.'' *Id.* at fn. 36. Likewise, in addressing directed selling efforts, the Commission stated, ''Offering activities in contemporaneous registered offerings or offerings exempt from registration will not preclude reliance on the safe harbors.'' *Id.* at fn. 47. *See also* Rule 500(g) of Regulation D [17 CFR 230.500(g)] (formerly Preliminary Note No. 7 to Regulation D) (''Regulation S may be relied upon for such offers and sales even if coincident offers and sales are made in accordance with Regulation D inside the United States.'').

[107] 44 U.S.C. 3501 *et seq.*

[108] Form D was adopted pursuant to Sections 2(a)(15), 3(b), 4(a)(2), 19(a) and 19(c)(3) of the Securities Act (15 U.S.C. 77b(a)(15), 77c(b), 77d(a)(2), 77s(a) and 77s(c)(3)).

[109] 44 U.S.C. 3507(d); 5 CFR 1320.11.

We are proposing to amend Form D to add a check box to indicate an offering relying on the Rule 506(c) exemption. We believe this proposed change would have a negligible effect on the paperwork burden of the form. Accordingly, we estimate that under the proposed amendment to Form D, the burden for responding to the collection of information in Form D would be substantially the same as before the proposed amendment to Form D because the additional information required in the form is minimal. However, we believe that the proposed amendment to Rule 506 would increase the number of Form D filings that are made with the Commission.

The table below shows the current total annual compliance burden, in hours and in costs, of the collection of information pursuant to Form D. For purposes of the PRA, we estimate that, over a three-year period, the average burden estimate will be 4 hours per Form D. Our burden estimate represents the average burden for all issuers. This burden is reflected as a one hour burden of preparation on the company and a cost of $1,200 per filing. In deriving these estimates, we assume that 25% of the burden of preparation is carried by the issuer internally and that 75% of the burden of preparation is carried by outside professionals retained by the issuer at an average cost of $400 per hour. The portion of the burden carried by outside professionals is reflected as a cost, while the portion of the burden carried by the issuer internally is reflected in hours.

TABLE 1—ESTIMATED PAPERWORK BURDEN UNDER FORM D, PRE-AMENDMENT TO RULE 506

	Number of responses (A) [110]	Burden hours/ form (B)	Total burden hours (C) = (A)*(B)	Internal issuer time (D)	External professional time (E)	Professional costs (F) = (E)*$400
Form D	25,000	4	100,000	25,000	75,000	$30,000,000

According to our Division of Risk, Strategy, and Financial Innovation, in 2011, 15,930 companies made 18,174 new Form D filings. The annual number of new Form D filings rose from 13,764 in 2009 to 18,174 in 2011, an average increase of approximately 2,205 Form D filings per year, or approximately 15%. Assuming the number of Form D filings continues to increase by 2,205 filings per year for each of the next three years, the average number of Form D filings in each of the next three years would be approximately 22,584.

We estimate that the proposed amendment to Rule 506 would result in an even greater annual increase in the number of Form D filings. As a reference point, we use the impact of a past rule change on the market for Regulation D offerings. In 1997, the Commission amended Rule 144(d) under the Securities Act [111] to reduce the holding period for restricted securities from two years to one year,[112] thereby increasing the attractiveness of Regulation D offerings to investors and to issuers. There were 10,341 Form D filings in 1996. This was followed by a 20% increase in the number of Form D filings in each of the subsequent three calendar years, reaching 17,830 by 1999. Although it is not possible to predict with any degree of accuracy the increase in the number of Rule 506 offerings following the elimination of the prohibition against general solicitation, we anticipate that there would be a similarly significant increase. For purposes of the PRA, we estimate that the proposed amendment to Rule 506 would result in a 20% increase in Form D filings relying on the Rule 506 exemption, or approximately 5,000 filings, based on the number of responses as reported in the OMB's Inventory of Currently Approved Information Collections.[113] We also assume that the number of Form D filings would increase by approximately 5,000 in each year following the adoption of the rule.

Based on this increase, we estimate that the annual compliance burden of the collection of information requirements for issuers making Form D filings after Rule 506 is amended to eliminate the prohibition against general solicitation would be an aggregate 30,000 hours of issuer personnel time and $36,000,000 for the services of outside professionals per year.

TABLE 2—ESTIMATED PAPERWORK BURDEN UNDER FORM D, POST-AMENDMENT TO RULE 506

	Number of responses (A) [114]	Burden hours/ form (B)	Total burden hours (C) = (A)*(B)	Internal issuer time (D)	External professional time (E)	Professional costs (F) = (E)*$400
Form D	30,000	4	120,000	30,000	90,000	$36,000,000

We request comment on the accuracy of our estimates. Pursuant to 44 U.S.C. 3506(c)(2)(A), the Commission solicits comments to: (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of burden of the collection of information; (3) determine whether there are ways to enhance the quality, utility and clarity of the information to be collected; and (4) evaluate whether there are ways to minimize the burden of the collection of information on those who are required to respond, including

[110] The information in this column is based on the number of responses for Form D as reported in the OMB's Inventory of Currently Approved Information Collections, available at *http://www.reginfo.gov/public/do/PRAMain;jsessionid=D37174B5F6F9148DB767D63DF6983A65.*

[111] 17 CFR 230.144(d).

[112] *See Revision of Holding Period Requirements in Rules 144 and 145,* Release No. 33–7390 (Feb. 20, 1997) [62 FR 9242].

[113] Based on the 18,174 new Form D filings that were actually made in 2011, the annual increase would be 3,635 filings.

[114] The information in this column is based on the 25,000 filings reported in the OMB's Inventory of Currently Approved Information Collections, plus the additional 5,000 filings we estimate would be filed as result of proposed Rule 506(c).

through the use of automated collection techniques or other forms of information technology.

Persons submitting comments on the collection of information requirements should direct the comments to the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503, and send a copy to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090, with reference to File No. S7–07–12. Requests for materials submitted to OMB by the Commission with regard to these collections of information should be in writing, refer to File No. S7–07–12, and be submitted to the Securities and Exchange Commission, Office of Investor Education and Advocacy, 100 F Street NE., Washington, DC 20549–1090. OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this release. Consequently, a comment to OMB is assured of having its full effect if OMB receives it within 30 days of publication.

VII. Economic Analysis

A. Background and Summary of Proposed Rule and Form Amendments

We are proposing amendments to Rule 506 and Rule 144A to implement the requirements of Section 201(a) of the JOBS Act. Section 201(a)(1) directs the Commission to revise Rule 506 to provide that the prohibition against general solicitation contained in Rule 502(c) shall not apply to offers and sales of securities made pursuant to Rule 506, as amended, provided that all purchasers of the securities are accredited investors. Section 201(a)(1) also provides that ''such rules shall require the issuer to take reasonable steps to verify that purchasers of the securities are accredited investors, using such methods as determined by the Commission.'' Section 201(a)(2) of the JOBS Act directs the Commission to revise Rule 144A(d)(1) to provide that securities sold pursuant to Rule 144A may be offered to persons other than QIBs, including by means of general solicitation, provided that securities are sold only to persons that the seller and any person acting on behalf of the seller reasonably believe are QIBs.

We are mindful of the costs imposed by and the benefits obtained from our rules. The discussion below attempts to address the economic effects of the proposed amendments, including the likely costs and benefits of the amendments as well as the effect of the amendments on efficiency, competition and capital formation.[115] Some of the costs and benefits stem from the statutory mandate of Section 201(a), while others are affected by the discretion we exercise in implementing this mandate. These two types of costs and benefits may not be entirely separable to the extent our discretion is exercised to realize the benefits that we believe were intended by Section 201(a). We request comment on all aspects of the economic effects, such as the costs and benefits, of the amendments that we are proposing. We particularly appreciate comments that distinguish between the economic effects that are attributed to the statutory mandate itself and the economic effects that are the result of policy choices made by the Commission in implementing the statutory mandate.

B. Baseline

The baseline for our economic analysis is the market for Rule 506 offerings and the market for Rule 144A offerings, as they exist today.

The Regulation D market is large compared to other markets, and offerings claiming the Rule 506 exemption are by far the dominant type of offering in the Regulation D market. In 2011, 2010 and 2009, issuers raised an estimated $895 billion, $902 billion and $581 billion, respectively, in transactions claiming the Rule 506 exemption.[116] These amounts represent approximately 99% of the capital reported as raised under Regulation D during this period and approximately 93% of the number of Regulation D offerings during this period. In 2011 and 2010, the estimated amounts raised in Regulation D offerings exceeded the amounts raised in all other private offerings (Rule 144A offerings, Regulation S offerings, and other Section 4(a)(2) offerings), public debt and public equity offerings, combined. In 2009, the estimated amounts raised in Regulation D offerings were second only to the amounts raised in public debt offerings.

The Rule 144A market is also an important market for raising capital. In 2011 and 2010, the estimated amount of capital (including both equity and debt securities) raised in Rule 144A offerings was $168 billion and $233 billion, compared to $984 billion and $1.07 trillion, respectively, raised in registered offerings.

C. Eliminating the Prohibition Against General Solicitation in Rule 506 Offerings and Rule 144A Offerings

The elimination of the prohibition against general solicitation for a subset of Rule 506 offerings would likely have a number of effects on issuers and investors. When using general solicitation, issuers would be able to reach a greater number of potential investors, thus increasing their access to capital. The proposed amendment to Rule 506 would likely reduce search costs associated with finding accredited investors who may be interested in a particular private offering, thus enhancing efficiency. The increase in the number of potential investors could result in greater competition among investors interested in investing in an issuer, which may result in a lower cost of capital for issuers. We expect these benefits to issuers to generally be lower for Rule 144A offerings because QIBs, who are the investors in Rule 144A offerings, are generally fewer in number, known by market participants, and better networked than accredited investors. Thus, the elimination of the prohibition against general solicitation for Rule 144A offerings is unlikely to dramatically increase issuers' access to QIBs in such offerings or to have a meaningful effect on the cost of capital in Rule 144A offerings.

When using general solicitation, issuers may be able to reach investors directly, without the need of an intermediary, which could result in lower transaction costs, and perhaps a lower cost of capital, for issuers. An analysis of all Form D filings on EDGAR made during the period from 2009 to 2011 shows that approximately 11% of all new offerings reported sales commissions of greater than zero because the issuers used intermediaries.[117] The average commission paid to these intermediaries was 5.7% of the offering size, with the median commission being approximately 5%. For a $5 million offering, which was the median size of a Regulation D offering with a commission during this period, an

[115] Section 2(b) of the Securities Act requires the Commission, when engaging in rulemaking that requires it to consider whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action would promote efficiency, competition, and capital formation. 15 U.S.C. 77b(b).

[116] The statistics in this section are based on a review of Form D electronic filings with the Commission—specifically, the ''total amount sold'' as reported in Form D—and data regarding other types of offerings (*e.g.,* public debt offerings and Rule 144A offerings) from Securities Data Corporation's New Issues database (Thomson Financial). *See* note 25, supra.

[117] Ivanov/Bauguess Study.

issuer could potentially save up to $250,000 if the issuer reaches investors directly rather than through an intermediary, minus the cost of its own solicitation efforts and the cost associated with verifying accredited investor status.[118] This potential benefit would likely be larger for smaller issuers. Based on the analysis of these Form D filings as described above, issuers reporting annual revenues up to $25 million pay on average a 6.4% commission, while issuers with annual revenues over $100 million pay approximately a 3.3% commission and hedge funds and other privately offered funds pay approximately a 2.7% commission.

The elimination of the prohibition against general solicitation also would reduce the uncertainty for issuers as to whether a Rule 506 offering can be completed in certain situations, and would eliminate the costs of complying with the prohibition.[119] Under existing Rule 506, an inadvertent leak of information about an offering to entities or persons with whom the issuer does not have a pre-existing substantive relationship has been viewed by some as raising questions about the issuer's ability to rely on the exemption for the entire offering.[120] In addition, some privately offered funds have been reluctant to respond to press inquiries or to correct inaccurate reports due to concerns about these discussions being misconstrued as a general solicitation.[121] Under proposed Rule 506(c), any such uncertainty as to the availability of the exemption would likely be reduced, so long as issuers take reasonable steps to verify that they are selling only to accredited investors.

From the standpoint of investors, accredited investors who previously have found it difficult to identify investment opportunities in Rule 506 offerings would be able to identify, and potentially invest in, a larger and more diverse pool of potential investment opportunities. In addition, the elimination of the prohibition against general solicitation in some Rule 506 offerings would likely increase the flow of information about issuers to investors that may not have been publicly available previously, thereby potentially leading to more efficient pricing for the offered securities.[122] Thus, the proposed rule amendment may increase capital formation and at the same time improve its allocative efficiency.[123] With respect to privately offered funds in particular, eliminating the prohibition would allow accredited investors to gather information about privately offered funds at relatively lower costs and to allocate their capital more efficiently.[124] Increased information about privately offered fund strategies, management fees and performance information would likely lead to greater competition among privately offered funds for investor capital.

Although proposed Rule 506(c) would directly affect the private offering market, it could also have an indirect effect on other markets. The elimination of the prohibition against general solicitation for a subset of Rule 506 offerings may lower the degree of information asymmetry between Rule 506 issuers and potential investors. The lower search costs associated with finding Rule 506(c) offerings may cause some investors that currently invest in public equity and debt markets or other private offering markets to reallocate capital to the offerings made under proposed Rule 506(c). If a significant number of investors make a greater proportion of their investments in the Rule 506(c) market, such investor behavior may have a negative effect on the supply of capital and prices in the public equity and debt markets and in other non-registered offering markets. For example, issuers currently using the exemptions in Regulation A [125] and in Rule 504(b)(1)(i)–(iii) to solicit investors could prefer to rely on the exemption under proposed Rule 506(c) because they would be able to raise unlimited amounts of capital under proposed Rule 506(c) and state blue sky securities registration requirements would not apply to these offerings. While it is difficult to estimate how many of these issuers would choose to rely on proposed Rule 506(c) in lieu of the other available exemptions from registration, we believe that it is likely that Rule 506(c) would have a larger impact on issuers using Rule 504 rather than Regulation A, mainly because very few issuers have been using the Regulation A exemption in recent years.[126] In addition, to the extent that accredited investors have invested in registered investment companies instead of privately offered funds because of information asymmetry between privately offered funds and registered investment companies, it is possible that registered investment companies' assets may be negatively affected if these investors now transfer their assets to privately offered funds.

We believe that retaining the existing Rule 506 as Rule 506(b) would generate benefits for both issuers and investors. It would allow issuers that do not wish to generally solicit in their private offerings to avoid the added expense of complying with the rules applicable to Rule 506(c) offerings. It would also allow issuers to continue selling privately to up to 35 non-accredited investors who meet existing Rule 506's sophistication requirements. The continued availability of Rule 506(b) may also be beneficial to investors with whom the issuer has a pre-existing substantive relationship and who do not wish to bear additional verification costs that may be associated with participation in Rule 506(c) offerings.

On the other hand, eliminating the prohibition against general solicitation could make it easier for promoters of fraudulent schemes to reach potential investors through public solicitation and other methods previously not allowed. This could result in an increase in the level of due diligence conducted by investors in assessing proposed Rule 506(c) offerings, and in the event of fraud, would likely lead to costly lawsuits for investors seeking damages. In general, an increase in fraud in this market would harm investors who are defrauded, would undermine investor confidence in Rule 506 offerings and could negatively affect

[118] We recognize, of course, that the involvement of an intermediary can provide benefits in addition to locating investors. For example, an intermediary may be able to help an issuer obtain better pricing and terms or provide access to investors that can provide strategic or other advice to the issuer.

[119] Letter from MFA (May 4, 2012).

[120] *See, e.g.,* letter from Simon M. Lorne and Joseph McLaughlin (Aug. 5, 2008) on *Revisions of Limited Offering Exemptions in Regulation D,* Release No. 33–8828 (Aug. 3, 2007) [72 FR 45116] (''On occasion, the prohibition forces issuers to delay or even cancel offerings because of communications—sometimes inadvertent—that could be viewed in hindsight as a solicitation. The need to police communications by transaction participants, and to analyze and remedy inadvertent communications, also adds significantly to the cost of effecting private placements.'').

[121] *See, e.g.,* letters from D.E. Shaw & Co. (Apr. 3, 2006) on *Exposure Draft of Final Report of Advisory Committee on Smaller Public Companies,* Release No. 33–8666 (Feb. 28, 2006); MFA (May 4, 2012).

[122] This may not be applicable with respect to every issuer (*e.g.,* certain privately offered funds that offer their shares continuously at net asset value).

[123] Allocative efficiency is a condition that is reached when resources are allocated in a way that allows the maximum possible net benefit from their use. In this context, it means the right number of dollars from the right types of investors going to the most suitable investments on efficient terms.

[124] *See, e.g.,* letter from MFA (May 4, 2012) and *Managed Funds Association, Petition for Rulemaking on Rule 502 of Regulation D under the Securities Act of 1933,* File No. 4–643 (Jan. 9, 2012).

[125] 17 CFR 230.251 through 17 CFR 230.263.

[126] From 2009 to 2011, based on our review of Form D filings and Forms 1–A, 1,735 issuers relied on the Rule 504 exemption, and 10 issuers relied on Regulation A. The number of issuers using Regulation A to raise capital may increase once the Commission adopts rules implementing Title IV of the JOBS Act.

capital-raising by legitimate issuers—for example, by reducing investor participation in Rule 506 offerings—thus inhibiting capital formation and reducing efficiency. Further, one commentator is concerned that investors may confuse privately offered funds with registered investment companies.[127] In such cases, fraud that occurs with privately offered funds may cause investors to associate the wrongdoing with registered investment companies, and therefore refrain from investing in registered investment companies. In addition, some issuers with publicly-traded securities may use general solicitation for a purported Rule 506 offering to generate investor interest in the secondary trading markets, especially in the over-the-counter markets, which could be used by insiders to resell securities at inflated prices. This ''pump and dump'' activity would impose costs to investors in these secondary markets, as well as investors in Rule 506 offerings, and could erode investor confidence in Rule 506 offerings, thus potentially raising the cost of capital for issuers in this market.

The risks to investors of fraudulent offerings conducted under proposed Rule 506(c) may be mitigated to some extent by the requirement that issuers sell only to accredited investors (with reasonable steps to verify such status), who may be better able to assess their ability to take financial risks and bear the risk of loss than investors who are not accredited. In addition, issuers would still be subject to the antifraud provisions under the federal securities laws, and the public nature of these solicitations may facilitate detection of fraudulent activity.

We expect that there would be fewer occurrences of general solicitation-facilitated fraud in Rule 144A offerings, as compared to Rule 506(c) transactions. Unlike most Rule 506 transactions, Rule 144A offerings always include a financial intermediary. The due diligence conducted by these intermediaries is an additional layer of protection against fraud. Also, Rule 144A investors are generally large institutions, which are better able to identify fraudulent activities than smaller institutions and retail investors.

In regard to Rule 144A, we anticipate that eliminating the prohibition against general solicitation would significantly affect private trading systems by permitting information vendors to provide more information about Rule 144A securities. Indeed, since offers could be made to the public, the information on private trading systems for Rule 144A securities could be made available to all investors, even though sales would be limited to QIBs.[128] In addition, currently there is no public dissemination through Trade Reporting and Compliance Engine (''TRACE'') of transactions in Rule 144A securities.[129] Once Rule 144A is amended to permit offers to be made to persons other than QIBs, FINRA may decide to amend its rules to permit public dissemination of transaction information with respect to Rule 144A securities. Such improvements in the information available to potential investors could enhance efficiency in this market.

D. Verifying Accredited Investor Status in Rule 506(c) Offerings

The requirement in proposed Rule 506(c) for issuers to take reasonable steps to verify that purchasers are accredited investors would likely make it more difficult for those issuers whose existing practices do not already satisfy the verification requirement to sell securities to non-accredited investors, thereby lessening the likelihood that fraudulent offerings would be completed because those who are eligible to purchase are more likely to be able to protect their interests than investors who are not accredited investors. Preserving the integrity of the Rule 506 market and reducing the incidence of fraud would benefit investors by giving them greater assurance that they are investing in legitimate issuers. In turn, issuers would also benefit from measures that improve the integrity and reputation of the Rule 506 market because they would be able to attract more investors and capital. Issuers would benefit as well from the additional certainty that the Rule 506 safe harbor is available for an offering when this verification requirement is met.

Our proposal not to specify the verification methods that an issuer must use or could use in taking reasonable steps to verify accredited investor status would provide issuers with flexibility to use methods that are appropriate, given the facts and circumstances of each offering and each purchaser. Such flexibility is likely to mitigate the cost to issuers of complying with proposed Rule 506(c) because it would allow them to select the most cost-effective verification method for each offering.

The verification requirement in proposed Rule 506(c) would impose costs as well. Some potential investors likely would have to provide more information to issuers than they currently provide, while some issuers may have to apply a stricter and more costly process to determine accredited investor status than what they currently use. While it is reasonable to expect that the costs associated with the verification requirement could be offset somewhat by its benefits, it is also reasonable to expect that some accredited investors who would participate in existing Rule 506(b) offerings would decline to participate in proposed Rule 506(c) offerings. Compared to an alternative that prescribes specific verification methods or provides a non-exclusive list of verification methods, the greater flexibility of the proposed verification standard could result in less rigorous verification, thus allowing some unscrupulous issuers to more easily sell securities to purchasers who are not accredited investors and perpetrate fraudulent schemes. In addition, a flexible ''reasonableness'' verification approach may create or promote legal uncertainty about the availability of the exemption from Section 5 registration, which may cause some issuers to interpret ''reasonable steps to verify'' in a manner that is more burdensome than if specific verification methods were prescribed, thus incurring higher cost. Similarly, some issuers may decide to use additional internal or external resources (*e.g.,* retaining lawyers, soliciting opinions, etc.) that they would not have used if specific verification methods were prescribed or if a non-exclusive list of methods was provided, in order to make sure they are compliant with the rule, which would also increase their costs.

To the extent that issuers require investors to provide personally identifiable information (*e.g.,* Social Security numbers, tax information, bank or brokerage account information) in order to verify their accredited investor status, these investors may be reluctant to do so in the context of making an investment in an issuer, particularly an issuer with which they may have no prior relationship.[130] In addition to concerns about maintaining personal privacy, investors may be concerned that their personally identifiable information could be stolen or accessed

[127] *See* letter from ICI re: Rulemaking Petition File No. 4–463: Request by MFA for Rulemaking to Amend Rule 502(c) of Regulation D to Eliminate the Prohibition on Offers or Sales of Securities by General Solicitation or Advertising With Respect to Private Funds (Feb. 7, 2012); and letter from ICI (May 21, 2012).

[128] Under the PORTAL Trading System developed by the Nasdaq Stock Market for trading Rule 144A securities, access is restricted to QIBs. Other privately developed Rule 144A trading systems, such as Portal Alliance, have similar restrictions.

[129] *See* FINRA Rule 6750. There is mandatory reporting of over-the-counter trades in fixed income securities.

[130] Letter from SecondMarket.

by third parties or used by unscrupulous issuers in various ways (*e.g.,* identity theft, which could impose costs to investors that go well beyond the costs typically associated with investing). As a consequence, some potential investors may elect not to participate in this market, thus impeding capital formation to some extent.

As there is no information available to us on the costs currently incurred by issuers to form a reasonable belief that a purchaser in a Rule 506 offering is an accredited investor, we are unable to quantify the estimated costs and benefits of the verification requirement in proposed Rule 506(c). We are requesting comment from the public on this issue.

E. Form D Check Box for Rule 506(c) Offerings

Much of what we know about the size and characteristics of the private offering market comes from Form D filings. The information collected to date and described in this release illustrates and underscores the importance of the private offering market in the U.S. economy. The continued collection of this information following the elimination of the prohibition against general solicitation in Rule 506(c) and Rule 144A offerings will be an important monitoring tool in assessing the ongoing economic impact of the new rules. We are proposing to amend Form D to add a new check box in Item 6 of Form D, which would require an issuer to indicate whether it is relying on Rule 506(c) in conducting its offering. This information would assist the Commission in monitoring the use of proposed Rule 506(c), and the marginal cost to issuers of providing this information is likely to be low because Form D already requires issuers to identify the exemption on which they are relying.

F. Request for Comment

11. Are there other benefits and costs associated with the elimination of the prohibition against general solicitation that should be considered? Are those more pertinent to proposed Rule 506(c) offerings or Rule 144A offerings?

12. Is it likely that the removal of the prohibition against general solicitation would increase fraudulent activity in these markets? If so, to what extent, and what form is this fraudulent activity likely to take? Please provide data where possible.

13. How costly is it to comply with the existing requirements of Rule 506(b)? What would the incremental cost be to comply with the proposed requirements of Rule 506(c)? What would be the impact, if any, of the proposed Rule 506(c) check box on Form D? Please provide data where possible.

14. Are there any other benefits or costs associated with the accredited investor verification requirement in proposed Rule 506(c) that the Commission has not identified?

15. Do the types, or extent, of any benefits or costs from the proposed amendments to Rule 506 and Rule 144A differ depending on the type of issuer, other than as described above? If so, please explain.

16. Are there any additional economic effects related to efficiency, capital formation, or competition that the Commission has not identified?

VIII. Small Business Regulatory Enforcement Fairness Act

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996 (''SBREFA''),[131] the Commission must advise the OMB as to whether a proposed regulation constitutes a ''major'' rule. Under SBREFA, a rule is considered ''major'' where, if adopted, it results or is likely to result in:

- An annual effect on the economy of $100 million or more (either in the form of an increase or a decrease);
- A major increase in costs or prices for consumers or individual industries; or
- Significant adverse effects on competition, investment or innovation.

If a rule is ''major,'' its effectiveness will generally be delayed for 60 days pending Congressional review.

We request comment on whether our proposed amendments would be a ''major rule'' for purposes of SBREFA. We solicit comment and empirical data on:

- The potential effect on the U.S. economy on an annual basis;
- Any potential increase in costs or prices for consumers or individual industries; and
- Any potential effect on competition, investment or innovation.

We request those submitting comments to provide empirical data and other factual support for their views to the extent possible.

IX. Initial Regulatory Flexibility Analysis

The Commission has prepared this Initial Regulatory Flexibility Analysis (''IRFA'') in accordance with Section 603 of the Regulatory Flexibility Act.[132] This IRFA relates to the amendments to Rules 500, 501, 502 and 506 of Regulation D, Form D and Rule 144A that we are proposing in this release.

A. Reasons for, and Objectives of, the Action

The primary reason for, and objective of, the proposed amendments to Rule 502 and Rule 506 is to implement the statutory requirements of Section 201(a)(1) of the JOBS Act, which directs the Commission to revise Rule 506 to provide that the prohibition against general solicitation in Rule 502(c) shall not apply to offers and sales of securities made pursuant to Rule 506, provided that all purchasers of the securities are accredited investors. Consistent with the language in Section 201(a), the proposed amendments to Rule 506 require issuers to take reasonable steps to verify that purchasers in any Rule 506 offering using general solicitation are accredited investors. The primary reason for, and objective of, the proposed amendment to Form D is to assist our efforts to monitor the use of general solicitation in Rule 506(c) offerings and the size of this offering market.

The primary reason for, and objective of, the proposed amendment to Rule 144A is to implement the statutory requirements of Section 201(a)(2) of the JOBS Act, which directs the Commission to revise Rule 144A(d)(1) to provide that securities sold pursuant to Rule 144A may be offered to persons other than QIBs, including by means of general solicitation, provided that securities are sold only to persons that the seller and any person acting on behalf of the seller reasonably believe are QIBs.

B. Small Entities Subject to the Proposed Rule and Form Amendments

For purposes of the Regulatory Flexibility Act, under our rules, an issuer, other than an investment company, is a ''small business'' or ''small organization'' if it has total assets of $5 million or less as of the end of its most recent fiscal year and is engaged or proposing to engage in an offering of securities which does not exceed $5 million.[133] For purposes of the Regulatory Flexibility Act, an investment company is a small entity if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year.[134]

[131] Public Law 104–121, Tit. II, 110 Stat. 857 (1996).

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

[133] 17 CFR 230.157.

[134] 17 CFR 270.0–10(a).

Proposed Rule 506(c) would affect small issuers (including both operating businesses and investment funds that raise capital under Rule 506) relying on this safe harbor from Securities Act registration. All issuers that sell securities in reliance on Regulation D are required to file a Form D with the Commission reporting the transaction. For the fiscal year ended December 31, 2011, 18,174 issuers filed an initial notice on Form D, of which 16,692 relied on the Rule 506 exemption. Based on information reported by issuers on Form D, there were 3,823 small issuers [135] relying on the Rule 506 exemption in 2011. This number likely underestimates the actual number of small issuers relying on the Rule 506 exemption, however, because over 50% of issuers declined to report their size.

The proposed amendment to Rule 144A would affect small entities that engage in Rule 144A offerings.[136] Unlike issuers that use Regulation D, issuers conducting Rule 144A offerings are not required to file any form with the Commission. This lack of data significantly limits our ability to assess the number and the size of issuers that use Rule 144A offerings. Still, we are able to obtain some data on Rule 144A offerings during the 2009 to 2011 period from two commercial databases.[137] Based on these data, we identified 681 offerings involving 607 issuers from 2009 to 2011. Of these 607 issuers, only 316 provided information on their total assets. With respect to these 316 issuers, we identified 42 issuers with total assets of less than $50 million.

C. Projected Reporting, Recordkeeping and Other Compliance Requirements

The proposed amendments to Rule 506 would impose certain reporting and compliance requirements on issuers that engage in general solicitation in Rule 506 offerings. As discussed above, issuers taking advantage of proposed Rule 506(c) to engage in general solicitation in Rule 506 offerings would be required to take reasonable steps to verify that the purchasers of the securities are accredited investors. The steps required would vary with the circumstances, but we anticipate that some potential investors may have to provide more information to issuers than they currently provide, while issuers may have to apply a stricter and more costly process to verify accredited investor status than what they currently use. We expect that the costs of compliance would vary depending on the size and nature of the offering, the nature and extent of the verification methods used, and the number and nature of potential purchasers in the offering. Proposed Rule 506(c) does not impose any recordkeeping requirements. However, we anticipate that issuers would document the steps they take to verify that purchasers are accredited investors in Rule 506 offerings involving general solicitation.

The proposed amendment to Form D would also impose an information requirement with respect to Rule 506 offerings that use general solicitation. Each issuer submitting a Form D for a Rule 506 offering would be required to check a box on the form to indicate whether the issuer is relying on the proposed Rule 506(c) exemption. We do not believe that this proposed revision to Form D would increase in any material way the time or information required to complete the Form D that must be filed with the Commission in connection with a Rule 506 offering.

The proposed amendment to Rule 144A contains no reporting, recordkeeping or compliance requirements for issuers that engage in Rule 144A offerings.

D. Duplicative, Overlapping or Conflicting Federal Rules

The Commission believes that there are no rules that duplicate, overlap or conflict with the proposed amendments to Rule 144A, Form D, and Rules 500, 501, 502 and 506 of Regulation D.

E. Significant Alternatives

The Regulatory Flexibility Act directs us to consider significant alternatives that would accomplish the stated objectives of our amendments, while minimizing any significant adverse impact on small entities. In regard to the proposed amendment to Rule 144A and the proposed amendment to Rule 506 to remove the prohibition against general solicitation in Rule 506 offerings where all purchasers are accredited investors, there are no significant alternatives to these amendments that would accomplish the stated objectives of Section 201(a) of the JOBS Act.

In connection with the proposed amendment to Form D and the proposed amendment to Rule 506 that requires issuers to take reasonable steps to verify that purchasers of securities are accredited investors, the Commission considered the following alternatives: (1) Establishing different compliance or reporting standards that take into account the resources available to small entities; (2) clarifying, consolidating or simplifying compliance requirements under the rule; (3) using design rather than performance standards; and (4) exempting small entities from coverage of all or part of the proposed amendment to Rule 506.

With respect to using design rather than performance standards, we note that the ''reasonable steps to verify'' requirement in proposed Rule 506(c) is a performance standard. We believe that the flexibility of a performance standard accommodates different types of offerings and purchasers without imposing overly burdensome methods that may be ill-suited or unnecessary to a particular offering or purchaser, given the facts and circumstances. The Commission is not proposing the establishment of different compliance or reporting requirements or timetables for the rule, as proposed, for small entities. The particular steps necessary to meet the proposed requirement to take reasonable steps to verify that purchasers are accredited investors would vary according to the circumstances. Different compliance requirements for small entities may create the risk that the requirements may be too prescriptive or, alternatively, insufficient to verify a purchaser's accredited investor status. Special requirements for small entities may also lead to investor confusion or reduced investor confidence in Rule 506 offerings if they create the impression that small entities have a different standard of verification than other issuers of securities. As the verification requirement is intended to protect investors by limiting participating in unregistered offerings to those who are most able to bear the risk, we are preliminarily of the view that a flexible standard applicable to all issuers better accomplishes the goal of investor protection that this requirement is intended to serve. The Commission is not proposing a different reporting requirement for small entities because the additional information that would be required in the Form D is minimal and should not be unduly burdensome or costly for small entities.

We similarly believe that it does not appear consistent with the objective of the proposed amendments or the considerations described above regarding investor confusion and

[135] Of this number, 3,344 of these issuers are not investment companies, and 479 are investment companies.

[136] While it may be theoretically possible for a small entity to meet one part of the definition of ''qualified institutional buyer'' (*e.g.,* an ''entity, all of the equity owners of which are qualified institutional buyers, acting for its own account or the accounts of other qualified institutional buyers''), we do not have any information to suggest that there are such small entities. Accordingly, the regulatory flexibility analysis in regard to Rule 144A is focused on small issuers that engage in Rule 144A offerings.

[137] Thomson Financial's SDC Platinum Service and Sagient Research System's Placement Tracker database.

investor confidence to further clarify, consolidate or simplify the amendments for small entities. With respect to exempting small entities from coverage of these proposed amendments, we believe such an approach would be contrary to the requirements of, and the legislative intent behind, Section 201(a), as evidenced by the plain language of the statute.

F. General Request for Comment

The Commission is soliciting comments regarding this analysis. The Commission requests comment on the number of small entities that would be subject to the rules and whether the proposed rules would have any effects that have not been discussed. The Commission requests that commentators describe the nature of any effects on small entities subject to the rules and provide empirical data to support the nature and extent of the effects.

X. Statutory Authority and Text of Proposed Rule and Form Amendments

The amendments contained in this release are being proposed under the authority set forth in Sections 4(a)(1), 4(a)(2) and 19 of the Securities Act, as amended, and Section 201(a) of the JOBS Act.

List of Subjects in 17 CFR Parts 230 and 239

Reporting and recordkeeping requirements, Securities.

For the reasons set out above, the Commission proposes to amend Title 17, chapter II of the Code of Federal Regulations, as follows:

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

1. The general authority citation for Part 230 is revised to read as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78o–7 note, 78t, 78w, 78ll(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, § 201(a), 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

2. Amend § 230.144A by:

a. Removing the reference to ''section 4(2)'' and adding in its place ''section 4(a)(2)'' in Preliminary Note 7;

b. Removing the reference to ''section 2(13)'' and adding in its place ''section 2(a)(13)'' in paragraph (a)(1)(i)(A);

c. Removing the reference to ''sections 2(11) and 4(1)'' and adding in its place ''sections 2(a)(11) and 4(a)(1)'' in paragraph (b);

d. Removing the references to ''section 4(3)(C),'' ''section 2(11)'' and ''section 4(3)(A)'' and adding in their place ''section 4(a)(3)(C),'' ''section 2(a)(11)'' and ''section 4(a)(3)(A),'' respectively, in paragraph (c);

e. Removing the phrase ''offered or'' after the phrase ''The securities are'' in paragraph (d)(1); and

f. Removing the phrase ''an offeree or'' after the phrase ''a qualified institutional buyer or to'' and adding in its place ''a'' in paragraph (d)(1).

* * * * *

3. Amend § 230.500(c) by removing the reference to ''section 4(2)'' and adding in its place ''section 4(a)(2)''.

* * * * *

4. Amend § 230.501 by:

a. Removing the reference to ''section 2(13)'' and adding in its place ''section 2(a)(13)'' in paragraph (a)(1); and

b. Removing the reference to ''section 2(4)'' and adding in its place ''section 2(a)(4)'' in paragraph (g).

* * * * *

5. Amend § 230.502 by:

a. Removing the reference to ''§ 230.506'' and adding in its place ''§ 230.506(b)'' in paragraph (b)(1);

b. Removing the reference to ''§ 230.506'' and adding in its place ''§ 230.506(b)'' in paragraph (b)(2)(iv);

c. Removing the reference to ''§ 230.506'' and adding in its place ''§ 230.506(b)'' in paragraph (b)(2)(v);

d. Removing the reference to ''§ 230.506'' and adding in its place ''§ 230.506(b)'' in the first sentence of paragraph (b)(2)(vii);

e. Adding to the first sentence of paragraph (c) the phrase ''or § 230.506(c)'' after the phrase ''Except as provided in § 230.504(b)(1)'';

f. Removing the reference to ''section 4(2)'' and adding in its place ''section 4(a)(2)'' in paragraph (d); and

g. Removing the reference to ''section 2(11) of the Act'' and adding in its place ''section 2(a)(11) of the Act'' in paragraph (d).

* * * * *

6. Amend § 230.506 by:

a. Adding to paragraph (a) the phrase ''or paragraph (c)'' after the phrase ''satisfy the conditions in paragraph (b)'';

b. Removing the reference to ''section 4(2)'' and adding in its place ''section 4(a)(2)'' in paragraph (a);

c. Adding to paragraph (b) the phrase ''in offerings not using general solicitation or general advertising'' after the phrase ''Conditions to be met'';

d. Removing the reference to ''this section'' and adding in its place ''§ 230.506(b)'' in the note to paragraph (b)(2)(i); and

e. Adding paragraph (c).

The addition reads as follows:

§ 230.506 Exemption for limited offers and sales without regard to dollar amount of offering.

* * * * *

(c) *Conditions to be met in offerings using general solicitation or general advertising.*

(1) *General conditions.* To qualify for exemption under this section, sales must satisfy all the terms and conditions of §§ 230.501 and 230.502(a) and (d).

(2) *Specific conditions.*

(i) *Nature of purchasers.* All purchasers of securities sold in any offering under this § 230.506(c) are accredited investors.

(ii) *Verification of accredited investor status.* The issuer shall take reasonable steps to verify that purchasers of securities sold in any offering under this § 230.506(c) are accredited investors.

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

7. The authority citation for Part 239 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78l, 78m, 78n, 78o(d), 78o–7 note, 78u–5, 78w(a), 78ll, 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

8. Amend Form D (referenced in § 239.500) by:

a. Removing the phrase ''Rule 506'' and adding in its place ''Rule 506(b)'' next to the appropriate check box;

b. Removing the phrase ''Securities Act Section 4(5)'' and adding in its place ''Securities Act Section 4(a)(5)'' next to the appropriate check box; and

c. Adding a check box that reads ''Rule 506(c)'' between the revised ''Rule 506(b)'' check box and the revised ''Securities Act Section 4(a)(5)'' check box.

Note: The text of Form D does not, and the amendments will not, appear in the Code of Federal Regulations.

Dated: August 29, 2012.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–21681 Filed 9–4–12; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–126770–06]

RIN 1545–BG07

Allocation of Costs Under the Simplified Methods

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations on allocating costs to certain property produced by the taxpayer or acquired by the taxpayer for resale. The proposed regulations affect taxpayers that are producers or resellers of property that are required to capitalize certain costs to the property and that allocate costs under the simplified production method or the simplified resale method. The proposed regulations provide rules for the treatment of negative additional costs.

DATES: Written (including electronic) comments and requests for a public hearing must be received by December 4, 2012.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–126770–06), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–126770–06), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Taxpayers also may submit comments electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–126770–06).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Christopher Call, (202) 622–4970; concerning submissions of comments or to request a public hearing, Oluwafunmilayo Taylor, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Income Tax Regulations, 26 CFR part 1, relating to the allocation of costs under the simplified methods of accounting under section 263A of the Internal Revenue Code (Code).

Section 263A requires taxpayers to capitalize the direct costs and indirect costs that are properly allocable to: (1) Real or tangible personal property the taxpayer produces, and (2) real property and personal property described in section 1221(a)(1) that the taxpayer acquires for resale. Section 1.263A–1(e)(2)(i) of the Income Tax Regulations provides that direct costs for producers are direct material costs and direct labor costs. Section 1.263A–1(e)(2)(ii) provides that resellers must capitalize the acquisition cost of property acquired for resale. Section 1.263A–1(e)(3)(i) defines indirect costs as all costs other than direct material costs and direct labor costs (in the case of property produced) or acquisition costs (in the case of property acquired for resale). Indirect costs are properly allocable to property produced or acquired for resale when the costs directly benefit or are incurred by reason of the performance of production or resale activities.

Section 263A generally requires taxpayers to allocate capitalizable section 263A costs to specific items in inventory. The legislative history of section 263A indicates that Congress intended that taxpayers would allocate additional section 263A costs (costs, other than interest, that were not capitalized under the taxpayer's method of accounting immediately prior to the effective date of section 263A, but that are required to be capitalized under section 263A) with the same degree of specificity that was required of inventoriable costs prior to the enactment of section 263A. Congress contemplated that taxpayers would continue to use the same methods of allocating costs to items in their inventory that were available under prior law. *See* S. Rep. No. 313, 99th Cong. 2d Sess. 142 (1986). Consistent with these principles, the regulations under § 1.263A–1(f)(2) and (f)(3) provide that taxpayers may elect to use a ''facts-and-circumstances'' allocation method, such as the specific identification method, burden rate, standard cost method, or any other method to allocate direct and indirect costs to units of property produced or acquired for resale, if the method is reasonable within the meaning of § 1.263A–1(f)(4).

Section 1.263A–1(f)(1) authorizes taxpayers to use the simplified methods provided in § 1.263A–2(b) (the simplified production method) or § 1.263A–3(d) (the simplified resale method) to allocate costs to eligible property produced or eligible property acquired for resale in lieu of a facts-and-circumstances allocation method. The simplified methods differ from facts-and-circumstances methods in that, as applied to inventories, they allocate a pool of capitalizable costs (additional section 263A costs) between ending inventory and cost of goods sold using a defined ratio and are an exception to the general rule that additional section 263A costs must be allocated to specific items of inventory. Thus, the simplified methods are intended to reduce the complexity and administrative burdens of having to develop detailed cost accounting systems for the additional costs required to be capitalized under section 263A.

Under the simplified production method, a taxpayer must allocate additional section 263A costs to produced property on hand at the end of the taxable year based on the ratio of these costs incurred during the year to the taxpayer's total section 471 costs incurred during the year (the absorption ratio). The current regulations define additional section 263A costs as the costs, other than interest, that were not capitalized under the taxpayer's method of accounting immediately prior to the effective date of section 263A, but that are required to be capitalized under section 263A. See § 1.263A–1(d)(3). The current regulations define section 471 costs as costs, other than interest, capitalized under the taxpayer's method of accounting immediately prior to the effective date of section 263A. If a taxpayer was not in existence before the effective date of section 263A, section 471 costs are generally those costs that would have been required to be capitalized under § 1.471–11. See § 1.263A–1(d)(2). The absorption ratio is multiplied by the section 471 costs incurred during the taxable year that remain in ending inventory or are otherwise on hand at year end to determine the additional section 263A costs allocable to produced property on hand at the end of the taxable year.

Under the simplified resale method, an eligible taxpayer computes a combined absorption ratio and multiplies it by the section 471 costs incurred during the taxable year that remain in its ending inventory or are otherwise on hand at year end to determine the additional section 263A costs allocable to eligible property on hand at year end. Section 1.263A–3(d)(3)(i)(C)(*1*) defines the combined absorption ratio as the sum of the storage and handling costs absorption ratio as defined by § 1.263A–3(d)(3)(i)(D) and the purchasing costs absorption ratio as defined by § 1.263A–3(d)(3)(i)(E).

Notice 2007–29 (2007–1 CB 881) requests comments on the treatment of negative amounts under the simplified methods. A negative amount generally occurs when a taxpayer capitalizes a cost as a section 471 cost in an amount that is greater than the amount required to be capitalized for tax purposes. For

example, if a taxpayer included book depreciation in section 471 costs in accordance with § 1.471–11(c)(2)(iii)(b) and the book depreciation is greater than tax depreciation for the year, the taxpayer would have capitalized more depreciation than is required to be capitalized under section 263A for that year. A negative amount may result if the taxpayer does not remove this excess depreciation amount by adjusting section 471 costs but instead makes an adjustment to its additional section 263A costs. See § 601.601(d)(2)(ii)(*b*).

In some situations, including negative amounts in the numerator of the simplified production method formula may result in significant distortions of the amount of additional section 263A costs that is allocated to ending inventory. Distortions may also occur when the method used to capitalize a cost under section 471 is different than the method used under the simplified production method to remove the cost from ending inventory. The extent of the distortion, and whether it is favorable or unfavorable to the taxpayer, generally depends on when the cost is incurred in the production process and how the cost was allocated to raw materials, work-in-process, or finished goods inventories for purposes of section 471.

Notice 2007–29 provides that, pending the issuance of additional published guidance, the IRS will not challenge the inclusion of negative amounts in computing additional costs under section 263A or the permissibility of aggregate negative additional section 263A costs. The notice solicits public comments regarding possible changes to the simplified methods involving negative additional section 263A costs. Comments were received and considered in developing these proposed regulations.

Explanation of Provisions

1. Prohibition on Negative Amounts

To reduce the distortions that occur by including negative amounts under the simplified methods, the proposed regulations provide that, subject to certain exceptions described later in this preamble, taxpayers may not include negative amounts in additional section 263A costs. Specific comments are requested on transition rules for taxpayers currently using the simplified production method with the historic absorption ratio election (see section 1.263A–2(b)(4)), including comments on how the regulations should apply to taxpayers that are part way through the qualifying period as described in section 1.263A–2(b)(4)(ii)(C).

To reduce the administrative burden for smaller taxpayers using the simplified production method for which the costs and burdens of excluding negative amounts from additional section 263A costs may otherwise outweigh the benefits, the proposed regulations allow producers with average annual gross receipts of $10,000,000 or less to include negative amounts in additional section 263A costs under the simplified production method.

Additionally, because negative additional section 263A costs cause less distortion under the simplified resale method than under the simplified production method, the proposed regulations allow taxpayers using the simplified resale method to remove section 471 costs that are not required to be capitalized for tax purposes from ending inventory by treating them as negative additional section 263A costs.

The proposed regulations generally prohibit treating cash or trade discounts described in § 1.471–3(b) as negative amounts under any of the simplified methods. Comments are requested on reasonable methods of allocating between ending inventory and cost of goods sold cash or trade discounts that taxpayers do not capitalize for book purposes (and therefore are not section 471 costs within the meaning of § 1.263A–1(d)(2)).

2. New Modified Simplified Production Method

In response to Notice 2007–29, a commentator suggested an alternative to the simplified production method that would reduce overcapitalization and distortion, including distortions resulting from including negative amounts in additional section 263A costs. The commentator suggested that the simplified production method may allocate an excessive amount of section 263A costs to raw materials inventories because the formula does not take into account the fact that taxpayers incur fewer indirect costs for raw materials and because different inventoriable costs turn over at different rates. The commentator's alternative simplified method would allocate additional section 263A costs related to raw materials using a formula that is different from the formula used to allocate additional section 263A costs related to work-in-process and finished goods.

As suggested by this comment, the proposed regulations allow producers to use a new modified simplified production method that reduces the distortions that exist under the traditional simplified methods by more precisely allocating additional section 263A costs, including negative amounts, among raw materials, work-in-process, and finished goods inventories. Under the modified simplified production method, producers determine the allocable portion of preproduction related additional section 263A costs (such as storage and handling for raw materials) using a preproduction cost absorption ratio. The preproduction cost absorption ratio is applied to raw material section 471 costs incurred during the taxable year and remaining on hand at year end. For purposes of computing the allocable portion of preproduction related additional section 263A costs, raw material costs on hand at year end include unprocessed raw materials and raw materials that are integrated into work-in-progress and finished goods. Under the modified simplified production method, producers determine the allocable portion of all other additional section 263A costs using a production cost absorption ratio.

In addition to reducing distortions that exist under the simplified production method by more precisely allocating additional section 263A costs to raw materials, the modified simplified production method provides producers with a method to remove section 471 costs that are not required to be capitalized for tax purposes from ending inventory by treating them as negative additional section 263A costs. Both resellers and producers, thereby, are allowed to use methods that more precisely allocate additional section 263A costs while alleviating administrative burden, consistent with the purpose of the simplified methods.

As with other simplified methods, a taxpayer must maintain adequate records substantiating proper use of the modified simplified production method (see section 6001).

Comments are requested on the modified simplified production method, including: (1) Whether distortions will occur if preproduction related additional section 263A costs are not directly traced from raw materials through work-in-process and finished goods inventories from year to year; (2) how mixed service costs should be allocated between raw materials, work-in-process, and finished goods inventories under the new formula; and (3) how the new formula should apply to a taxpayer using the last-in, first-out method of accounting.

3. Simplified Definition of Section 471 Costs and Elimination of Separate Provisions for New Taxpayers

For most taxpayers, section 471 costs generally are the acquisition or production costs, other than interest, that the taxpayer capitalized under its method of accounting immediately before the effective date of section 263A. See § 1.263A–1(d)(2)(i). If a taxpayer was not in existence at that time, section 471 costs generally are the acquisition or production costs, other than interest, that the taxpayer would have been required to capitalize if the taxpayer had been in existence immediately before the effective date of section 263A. See § 1.263A–1(d)(2)(ii).

To provide greater simplicity and consistency among taxpayers, the proposed regulations adopt a single definition of section 471 costs that applies to taxpayers that were in existence before the effective date of section 263A and to newer taxpayers, whether using the simplified production method, the modified simplified production method, or the simplified resale method. The proposed regulations provide that, for purposes of the simplified methods, a taxpayer's section 471 costs, in general, are the costs, other than interest, that a taxpayer capitalizes to its inventory in its financial statements. However, a taxpayer must include all direct costs in its section 471 costs regardless of the taxpayer's treatment of the costs in its financial statements. The proposed regulations require a taxpayer that is not permitted to remove section 471 costs as negative additional section 263A costs to reduce its section 471 costs. The proposed regulations provide that a taxpayer that reduces its section 471 costs must use a reasonable method that approximates the manner in which the taxpayer originally capitalized the costs.

Effective/Applicability Date

The regulations are proposed to apply to taxable years ending on or after the date the regulations are published as final regulations in the **Federal Register**.

Effect on Other Documents

Notice 2007–29 would be superseded as of the date these regulations are published as final regulations in the **Federal Register**.

Special Analyses

This notice of proposed rulemaking 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. Section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. Because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The IRS and the Treasury Department request comments on all aspects of the proposed rules. All comments will be available at *www.regulations.gov* or upon request.

A public hearing will be scheduled if requested in writing by any person who timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is W. Thomas McElroy, Jr. of the Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART I—INCOME TAXES

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

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

Section 1.263A–1 also issued under 26 U.S.C. 263A. * * *

Section 1.263A–2 also issued under 26 U.S.C. 263A. * * *

Par. 2. Section 1.263A–0 is amended as follows:

1. Revising the entries in § 1.263A–1 for paragraphs (d)(2) and (d)(3).

2. Revising the entries in § 1.263A–2 for paragraphs (c) and (d).

3. Adding new entries to § 1.263A–2 for paragraphs (e), (f) and (g).

The revisions and addition read as follows:

§ 1.263A–0 Outline of regulations under section 263A.

* * * * *

§ 1.263A–1 Uniform capitalization of costs.

* * * * *

(d) * * *

(2) Section 471 costs.

(i) In general.

(ii) Removal of costs from inventory.

(iii) Method changes.

(3) Additional section 263A costs

(i) In general.

(ii) Negative amounts.

(A) In general.

(B) Exception for small taxpayers using the simplified production method.

(C) Exception for modified simplified production method and simplified resale method.

* * * * *

§ 1.263A–2 Rules relating to property produced by the taxpayer.

* * * * *

(c) Modified simplified production method.

(1) In general.

(2) Eligible property.

(3) Modified simplified production method without historic absorption ratio election.

(i) General allocation formula.

(A) In general.

(B) Allocable preproduction additional section 263A costs.

(C) Allocable production additional section 263A costs.

(D) Effect of allocation.

(E) Treatment of mixed service costs.

(ii) Definitions

(A) Preproduction absorption ratio.

(*1*) In general.

(*2*) Preproduction additional section 263A costs.

(*3*) Raw material costs.

(B) Production absorption ratio.

(*1*) In general.

(*2*) Production additional section 263A costs.

(*3*) Production section 471 costs.

(iii) LIFO taxpayers electing the modified simplified production method.

(A) In general.

(B) LIFO increment.

(*1*) In general.

(*2*) Combined absorption ratio defined.

(C) LIFO decrement.

(iv) De minimis rule for producers with total indirect costs of $200,000 or less.

(v) Examples.

(4) Modified simplified production method with historic absorption ratio election.

(i) In general.
(ii) General allocation formula.
(A) In general.
(B) Preproduction historic absorption ratio.
(C) Production historic absorption ratio.
(iii) LIFO taxpayers making the historic absorption ratio election.
(A) In general.
(B) Combined historic absorption ratio.
(C) Total allocable additional section 263A costs incurred during the test period.
(D) Total section 471 costs remaining on hand at year end during the test period.
(iv) Extension of qualifying period.
(v) Transition rule.
(vi) Examples.
(d) Additional simplified methods for producers.
(e) Cross reference.
(f) Change in method of accounting.
(1) In general.
(2) Scope limitations.
(3) Audit protection.
(4) Section 481(a) adjustment.
(5) Time for requesting change.
(g) Effective/applicability date.

Par. 3. Section 1.263A–1 is amended by:

1. Revising paragraphs (d)(2) and (d)(3).
2. Adding a sentence to the end of paragraph (m).

The addition and revisions read as follows:

§ 1.263A–1 Uniform capitalization of costs.

* * * * *

(d) * * *

(2) *Section 471 costs*—(i) *In general.* Except as otherwise provided in paragraph (d)(2)(ii) of this section, for purposes of section 263A, a taxpayer's section 471 costs are the costs, other than interest, that a taxpayer capitalizes to its inventory (or other eligible property) in its financial statements. Thus, although section 471 applies only to inventories, section 471 costs include any non-inventory costs, other than interest, that a taxpayer capitalizes or includes in acquisition or production costs in its financial statements. However, notwithstanding the last sentence of paragraph (g)(2) of this section, section 471 costs must include all direct costs of producing property and of acquiring property held for resale, whether or not a taxpayer capitalizes these costs to inventory or to other eligible property in its financial statements. See paragraph (e)(2) of this section for a description of direct production costs and direct costs of acquiring property held for resale.

(ii) *Removal of costs from inventory.* A taxpayer must reduce its section 471 costs by those costs that the taxpayer capitalizes to its inventory (or other eligible property) in its financial statements that may not be capitalized under either § 1.263A–1(c)(2) or § 1.263A–1(j)(2)(ii), and those period costs that the taxpayer capitalizes to its inventory (or other eligible property) in its financial statements that, under § 1.263A–1(j)(2), the taxpayer chooses not to capitalize under section 263A (for example, section 179 costs). A taxpayer described in paragraph (d)(3)(ii)(B) or (d)(3)(ii)(C) of this section that may remove these costs from inventory by including them as negative amounts in additional section 263A costs instead may reduce its section 471 costs for these costs. A taxpayer that reduces its section 471 costs must use a reasonable method that approximates the manner in which the taxpayer originally capitalized the costs to its inventory (or other eligible property) in its financial statements.

(iii) *Method changes.* A taxpayer may change its method of accounting for determining section 471 costs only with the consent of the Commissioner as required under section 446(e) and the corresponding regulations. If a taxpayer is using the simplified production method described in § 1.263A–2(b), the modified simplified production method described in § 1.263A–2(c), or the simplified resale method described in § 1.263A–3(d), and changes its financial reporting practices regarding the costs capitalized to its inventory (or other eligible property) in a manner that would change its section 471 costs under the general provisions of paragraph (d)(2)(i) of this section, then the taxpayer must secure the Commissioner's consent prior to computing its taxable income under the new method of accounting for section 471 costs.

(3) *Additional section 263A costs*—(i) *In general. Additional section 263A costs* are defined as the costs, other than interest, that are not included in a taxpayer's section 471 costs, but that are required to be capitalized under section 263A. Additional section 263A costs do not include the direct costs that are required to be included in a taxpayer's section 471 costs under paragraph (d)(2)(i) of this section.

(ii) *Negative amounts*—(A) *In general.* Except as otherwise provided by regulations or other published guidance, see § 601.601(d)(2), a taxpayer may not include negative amounts in additional section 263A costs.

(B) *Exception for small taxpayers using the simplified production method.* Paragraph (d)(3)(ii)(A) of this section does not apply to a taxpayer using the simplified production method under § 1.263A–2(b) if the taxpayer's (or its predecessors') average annual gross receipts for the three previous taxable years (test period) do not exceed $10,000,000. The rules of § 1.263A–3(b) apply for purposes of determining the amount of a taxpayer's gross receipts and the test period.

(C) *Exception for modified simplified production method and simplified resale method.* In general, a taxpayer using the modified simplified production method under § 1.263A–2(c) or the simplified resale method under § 1.263A–3(d) may (but is not required to) remove as negative amounts under section 263A indirect costs that are included in the taxpayer's section 471 costs but that are not required to be, or may not be, capitalized into inventory (or other eligible property) for federal income tax purposes. However, a taxpayer using the modified simplified production method or the simplified resale method may not use negative amounts to adjust additional section 263A costs for cash or trade discounts described in § 1.471–3(b).

* * * * *

(m) * * * Paragraphs (d)(2) and (d)(3) of this section apply for taxable years ending on or after the date these regulations are published as final regulations in the **Federal Register**.

Par. 4. Section 1.263A–2 is amended by:

1. Redesignating paragraphs (c), (d), (e), and (f) as paragraphs (d), (e), (f), and (g).
2. Adding a new paragraph (c).
3. Revising newly designated paragraph (g).

The addition and revisions read as follows:

§ 1.263A–2 Rules relating to property produced by the taxpayer.

* * * * *

(c) *Modified simplified production method*—(1) *In general.* This paragraph (c) provides a modified simplified method for determining the additional section 263A costs properly allocable to ending inventories of property produced and other eligible property on hand at the end of the taxable year.

(2) *Eligible property.* For purposes of this paragraph (c), *eligible property* has the same meaning as in paragraph (b)(2) of this section.

(3) *Modified simplified production method without historic absorption ratio election*—(i) *General allocation formula*—(A) *In general.* Except as otherwise provided in paragraph (c)(3)(iv) of this section, a taxpayer may

compute the total additional section 263A costs allocable to eligible property remaining on hand at the close of the taxable year under the modified simplified production method as follows:

Allocable preproduction additional section 263A costs + Allocable production additional section 263A costs.

(B) *Allocable preproduction additional section 263A costs.* The amount of preproduction additional section 263A costs allocable to ending inventory or to other eligible property on hand at the end of the taxable year is computed as follows:

Preproduction absorption ratio × raw material section 471 costs incurred during the taxable year and remaining on hand at year end.

(C) *Allocable production additional section 263A costs.* The amount of production additional section 263A costs allocable to ending inventory or to other eligible property on hand at the end of the taxable year is computed as follows:

Production absorption ratio × production section 471 costs incurred during the taxable year and remaining on hand at year end.

(D) *Effect of allocation.* The allocable preproduction additional section 263A costs and the allocable production additional section 263A costs are totaled to compute the additional section 263A costs, which are added to the taxpayer's ending section 471 costs to determine the total section 263A costs that are capitalized. See, however, paragraph (c)(3)(iii) of this section for special rules for LIFO taxpayers. Except as otherwise provided in this section or in § 1.263A–1 or § 1.263A–3, additional section 263A costs that are allocated to inventories on hand at the close of the taxable year under the modified simplified production method are treated as inventory costs for all purposes of the Internal Revenue Code.

(E) *Treatment of mixed service costs.* A taxpayer must apportion capitalizable mixed service costs (the aggregate portion of mixed service costs that are properly allocable to the taxpayer's production or resale activities as additional section 263A costs) between preproduction additional section 263A costs described in paragraph (c)(3)(ii)(A)(*2*) of this section and production additional section 263A costs described in paragraph (c)(3)(ii)(B)(*2*) of this section. Under the modified simplified production method, a taxpayer must allocate capitalizable mixed service costs to preproduction additional section 263A costs in proportion to the raw material costs in total section 471 costs. The taxpayer must include the capitalizable mixed service costs that are not allocated to preproduction additional section 263A costs in production additional section 263A costs.

(ii) *Definitions*—(A) *Preproduction absorption ratio*—(*1*) *In general.* Under the modified simplified production method, the preproduction absorption ratio is determined as follows:

$$\frac{\text{Preproduction additional section 263A costs}}{\text{Raw material costs}}$$

(*2*) *Preproduction additional section 263A costs.* Preproduction additional section 263A costs are the sum of the additional section 263A costs (as defined in § 1.263A–1(d)(3)) incurred during the current taxable year that are described in paragraph (a)(3)(ii) of this section to the extent the costs are not treated as section 471 costs and the allocable portion of capitalizable mixed service costs as described in paragraph (c)(3)(i)(E) of this section.

(*3*) *Raw material costs.* Raw material costs are defined as the direct costs of acquiring raw materials that a taxpayer purchases during its current taxable year. Raw material section 471 costs incurred during the taxable year and remaining on hand at year end include the raw material costs in work-in-process and finished goods as well as unprocessed raw materials.

(B) *Production absorption ratio*—(*1*) *In general.* Under the modified simplified production method, the production absorption ratio is determined as follows:

$$\frac{\text{Production additional section 263A costs}}{\text{Production section 471 costs}}$$

(*2*) *Production additional section 263A costs.* Production additional section 263A costs are the sum of all additional section 263A costs (as defined in § 1.263A–1(d)(3)) incurred during the current taxable year that are not preproduction additional section 263A costs as described in this section and the allocable portion of capitalizable mixed service costs as described in paragraph (c)(3)(i)(E) of this section. For example, production additional section 263A costs include the additional section 263A costs that constitute post-production costs as defined in paragraph (a)(3)(iii) of this section.

(*3*) *Production section 471 costs. Production section 471 costs* are defined as the total section 471 costs that a taxpayer incurs during its current taxable year less the taxpayer's raw material costs.

(iii) *LIFO taxpayers electing the modified simplified production method*—(A) *In general.* Under the modified simplified production method, a taxpayer using a LIFO method must calculate a particular year's index (for example, under § 1.472–8(e)) without regard to its additional section 263A costs. Similarly, a taxpayer that adjusts current-year costs by applicable indexes to determine whether there has been an inventory increment or decrement in the current year for a particular LIFO pool must disregard the additional section 263A costs in making that determination.

(B) *LIFO increment*—(*1*) *In general.* If a taxpayer determines there has been an inventory increment, the taxpayer must state the amount of the increment in current-year dollars (stated in terms of section 471 costs). The taxpayer then multiplies this amount by the combined absorption ratio, as defined in paragraph (c)(3)(iii)(B)(*2*) of this section. The resulting product is the additional section 263A costs that must be added to the taxpayer's increment for the year stated in terms of section 471 costs.

(*2*) *Combined absorption ratio defined.* For purposes of this paragraph (c)(3)(iii), the numerator of the combined absorption ratio is the total additional section 263A costs allocable to eligible property remaining on hand at the close of the taxable year, as

described in paragraph (c)(3)(i)(A) of this section. The denominator of the combined absorption ratio is the total section 471 costs remaining on hand at year end, as described in paragraph (b)(3)(ii)(B) of this section.

(C) *LIFO decrement.* If a taxpayer determines there has been an inventory decrement, the taxpayer must state the amount of the decrement in dollars for the particular year for which the LIFO decrement has occurred. The additional section 263A costs incurred in prior years that apply to the decrement are included in cost of goods sold. The taxpayer determines the additional section 263A costs that apply to the decrement by multiplying the additional section 263A costs allocated to the layer of the pool in which the decrement occurred by the ratio of the decrement (excluding additional section 263A costs) to the section 471 costs in the layer of that pool.

(iv) *De minimis rule for producers with total indirect costs of $200,000 or less.* Paragraph (b)(3)(iv) of this section, which provides that the additional section 263A costs allocable to eligible property remaining on hand at the close of the taxable year are deemed to be zero for producers with total indirect costs of $200,000 or less, applies to the modified simplified production method.

(v) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples:

Example 1. FIFO inventory method. (i) Taxpayer P uses the first-in, first-out (FIFO) method of accounting for inventories and a calendar taxable year. P's beginning inventory for 2010 is $2,500,000, including $2,000,000 of section 471 costs and $500,000 of additional section 263A costs.

(ii) During 2010, P incurs $10,000,000 of section 471 costs, including $4,000,000 of raw material costs (as defined in paragraph (c)(3)(ii)(A)(*3*) of this section) and $6,000,000 of production section 471 costs (as defined in paragraph (c)(3)(ii)(B)(*3*) of this section). P also incurs $1,060,000 of additional section 263A costs, including $340,000 of preproduction additional section 263A costs (as defined in paragraph (c)(3)(ii)(A)(*2*) of this section) and $720,000 of production additional section 263A costs (as defined in paragraph (c)(3)(ii)(B)(*2*) of this section).

(iii) At the end of 2010, P's section 471 costs incurred during the taxable year remaining in ending inventory are $3,500,000, including $2,000,000 of raw materials section 471 costs and $1,500,000 of production section 471 costs.

(iv) P computes its preproduction absorption ratio for 2010 under paragraph (c)(3)(ii)(A) of this section as follows:

$$\frac{\text{Preproduction additional section 263A costs}}{\text{Raw material costs}} = \frac{\$\ 340{,}000}{\$4{,}000{,}000} = 8.5 \text{ percent}$$

(v) P computes its production absorption ratio for 2010 under paragraph (c)(3)(ii)(B)(*1*) of this section as follows:

$$\frac{\text{Production additional section 263A costs}}{\text{Production section 471 costs}} = \frac{\$\ 720{,}000}{\$6{,}000{,}000} = 12 \text{ percent}$$

(vi) Under paragraph (c)(3)(i)(B) of this section, P computes its allocable preproduction additional section 263A costs by multiplying the preproduction absorption ratio by raw materials section 471 costs incurred during the taxable year and remaining in ending inventory (8.5 percent * $2,000,000 = $170,000).

(vii) Under paragraph (c)(3)(i)(C) of this section, P computes its allocable production additional section 263A costs by multiplying the production absorption ratio by production section 471 costs incurred during the taxable year and remaining in ending inventory at year end (12 percent * $1,500,000 = $180,000).

(viii) Under paragraph (c)(3)(i)(A) of this section, P computes its total additional section 263A costs allocable to ending inventory by adding its allocable preproduction additional section 263A costs to its allocable production additional section 263A costs ($170,000 + $180,000 = $350,000).

(ix) P adds the $350,000 additional section 263A costs to the $3,500,000 of section 471 costs remaining in its ending inventory to calculate its total ending inventory of $3,850,000. P includes the balance of P's additional section 263A costs incurred during 2010, $710,000 ($1,060,000 less $350,000), in P's cost of goods sold.

Example 2. LIFO inventory method. (i) The facts are the same as in *Example 1,* except that P uses the LIFO inventory method rather than the FIFO method. P's 2010 LIFO increment is $1,500,000.

(ii) Under paragraph (c)(3)(iii)(B)(*1*) of this section, P determines the additional section 263A costs allocable to its 2010 LIFO increment by multiplying the increment by a combined absorption ratio. Under paragraph (c)(3)(iii)(B)(*2*) of this section, P computes the combined absorption ratio as follows:

$$\frac{\text{Additional section 263A costs allocable to eligible property remaining in ending inventory at the close of 2010}}{\text{Section 471 costs remaining in ending inventory at the end of 2010}} = \frac{\$\ 350{,}000}{\$3{,}500{,}000} = 10 \text{ percent}$$

(iii) P's additional section 263A costs allocable to its 2010 increment are $150,000 (10 percent * $1,500,000). Under paragraph (c)(3)(iii)(B)(*1*) of this section, P adds the $150,000 additional section 263A costs to its $1,500,000 LIFO increment to determine a total 2010 LIFO increment of $1,650,000. P's ending inventory is $4,150,000 (its beginning inventory of $2,500,000 plus the $1,650,000 increment). P includes the remaining $910,000 ($1,060,000 less $150,000) of additional section 263A costs incurred during 2010 in P's cost of goods sold.

Example 3. Mixed service costs. (i) During 2010, Taxpayer R incurs $200,000 of capitalizable mixed service costs (within the meaning of paragraph (c)(3)(i)(E) of this section). R incurs $8,000,000 of section 471 costs, including $2,000,000 of raw material costs (as defined in paragraph (c)(3)(ii)(A)(*3*) of this section).

(ii) Under paragraph (c)(3)(i)(E) of this section, R allocates its mixed service costs to preproduction additional section 263A costs

by computing the proportion of raw material costs in its section 471 costs and multiplying its mixed service costs by this percentage. The proportion of raw material costs in R's section 471 costs is 25 percent ($2,000,000/$8,000,000). R allocates $50,000 (25 percent * $200,000) of mixed service costs to preproduction additional section 263A costs. R includes the remaining $150,000 ($200,000 less $50,000) of capitalizable mixed service costs as production additional section 263A costs.

(4) *Modified simplified production method with historic absorption ratio election*—(i) *In general.* Except as otherwise provided in this paragraph (c)(4), paragraph (b)(4) of this section applies to the historic absorption ratio election under the modified simplified production method.

(ii) *General allocation formula*—(A) *In general.* Except as provided in paragraph (c)(4)(iii) of this section (relating to LIFO taxpayers), a taxpayer making the historic absorption ratio election under the modified simplified production method uses a preproduction historic absorption ratio and a production historic absorption ratio in place of the actual preproduction absorption ratio and production absorption ratio under paragraph (c)(3)(ii) of this section. The preproduction and production historic absorption ratios are based on costs a taxpayer capitalizes during its test period.

(B) *Preproduction historic absorption ratio.* The preproduction historic absorption ratio is computed as follows:

$$\frac{\text{Preproduction additional section 263A costs incurred during the test period}}{\text{Raw material costs incurred during the test period}}$$

(C) *Production historic absorption ratio.* The production historic absorption ratio is computed as follows:

$$\frac{\text{Production additional section 263A costs incurred during the test period}}{\text{Production section 471 costs incurred during the test period}}$$

(iii) *LIFO taxpayers making the historic absorption ratio election*—(A) *In general.* Instead of the combined absorption ratio under paragraph (c)(3)(iii)(B)(*2*) of this section, a LIFO taxpayer making the historic absorption ratio election under the modified simplified production method calculates a combined historic absorption ratio based on costs a taxpayer capitalizes during its test period.

(B) *Combined historic absorption ratio.* The combined historic absorption ratio is computed as follows:

$$\frac{\text{Total allocable additional section 263A costs incurred during the test period}}{\text{Total section 471 costs remaining on hand at each year end of the test period}}$$

(C) *Total allocable additional section 263A costs incurred during the test period.* Total allocable additional section 263A costs incurred during the test period are the sum of the total additional section 263A costs allocable to eligible property on hand at year end as described in paragraph (c)(3)(i)(A) of this section, for all years in the test period.

(D) *Total section 471 costs remaining on hand at each year end of the test period.* Total section 471 costs remaining on hand at each year end of the test period are the sum of the total section 471 costs remaining on hand at year end described in paragraph (b)(3)(ii)(B) of this section, for all taxable years in the test period.

(iv) *Extension of qualifying period.* In the first taxable year following the close of each qualifying period (for example, the sixth taxable year following the test period), a taxpayer must compute the actual absorption ratios under paragraph (c)(3) of this section (preproduction and production absorption ratios or, for LIFO taxpayers, the combined absorption ratio). If the actual combined absorption ratio or both the actual preproduction and production absorption ratios, as applicable, computed for this taxable year (the recomputation year) is within one-half of one percentage point (plus or minus) of the corresponding historic absorption ratio or ratios used in determining capitalizable costs for the qualifying period (the previous five taxable years), the qualifying period is extended to include the recomputation year and the following five taxable years, and the taxpayer must continue to use the historic absorption ratio or ratios throughout the extended qualifying period. If, however, the actual combined historic absorption ratio or either the actual preproduction absorption ratio or production absorption ratio, as applicable, is not within one-half of one percentage point (plus or minus) of the corresponding historic absorption ratio, the taxpayer must use the actual absorption ratio or ratios beginning with the recomputation year and throughout the updated test period. The taxpayer must resume using the historic absorption ratio or ratios based on the updated test period in the third taxable year following the recomputation year.

(v) *Transition rule.* [Reserved].

(vi) *Examples.* The provisions of this paragraph (c)(4) are illustrated by the following examples:

Example 1. FIFO inventory method. (i) Taxpayer S uses the FIFO method of accounting for inventories and a calendar taxable year, and in 2010 elects to use the modified simplified production method. In 2013, S makes the historic absorption ratio election. S identifies the following costs incurred during the test period:

	2010	2011	2012
Preproduction additional section 263A costs	$ 100	$ 200	$ 300
Production additional section 263A costs	200	350	450

	2010	2011	2012
Raw material costs	2,000	2,500	3,000
Production section 471 costs	2,500	3,500	4,000

In 2013, S incurs $10,000 of section 471 costs of which $1,000 raw material costs and $2,000 production 471 costs remain in ending inventory.

(ii) Under paragraph (c)(4)(ii)(B) of this section, in 2013 S computes the preproduction historic absorption ratio as follows:

$$\frac{\text{Preproduction additional section 263A costs}}{\text{Raw material costs}} = \frac{\$\ 100 + 200 + 300}{\$2{,}000 + 2{,}500 + 3{,}000} = \frac{600}{7{,}500} = 8 \text{ percent}$$

(iii) Under paragraph (c)(4)(ii)(C) of this section, S computes the production historic absorption ratio as follows:

$$\frac{\text{Production additional section 263A costs}}{\text{Production 471 costs}} = \frac{\$\ 200 + 350 + 450}{\$2{,}500 + 3{,}500 + 4{,}000} = \frac{1{,}000}{10{,}000} = 10 \text{ percent}$$

(iv) Under paragraph (c)(4)(ii)(A) of this section, S determines the preproduction additional section 263A costs allocable to its ending inventory for 2013 by multiplying its raw materials section 471 costs incurred during the 2013 taxable year and remaining in its ending inventory by its preproduction historic absorption ratio. S allocates $80 preproduction additional section 263A costs to its ending inventory ($1,000 * 8 percent).

(v) S determines the production additional section 263A costs allocable to its ending inventory for 2013 by multiplying its production section 471 costs incurred during the 2013 taxable year and remaining in its ending inventory by its production historic absorption ratio. S allocates $200 production additional section 263A costs to its ending inventory ($2,000 * 10 percent).

(vi) Under paragraph (c)(4)(ii) of this section, S's total additional section 263A costs allocable to ending inventory in 2013 are $280, which is the sum of the allocable preproduction additional section 263A costs ($80) and the allocable production additional section 263A costs ($200). S's ending inventory in 2013 is $3,280, which is the sum of S's additional section 263A costs allocable to ending inventory and S's section 471 costs remaining in ending inventory ($280 + $3,000). S includes the balance of S's additional section 263A costs incurred during 2013 in S's cost of goods sold.

Example 2. LIFO inventory method. (i) The facts are the same as in *Example 1*, except that S uses the LIFO inventory method rather than the FIFO method. S calculates additional section 263A costs incurred during the taxable year and allocable to ending inventory under paragraph (c)(3)(iii) of this section and identifies the following costs incurred during the test period:

	2010	2011	2012
Additional section 263A costs incurred during the taxable year allocable to ending inventory	$ 100	$ 150	$ 200
Section 471 costs incurred during the taxable year that remain in ending inventory	1,000	1,400	2,100

In 2013, the LIFO value of S's increment is $1,500.

(ii) Under paragraph (c)(4)(iii) of this section, S computes a combined historic absorption ratio as follows:

$$\frac{\text{Additional section 263A costs incurred during each taxable year in the test period allocable to ending inventory}}{\text{Section 471 costs incurred during each taxable year in the test period that remain in ending inventory}} = \frac{\$\ 100 + 150 + 200}{\$1{,}000 + 1{,}400 + 2{,}100} = \frac{\$\ 450}{\$4{,}500} = 10 \text{ percent}$$

(iii) S's additional section 263A costs allocable to its 2013 LIFO increment is $150 ($1,500 beginning LIFO increment * 10 percent combined historic absorption ratio). S adds the $150 to the $1,500 LIFO increment to determine a total 2013 LIFO increment of $1,650.

* * * * *

(g) *Effective/applicability date.* Paragraphs (b)(2)(i)(D), and (f) of this section apply for taxable years ending on or after August 2, 2005. Paragraph (c) of this section applies for taxable years ending on or after the date these

regulations are published as final regulations in the **Federal Register**.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2012–21743 Filed 9–4–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 901

[SATS No. AL–077–FOR; Docket ID: OSM–2012–0016]

Alabama Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are announcing receipt of a proposed amendment to the Alabama regulatory program (Alabama program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Alabama proposes revisions to its Program regarding revegetation success guidelines. Alabama intends to revise its program to improve operational efficiency.

This document gives the times and locations that the Alabama program and proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., c.d.t., October 5, 2012. If requested, we will hold a public hearing on the amendment on October 1, 2012. We will accept requests to speak at a hearing until 4 p.m., c.d.t. on September 20, 2012.

ADDRESSES: You may submit comments, identified by SATS No. AL–077–FOR by any of the following methods:

- *Mail/Hand Delivery:* Sherry Wilson, Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209.
- *Fax:* (205) 290–7280.
- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID OSM–2012–0016. If you would like to submit comments go to *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Alabama program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Birmingham Field Office or going to *www.regulations.gov.*

Sherry Wilson, Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209, Telephone: (205) 290–7282, Email: *swilson@osmre.gov.*

In addition, you may review a copy of the amendment during regular business hours at the following location:

Alabama Surface Mining Commission, 1811 Second Ave., P.O. Box 2390, Jasper, Alabama 35502–2390, Telephone: (205) 221–4130.

FOR FURTHER INFORMATION CONTACT: Sherry Wilson, Director, Birmingham Field Office. Telephone: (205) 290–7282. Email: *swilson@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Alabama Program
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Alabama Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Alabama program effective May 20, 1982. You can find background information on the Alabama program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Alabama program in the May 20, 1982, **Federal Register** (47 FR 22030). You can also find later actions concerning the Alabama program and program amendments at 30 CFR 901.10, 901.15, and 901.16.

II. Description of the Proposed Amendment

By letter dated June 26, 2012 (Administrative Record No. AL–0664), Alabama sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) at its own initiative. Below is a summary of the changes proposed by Alabama. The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES**.

Alabama 880–X–10C-.62 Revegetation: Standards for Success Alabama 880–X–10D-.56 Revegetation: Standards for Success

Alabama proposes to add new language in both sections 880–X–10C-.62(1)(c) and (d) and 880–X–10D-.56(1)(c) and (d) regarding herbaceous ground cover and trees and shrubs for determining the success of stocking. Additionally, Alabama proposes to delete and revise specific language in both sections of 880–X–10C-.62(2)(c), (e), and (g) and 880–X–10D-.56(2)(c), (e) and (g) regarding herbaceous ground cover and woody plant standards for areas developed for post-mining landuse of forest land, recreation, wildlife habitat, and undeveloped land.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Electronic or Written Comments

If you submit written comments, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**)

will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone 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.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., c.d.t. on September 20, 2012. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSM for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 901

Intergovernmental relations, Surface mining, Underground mining.

Dated: June 29, 2012.

Ervin J. Barchenger,

Regional Director, Mid-Continent Region.

[FR Doc. 2012–21864 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 944

[SATS No. UT–049–FOR; Docket ID OSM–2012–0015]

Utah Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We are announcing receipt of a proposed amendment to the Utah regulatory program (hereinafter, the ''Utah program'') under the Surface Mining Control and Reclamation Act of 1977 (''SMCRA'' or ''the Act''). Utah proposes revisions and additions of rules pertaining to ownership and control. Utah intends to revise its program to be consistent with the corresponding Federal regulations.

This document gives the times and locations that the Utah program and proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., m.d.t. October 5, 2012. If requested, we will hold a public hearing on the amendment on October 1, 2012. We will accept requests to speak until 4 p.m., m.d.t. on September 20, 2012.

ADDRESSES: You may submit comments by either of the following two methods:

- *Federal eRulemaking Portal: www.regulations.gov.* This proposed rule has been assigned Docket ID: OSM–2012–0015. If you would like to submit comments through the Federal eRulemaking Portal, go to *www.regulations.gov* and do the following. Click in the SEARCH box and type in Docket ID ''OSM–2012–0015'' then click the ''Search'' button. The next screen will display the Docket Search Results for the rulemaking. You may comment from this screen by clicking the ''Comment Now!'' button. If you click on ''OSM–2012–0015,'' you can view the proposed rule as well as supporting material and any comments submitted by others.
- *Mail/Hand Delivery/Courier:* Kenneth Walker, Chief, Denver Field Division, Office of Surface Mining Reclamation and Enforcement, 1999 Broadway, Suite 3320, Denver, CO 80202.

For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''III. Public Comment Procedures'' in the **SUPPLEMENTARY INFORMATION** section of this document.

In addition to viewing the docket and obtaining copies of documents at *www.regulations.gov,* you may review copies of the Utah program, this amendment, a listing of any public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may also receive one free copy of the amendment by contacting OSM's Denver Office.

Kenneth Walker, Chief, Denver Field Division, Office of Surface Mining Reclamation and Enforcement, 1999 Broadway, Suite 3320, Denver, CO 80202, (303) 293–5012, *kwalker@OSMRE.gov.*

John R. Baza, Director, Utah Division of Oil, Gas and Mining, 1594 West North Temple, Suite 1210, Salt Lake City, UT 84116, (801) 538–5334, *johnbaza@utah.gov.*

FOR FURTHER INFORMATION CONTACT: Kenneth Walker, *Telephone:* (303) 293–5012, *Internet: kwalker@OSMRE.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background on the Utah Program
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Utah Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Utah program on January 21, 1981. You can find background information on the Utah program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Utah program in the January 21, 1981, **Federal Register** (46 FR 5899). You can also find later actions concerning Utah's program and program amendments at 30 CFR 944.15 and 944.30.

II. Description of the Proposed Amendment

By letter dated June 25, 2012, Utah sent us a proposed amendment to its program (Administrative Record Document ID No. OSM–2012–0015–0002) under SMCRA (30 U.S.C. 1201 *et seq.*). Utah sent the amendment in response to our October 2, 2009, letter (Administrative Record Document ID No. OSM–2012–0015–0003) sent in accordance with 30 CFR 732.17(c). The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES**.

The provisions of the Utah Administrative Code that Utah proposes to revise, delete and/or add are: R645–100–200, Definitions of Applicant/Violator System (AVS); Control or Controller; Knowingly; Knowing or Knowingly; Owned or Controlled; Own, Owner, or Ownership; Transfer, Assignment, or Sale of Permit Rights; Violation; Violation Notice; Willful or Willfully; Willful Violation; R645–300–132 through –132.520.3, Review of compliance and entry of information into the AVS; R645–300–148.100, Updating personnel info; R645–300–161, Review procedures and preliminary findings on improvidently issued permits; R645–300–162 and –162.300 through –162.320, Review criteria for improvidently issued permits; R645–300–164 through –164.200, Rescission procedures for improvidently issued permits; R645–300–171 through –173, Certifying and updating existing permit application information; R645–300–180 through –185, Post permit issuance requirements for the Division and other actions based on ownership, control, and violation information; R645–301–111.400, Applicant submittal requirements; R645–301–111.500 Division AVS data entry requirements; R645–301–112 through –112.420, Identification of interests; R645–301–113.100, –113.120, –113.300, and –113.340 through –113.360, Violation information required in a permit application; R645–302–240 through –242, –245.210, and –245.300, Permit application requirements for auger mining and remining operations; R645–301–245.410 through –245.420, auger mining and remining backfilling and grading requirements; R645–303–310, Transfer, assignment, or sale of permit rights; R645–400–319, Cessation order notification procedures; R645–403–100 through –133, Criminal penalties and civil actions.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Utah program.

Electronic or Written Comments

If you submit written comments, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent Tribal or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed above (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone 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 anytime. 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.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., m.d.t. on September 20, 2012. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold the hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at a public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSM for review, our regulations at 30 CFR 732.17(h) require

us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 944

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 2, 2012.

Billie E. Clark,

Acting Director, Western Region.

[FR Doc. 2012–21857 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket Number USCG–2012–0172]

RIN 1625–AA01

Special Anchorage Area; Stockton Springs, ME

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a special anchorage area in Stockton Springs, Maine. This proposed action is necessary to facilitate safe navigation in that area and provide safe and secure anchorages for vessels not more than 20 meters in length. This action is intended to increase the safety of life and property in Stockton Springs, improve the safety of anchored vessels, and provide for the overall safe and efficient flow of vessel traffic and commerce.

DATES: Comments and related material must be received by the Coast Guard on or before November 5, 2012. Requests for public meetings must be received by the Coast Guard on or before September 26, 2012.

ADDRESSES: You may submit comments identified by docket number using any one of the following methods:

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

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email BM1 William M. Ferretti, Waterways Management Branch, First Coast Guard District, telephone 617–223–8221, email *William.M.Ferretti@uscg.mil;* or Lieutenant Isaac M. Slavitt, Waterways Management Branch, First Coast Guard District, telephone 617–223–8385, email *Isaac.M.Slavitt@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number [USCG–2012–0172] in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number (USCG–2012–0172) in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of 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 a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public meeting

We do not now plan to hold a public meeting. But, you may submit a request for one on or before September 26, 2012, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that a public meeting would aid this rulemaking, we will hold one at a time and place

announced by a later notice in the **Federal Register**.

B. Basis and Purpose

The legal basis for the proposed rule is: 33 U.S.C. 471, 1221 through 1236, 2030, 2035, 2071; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define anchorage grounds.

The rule is intended to reduce the risk of vessel collisions by creating a special anchorage area in Stockton Springs. This proposed rule would establish a special anchorage area in the northeast portion of Stockton Harbor.

C. Discussion of Proposed Rule

The proposed rule would create a new special anchorage area in Stockton Springs, Maine. The location of the new special anchorage area in Stockton Springs is described in the regulatory text below. All proposed coordinates are North American Datum 1983 (NAD 83).

Smaller vessels frequent the area due to the recreational and tourist attractions in Penobscot Bay. Vessels not more than 20 meters in length are not required to sound signals as per Rule 35 of the Inland Navigation Rules (33 U.S.C. 2035) nor exhibit anchor lights or shapes as per Rule 30 of the Inland Navigation Rules (33 U.S.C 2030) when at anchor in a special anchorage area. Creation of the special anchorage area in Stockton Springs will provide an additional layer of safety for the smaller vessels who anchor there. Additionally, mariners utilizing the anchorage areas would be encouraged to contact local and state authorities, such as the local harbormaster, to ensure compliance with any additional applicable state and local laws. Such laws may involve, for example, compliance with direction from the local harbormaster when placing or using moorings within the anchorage.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. We expect minimal additional cost impacts on fishing or recreational boats anchoring because this rule would not affect normal surface navigation. Although this regulation may have some impact on the public, the potential impact will be minimized for the following reasons: Normal surface navigation will not be affected as this area has been historically used as a mooring field by the Town of Stockton Springs, and the number of vessels using the anchorage is limited due to depth (less than or equal to 15 feet).

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities.

This proposed rule would affect the following entities, some of which might be small entities: The owners or operators of recreational and small fishing vessels intending to anchor in Stockton Springs. The proposed rule would not have a significant economic impact on a substantial number of small entities for the following reasons: Normal surface navigation will not be affected as this area has been historically used as a mooring field by the Stockton Springs and the number of vessels using the anchorage is limited due to depth (less than or equal to 15 feet).

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

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children From Environmental Health Risks

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

11. Indian Tribal Governments

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

12. Energy Effects

This proposed rule is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

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

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves the establishment of special anchorage grounds. We believe the proposed rule is categorically excluded from further review under paragraph 34(f) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 110 as follows:

PART 110—ANCHORAGE REGULATIONS

1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471; 1221 through 1236, 2030, 2035, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

2. Add § 110.7 to subpart A to read as follows:

§ 110.7 Stockton Springs, Maine.

(a) *Anchorage A.* All of the waters enclosed by a line beginning at latitude 44°27′45.00″ N, longitude 068°51′28.08″ W; thence to latitude 44°28′07.32″ N, longitude 068°52′04.08″ W; thence to latitude 44°28′34.32″ N, longitude 068°51′43.20″ W; thence to latitude 44°28′14.52″ N, longitude 068°51′06.84″ W; thence along the shoreline to the beginning point. This encompasses the northeast portion of Stockton Springs Harbor.

(b) *Regulations.* This area is principally for use by recreational craft. Temporary floats or buoys for marking anchors or moorings in place are allowed in this area. Fixed mooring piles or stakes are not allowed. All moorings or anchors shall be placed well within the anchorage areas so that no portion of the hull or rigging will at any time extend outside of the anchorage.

Note to paragraph (b): All anchoring in the areas is under the supervision of the Stockton Springs Harbor Master or other such authority as may be designated by the authorities of the Town of Stockton Springs, Maine. All coordinates referenced use datum: NAD 83.

Dated: August 16, 2012.

James B. McPherson,

Captain, U.S. Coast Guard, Acting Commander, First Coast Guard District.

[FR Doc. 2012–21759 Filed 9–4–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0623]

RIN 1625–AA11

Regulated Navigation Area; Thames River Degaussing Range Replacement Operations; New London, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a regulated navigation area (RNA) on the navigable waters of the Thames River in New London Harbor, New London, CT. The proposed RNA would establish speed and wake restrictions as well as allow the Coast Guard to prohibit all vessel traffic through the RNA during degaussing range replacement operations, both planned and unforeseen, that could pose an imminent hazard to persons and vessels operating in the area. This rule is necessary to provide for the safety of life on the navigable waters during the replacement of the degaussing range and its supporting system.

DATES: Comments and related material must be received by the Coast Guard on or before October 5, 2012.

Requests for public meetings must be received by the Coast Guard on or before September 17, 2012.

ADDRESSES: You may submit comments identified by docket number using any one of the following methods:

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

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Joseph Graun, Prevention Department, U.S. Coast Guard Sector Long Island Sound, (203) 468–4544, *Joseph.L.Graun@uscg.mil;* or

Lieutenant Isaac M. Slavitt, Waterways Management, U.S. Coast Guard First District, (617) 223–8385. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

COTP Captain of the Port
DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking
RNA Regulated Navigation Area

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number (USCG–2012–0623) in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number (USCG–2012–0623) in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of 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 a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before September 17, 2012, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Basis and Purpose

Under the Ports and Waterways Safety Act, the Coast Guard has the authority to establish RNAs in defined water areas that are determined to have hazardous conditions and in which vessel traffic can be regulated in the interest of safety. See 33 U.S.C. 1231 and Department of Homeland Security Delegation No. 0170.1.

This proposal would establish speed and wake restrictions as well as allow the Coast Guard to prohibit all vessel traffic through the RNA during degaussing range replacement operations, both planned and unforeseen, that could pose an imminent hazard to persons and vessels operating in the area. The Coast Guard is not now planning (and will actively avoid) full closures of the waterway; however, given the nature of the work it is important that this regulatory tool be available if circumstances change. This rule is necessary to provide for the safety of life on the navigable waters during the replacement of the degaussing range and its supporting system.

C. Discussion of Proposed Rule

The U.S. Navy operates a fixed degaussing range in New London Harbor, New London, CT. This range is buried in sand on the bottom of the Thames River federal navigation channel southeast of Fort Trumbull State Park. The Navy uses this range to decrease unwanted magnetic fields in Navy vessels. On NOAA Charts, the degaussing range is outlined with a black dotted line and labeled ''Degaussing Range''. The associated system of sensors and cables encompasses a much larger area of the river bottom, from the river's west shore by Fort Trumbull State Park southeasterly across the river to the river's eastern bank. On NOAA Charts, this supporting system's boundaries are outlined with a magenta dotted line and labeled ''Cable Area''. The Navy is preparing to replace this range with new sensors, cables and supporting equipment. The replacement project is projected to last between four and six months, and is scheduled to begin on or about November 1, 2012.

The Coast Guard is not now planning (and will actively avoid) full closures of the waterway; however, given the nature of the work it is important that this regulatory tool be available if circumstances change. The Coast Guard attended the project's ''95% Design Review Meeting'' hosted by the U.S. Navy on April 17, 2012 in New London, CT. During the meeting, the Navy presented the project design and an overview of what operations must take place in order to complete the project. The Coast Guard discussed this project with the Navy to identify whether the project can be completed without channel closures. While the majority of the project will be completed without the need for full closures, the possibility remains that certain tasks will require closing the waterway due to the location of the degaussing range directly under the navigation channel.

The new trench will be located adjacent to the current degaussing range within the navigation channel. Excavating the trench and replacing equipment and cables will require barges and equipment to take up a portion of the channel while they perform various operations including excavating, diving, laying cables, and placing sensors. This process will be

extremely complex and involves many safety hazards. In order to minimize safety hazards, the Coast Guard proposes to make the ''Cable Area'' (which includes the ''Degaussing Range'') a temporary RNA.

This RNA would allow the Captain of the Port Sector Long Island Sound (COTP) to establish speed and wake restrictions and to prohibit vessel traffic on this portion of the river for limited periods when necessary for the safety of vessels and workers during construction work in the channel. The Coast Guard would enforce a five knot speed limit and ''NO WAKE'' zone and be able to close the designated area to all vessel traffic during any circumstance, planned or unforeseen, that poses an imminent threat to waterway users or construction operations in the area. Complete waterway closures would be minimized to that period absolutely necessary and made with as much advanced notice as possible.

Entry into, anchoring or movement within this proposed RNA during a closure would be prohibited unless authorized by the COTP or a designated representative. In the event of an emergency, all construction equipment would need to be vacated for emergency vessels (i.e. Fire Rescue Boat, Marine Police Boat, or Environmental Response Boat).

This project is expected to be completed within a four to six month period. However, in order to prepare for project delays associated with inclement weather, permitting and other circumstance we propose a twenty-four month effective period for the RNA from November 1, 2012 until October 31, 2014.

The project currently faces several factors that could lead to delays. A project coordinator has not yet been identified. Additionally, as of July 2012 state environmental and Army Corps of Engineers permits have not been requested by the Navy. These permits can take several months to obtain and once obtained may include restrictions on certain underwater activities. The Navy will not know the extent of all restrictions until the permits are issued.

If the project is completed before October 31, 2014, the COTP could suspend enforcement of the RNA. The COTP would ensure that notice of the suspension of enforcement reached affected segments of the public by all appropriate means. Such means of notification could include, but would not be limited to, Broadcast Notice to Mariners and Local Notice to Mariners.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The Coast Guard determined that this rulemaking would not be a significant regulatory action for the following reasons: vessel traffic would only be excluded from the RNA for limited durations (if at all), and speed and wake restrictions are not unduly restrictive, and the RNA covers a small geographic area. Advanced public notifications would also be made to local mariners through appropriate means, which could include, but would not be limited to, Local Notice to Mariners and Broadcast Notice to Mariners.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This rule would affect the following entities, some of which may be small entities: the owners or operators of vessels intending to enter or transit within the regulated areas during a vessel restriction period.

The RNA would not have a significant economic impact on a substantial number of small entities for the following reasons: vessel traffic would only be excluded from the RNA for limited durations (if at all), and speed and wake restrictions are not unduly restrictive, and the RNA covers a small geographic area. Additionally, before the effective period of a waterway closure, advanced public notifications would be made to local mariners through appropriate means, which could include, but would not be limited to, Local Notice to Mariners and Broadcast Notice to Mariners.

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

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or

more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children From Environmental Health Risks

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves restricting vessel movement within a regulated navigation area. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T01–0623 to read as follows:

§ 165.T01–0623 Regulated Navigation Area: Thames River, New London, CT.

(a) *Location.* The following area is a regulated navigation area: All navigable waters of the Thames River adjacent to Fort Trumbull State Park in New London, CT, from surface to bottom bounded to the north by a line connecting the following points: Point ''1'', 41°20′40″ N, 072°05′32″ W east to point ''2'', 41°20′40″ N, 072°05′15″ W then southeast to point ''3'', 41°20′31.8″ N, 072°05′03″ W then south to point ''4'', 41°20′28″ N, 072°05′03″ W then east to point ''5'', 41°20′30″ N, 072°04′48″ W; bounded to the east by following the shoreline south from point ''5'' to point ''6'', 41°20′19″ N, 072°04′46″ W; bounded to the south by a line connecting the following points: point ''6'' west to point ''7'', 41°20′17″ N, 072°05′13″ W then north to point ''8'' 41°20′27.2″ N, 072°05′15″ W then northwest to point ''9'' 41°20′29.5″ N, 072°05′17″ W then west to point ''10'' 41°20′29.5″ N, 072°05′30″ W then northwest to point ''11'' 41°20′31″ N, 072°05′34″ W; bounded to the west by following the shoreline north from point ''11'' back to the start, point ''1''.

(b) *Regulations.* (1) The general regulations contained in 33 CFR 165.10, 165.11, and 165.13 apply.

(2) In accordance with the general regulations, entry into, anchoring, or movement within this zone, during periods of enforcement, is prohibited unless authorized by the Captain of the Port Long Island Sound (COTP) or the COTP's designated representative.

(3) During periods of enforcement, a speed limit of five knots will be in effect within the regulated area and all vessels must proceed through the area with caution and operate in such a manner as to produce no wake.

(4) During periods of enforcement, all persons and vessels must comply with all orders and directions from the COTP or the COTP's designated representative.

(5) During periods of enforcement, upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light or other means, the operator of the vessel must proceed as directed.

(6) Persons and vessels may request permission to enter the zone during periods of enforcement on VHF–16 or via phone at 203–468–4401.

(7) Notwithstanding anything contained in this rule, the Rules of the Road (33 CFR part 84—Subchapter E, inland navigational rules) are still in effect and should be strictly adhered to at all times.

(c) *Effective Period.* This rule is effective from November 1, 2012 until October 31, 2014.

(d) *Enforcement Period.* (1) Except when suspended in accordance with paragraph (d)(2) of this section, this regulated navigation area is in force 24 hours a day from November 1, 2012 until October 31, 2014.

(2) Notice of suspension of enforcement: The COTP may suspend enforcement of the regulated navigation area. If enforcement is suspended, the COTP will cause notice of the suspension of enforcement to be made by all appropriate means to the affected segments of the public. Such means of notification may include, but are not limited to, Broadcast Notice to Mariners

and Local Notice to Mariners. Such notifications will include the date and time that enforcement is suspended as well as the date and time that enforcement will resume.

(3) Violations of this regulated navigation area should be reported to the COTP, at 203–468–4401 or on VHF–Channel 16. Persons in violation of this regulated navigation area may be subject to civil or criminal penalties.

Dated: August 22, 2012.

D.B. Abel,

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

[FR Doc. 2012–21760 Filed 9–4–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 725

[EPA–HQ–OPPT–2011–0740; FRL–9348–1]

RIN 2070–AJ65

Microorganisms; General Exemptions From Reporting Requirements; Revisions to Recipient Organisms Eligible for Tier I and Tier II Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA received petitions to add *Trichoderma reesei* and *Bacillus amyloliquefaciens* to the list of microorganisms that may be used as recipient microorganisms in order to qualify for the exemption from full notification and reporting procedures under the Toxic Substances Control Act (TSCA) for new microorganisms that are being manufactured for introduction into commerce. Based on EPA's evaluation of these petitions, EPA has made a preliminary determination that certain strains of both microorganisms will not present an unreasonable risk of injury to health or the environment when used as a recipient microorganism provided that certain criteria for the introduced genetic material and the physical containment conditions are met. Therefore, EPA is proposing to add two additional microorganisms to the list of recipient microorganisms that are eligible for exemptions from full reporting for the manufacture (including import) of new microorganisms.

DATES: Comments must be received on or before November 5, 2012.

You may submit a request for an opportunity to present oral comments in writing on or before October 5, 2012, and if a written request is received by EPA, an informal public hearing will be held on this proposed rule in Washington, DC. For further information on the informal public hearing, see Unit I.C.

ADDRESSES: Submit your written request for an opportunity to present oral comments, identified by docket identification (ID) number EPA–HQ–OPPT–2011–0740, to the mailing or hand delivery addresses in this unit.

Submit your comments, identified by docket ID number EPA–HQ–OPPT–2011–0740, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2011–0740. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2011–0740. EPA's policy is that all comments received will be included in the docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* 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 electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Brian Lee, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–6293; email address: *lee.brian@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you produce, import, process, or use either intergeneric *Trichoderma reesei* or intergeneric *Bacillus amyloliquefaciens.* Potentially affected entities may include, but are not limited to:

• Basic Chemical Manufacturing (NAICS code 3251).

• Pesticide, Fertilizer and other Agricultural Chemical manufacturing (NAICS code 3253).

• Other Chemical Product and Preparation Manufacturing (NAICS code 3259).

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

B. What should I consider as I prepare my comments for EPA?

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

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

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

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

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

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

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

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

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

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

C. Can I request an opportunity to present oral comments to the agency?

You may submit a request for an opportunity to present oral comments. This request must be made in writing and be identified by docket ID number EPA–HQ–OPPT–2011–0740. This written request must be submitted to the mailing or hand delivery addresses provided under **ADDRESSES**. If such a request is received on or before October 5, 2012, EPA will hold an informal public hearing on this proposed rule in Washington, DC. If such a request is received, EPA will announce the scheduling of the informal public hearing in a subsequent document in the **Federal Register**. If an informal public hearing is announced, and if you are interested in attending or presenting oral and/or written comments at the informal public hearing, you should follow the instructions provided in the subsequent **Federal Register** document announcing the informal public hearing.

II. Background

A. What action is the agency taking?

EPA received petitions to add *Trichoderma reesei* and *Bacillus amyloliquefaciens* to the list of recipient microorganisms at § 725.420 that are eligible for the regulatory exemptions applicable to new microorganisms that are manufactured for introduction into commerce (Refs. 1–3). EPA has made a preliminary determination that both of the microorganisms, with certain limitations, meet the criteria for addition to the list—i.e., they will not present an unreasonable risk of injury to health or the environment provided that the other conditions of the exemptions at 40 CFR part 725, subpart G, relating to the introduced genetic material, and the physical containment of the new microorganisms, have been met. Therefore, this document proposes to grant the exemption petition for these two microorganisms.

EPA is proposing to restrict the exemption for *Trichoderma reesei* to the *Trichoderma reesei* strain QM6a and its derivatives (hereafter, *T. reesei* QM6a). In addition, EPA is proposing to restrict the *T. reesei* QM6a exemption to use under submerged standard industrial fermentation conditions; as described in this proposed rule, these conditions are typical throughout industry and would also meet the existing physical containment and control requirements for the tiered exemptions under § 725.422. EPA would also restrict the *T. reesei* QM6a exemption to fermentation operations in which no solid plant material or insoluble substrate is present in the fermentation broth. EPA is also proposing to require that any fermentation of solid plant material or insoluble substrate may only be initiated after the inactivation of *T. reesei* QM6a by a procedure that meets the existing requirements in § 725.422(d), i.e., by a procedure that has been demonstrated and documented to be effective in reducing the viable microbial population by at least 6 logs.

Additionally, EPA is proposing to limit the exemption for *B. amyloliquefaciens* to only industrial strains of *Bacillus amyloliquefaciens* that would fall into the subspecies *Bacillus amyloliquefaciens* subsp. *amyloliquefaciens* (hereafter, *B. amyloliquefaciens*).

B. What is the agency's legal authority for taking this action?

This action is being taken under the authority of TSCA section 5(h)(4) (15 U.S.C. 2604(h)(4)).

Section 5(a)(1) of TSCA requires that persons notify EPA at least 90 days before they manufacture (the term ''manufacture'' includes import under TSCA) for commercial purposes a ''new'' chemical substance, or manufacture (including import) or process a chemical substance for a ''significant new use.'' TSCA defines ''chemical substance'' broadly and in terms that cover intergeneric microorganisms as well as traditional chemical substances. Therefore, for the purposes of TSCA, a ''new microorganism,'' like a ''new chemical substance,'' is one that is not listed on the TSCA Chemical Substances Inventory (TSCA Inventory) compiled under TSCA section 8(b). Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule, to exempt the manufacturer or importer of any new chemical substance from part or all of the provisions of TSCA section 5, if EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance will not present an unreasonable risk of injury to human health or the environment.

C. Existing EPA Regulatory Requirements and Exemption Standard

Manufacturers are required to report certain information to EPA 90 days

before commencing the manufacture of intergeneric microorganisms that are not listed on the TSCA Inventory. EPA regulations at 40 CFR part 725 establish the mechanisms for reporting this information.

Any manufacturer of a living intergeneric microorganism who is required to report under TSCA section 5 must file a Microbial Commercial Activity Notice (MCAN) with EPA, unless the activity is eligible for one of the specific exemptions. The general procedures for filing MCANs are described in 40 CFR part 725, subpart B.

EPA regulations establish two exemptions for new microorganisms, after the research and development stage, which are being manufactured for introduction into commerce: The Tier I and Tier II exemptions.

Under the Tier I exemption, if three criteria are met, manufacturers are only required to notify EPA that they are manufacturing a new microorganism that qualifies for this exemption 10 days before commencing manufacture, and to keep certain records. 40 CFR 725.400. To qualify for the Tier I exemption, a manufacturer must use one of the recipient organisms listed in § 725.420, and must implement specific physical containment and control technologies. In addition, the genetic material introduced into the recipient microorganism must be well-characterized, limited in size, poorly mobilizable, and free of certain sequences. 40 CFR 725.421.

A manufacturer who otherwise meets the conditions of the Tier I exemption may modify the specified containment restrictions, but must submit a Tier II exemption notification. 40 CFR 725.428. The Tier II exemption requires manufacturers to submit an abbreviated notification describing the modified containment, and provides for a 45 day period, during which EPA would review the proposed containment. 40 CFR 725.450 and 725.470. The manufacturer may not proceed under this exemption until EPA approves the exemption. 40 CFR 725.470.

EPA established a petition process at § 725.67 to provide a mechanism for the public to propose additional microorganisms as candidates for the tiered exemptions.

Section 725.67 directs a petitioner to submit information to demonstrate that ''any activities affected by the requested exemption will not present an unreasonable risk of injury to health or the environment.'' 40 CFR 725.67(a)(2). In addition, a petitioner is responsible to provide supporting information for this determination in four general categories:

1. The effects of the new microorganism on health and the environment.
2. The magnitude of exposure of human beings and the environment to the new microorganism.
3. The benefits of the new microorganism for various uses and the availability of substitutes for such uses.
4. The reasonably ascertainable economic consequences of granting or denying the petition, including effects on the national economy, small business, and technological innovation.

Section 725.67 also specifies that when applying to list a recipient microorganism for the tiered exemption under § 725.420, petitioners should include information addressing six specified criteria, which EPA will use to evaluate the microorganism for listing. 40 CFR 725.67(a)(3)(iii). The six criteria are:

- Identification and classification of the microorganism using available genotypic and phenotypic information.
- Information to evaluate the relationship of the microorganism to any other closely related microorganisms which have a potential for adverse effects on health or the environment.
- A history of safe commercial use for the microorganism.
- Commercial uses indicating that the microorganism products might be subject to TSCA.
- Studies which indicate the potential for the microorganism to cause adverse effects to health or the environment.
- Studies which indicate the survival characteristics of the microorganism in the environment.

III. EPA's Evaluation of Available Information on the Proposed Microorganisms for the Criteria Delineated in § 725.67

Pursuant to § 725.67, Genencor International, Inc., (subsequently supported by the Enzyme Technical Association (ETA)) and Novozymes North America, Inc., submitted Letters of Application to EPA requesting that *Trichoderma reesei* and *Bacillus amyloliquefaciens* (Refs. 1 and 2) be added to § 725.420 as candidate recipient microorganisms for the tiered exemptions. The letters of application provided information that the submitters believed demonstrate that activities affected by the requested exemptions would not present an unreasonable risk of injury to health or the environment. Information regarding the criteria specified in §§ 725.67(a)(2) and 725.67(a)(3)(iii) were addressed in these letters of application to list *Trichoderma reesei* and *Bacillus amyloliquefaciens* as recipient microorganisms under § 725.420.

EPA has made a preliminary determination based on the information provided in the Letters of Application (Refs. 1 and 2), supplemental information provided by ETA (Refs. 4 and 5), and other information available to EPA that *T. reesei* QM6a, with certain restrictions, and *B. amyloliquefaciens* will not present an unreasonable risk of injury to health or the environment when used as a recipient microorganism provided the existing criteria for the introduced genetic material and for physical containment conditions at § 725.422 are met. EPA's Risk Assessments for these two microorganisms (Refs. 6 and 7) are available in the docket. This unit presents a summary of EPA's evaluation of the available information pertinent to the six criteria delineated in § 725.67(a)(3)(iii) for both microorganisms. These criteria follow:

- Identification and classification of the microorganism using available genotypic and phenotypic information.
- Information to evaluate the relationship of the microorganism to any other closely related microorganisms that have a potential for adverse effects on health or the environment.
- A history of safe commercial use for the microorganism.
- Commercial uses indicating that the microorganism products might be subject to TSCA.
- Studies which indicate the potential for the microorganism to cause adverse effects to health or the environment.
- Studies which indicate the survival characteristics of the microorganism in the environment.

Units V. and VI. summarize EPA's evaluation of the information relating to the criteria delineated in § 725.67(a)(2) that address hazard, exposure, benefits, and economic consequences. Specifically:

- The effects of the new microorganism on health and the environment.
- The magnitude of exposure of human beings and the environment to the new microorganism.
- The benefits of the new microorganism for various uses and the availability of substitutes for such uses.
- The reasonably ascertainable economic consequences of granting or denying the exemption, including effects on the national economy, small business, and technological innovation.

Unit V. provides a summary of EPA's assessments of the risks to health and

the environment for both microorganisms. EPA's Risk Assessment documents (Refs. 6 and 7) provide more detailed information, and supporting references, for EPA's evaluation of the available information and the potential risks to health and the environment. Unit VI. provides a summary of EPA's assessments of the economic benefits and consequences of adding both microorganisms to § 725.420.

A. Evaluation of Available Information Relevant to the Criteria at § 725.67 for T. reesei QM6a as a Recipient Microorganism With Specified Conditions of Growth

1. *Identification and classification of the microorganism using available genotypic and phenotypic information. T. reesei* is a fungus originally isolated in the Solomon Islands in 1944. *T. reesei* is a hypercellulolytic fungus found on deteriorating military fabrics such as tents and clothing. This isolate, designated as QM6a, was initially named *Trichoderma viride.* Approximately 20 years later, QM6a was re-classified as *Trichoderma reesei.*

Trichoderma reesei is the species name given to the anamorphic form (this form reproduces asexually) of the fungus whose telemorphic form (this form reproduces sexually) is now understood to be *Hypocrea jecorina.*

Recent taxonomic studies have shown that the species *T. reesei* consists only of this single isolate QM6a and its derivatives. Many other strains called *T. reesei* isolated elsewhere have now been proposed as belonging to a newly named species, *T. parareesei,* based on differences in habitat, sporulation, and metabolic versatility. *T. reesei* has been shown to belong to a single species now referred to as *H. jecorina/T. reesei* (QM6a) which reflects its relationship to its teleomorph *H. jecorina.* The only anamorphic strains within the species *H. jecorina/T. reesei* are those of QM6a and its derivatives. The petition to add *T. reesei* to the list of microorganisms at § 725.420 requested that EPA include all strains of *T. reesei.* However, given these recent taxonomic publications, all fungal strains correctly named *T. reesei* are, by definition, QM6a or a derivative.

Adequate genotypic and phenotypic information is available for classification of *T. reesei* QM6a and its derivatives. The American Type Culture Collection (ATCC) designation for this original strain of *T. reesei* QM6a is ATCC 13631.

2. *Information to evaluate the relationship of the microorganism to any other closely related microorganisms that have a potential for adverse effects on health or the environment.* The petition to add *T. reesei* to the list of microorganisms at § 725.420 requested that EPA include all strains of *T. reesei.* Closely related members of section *Longibrachiatum* do not have a potential for adverse effects; other less closely related *Trichoderma* species have a potential to cause adverse effects as pathogens of commercially produced mushrooms. These less closely related species include various species of the Harzianum clade, *T. aggressivum, T. pleuotrophilum,* and *T. fulvidum* that are responsible for significant loss of the mushroom crops of *Agaricus bisporus* and *Pleurotus ostreatus.*

T. reesei/H. jecorina can be distinguished from other *Trichoderma* species by a comprehensive approach employing criteria of the Genealogical Concordance Phylogenetic Species Recognition (GCPSR) concept, which commonly requires the use of genealogies of three or four genes, not just the sequences of spacer regions as previously utilized for identification. Use of the GCPSR protocol will separate *T. reesei* (sensu lato) from the opportunistic pathogens within the section *Longibrachiatum,* including *T. longibrachiatum* and *T. citronoviridae/H. schweinitzii,* as well as the mold disease pathogens of mushrooms.

3. *A history of safe commercial use for the microorganism. T. reesei* QM6a has a long history of safe use producing a variety of commercial enzymes. *T. reesei* QM6a cellulases, beta-glucanases, and xylanases are used by the animal feed, baking, beverages, textile processing, detergent, pulp and paper, industrial chemicals, and biofuels industries.

For industrial enzyme production, *T. reesei* is generally grown in a closed, submerged fermentation system. In submerged fermentation, growth of the microorganism occurs beneath the surface of the liquid growth medium. As described in this unit, this type of fermentation system appears to be typical throughout the industry, based on EPA's review of MCAN submissions over the years. This type of fermentation system would also comply with the existing tiered exemption requirements relating to physical containment and control technologies, which are laid out in § 725.422.

Under this type of fermentation system, the fermentation broth is a defined mixture of carbon and nitrogen sources, minerals, salts, and other nutrients, is maintained at optimal pH and temperature, and is typically aerated and mixed with no solid plant material or insoluble substrate present. These conditions support the active growth and productivity of the organisms. Submerged fermentation systems reduce the potential for exposure of workers to the production organism and fermentation broth aerosols, reduce the potential for contamination of the culture and make the collection of extracellular enzyme simpler and less costly. The fermentation process is terminated before the *T. reesei* QM6a organisms go into the stationary growth phase (i.e., before secondary metabolism begins). At the end of the fermentation process, the production organisms are separated from the fermentation broth and inactivated. Throughout the **SUPPLEMENTARY INFORMATION** section, EPA refers to this process as ''submerged standard industrial fermentation.''

The Food and Drug Administration (FDA) has determined that several enzymes produced by *T. reesei* QM6a are Generally Recognized As Safe (GRAS). This determination supports the Agency's preliminary conclusion that commercial use of *T. reesei* QM6a as a recipient microorganism for commercial enzyme production will not present an unreasonable risk of injury to health or the environment. *T. reesei* QM6a enzymes used in foods that have been granted GRAS status include cellulase, hemicellulase, transglucosidase, pectin lyase, acid fungal protease, and a chymosin enzyme preparation. Data supporting the GRAS petitions included the results of pathogenicity tests for the *T. reesei* QM6a production organisms and toxicity tests for the enzyme products. The data showed that the production strains are not pathogenic and did not produce toxins during enzyme fermentation.

4. *Commercial uses indicating that the microorganism products might be subject to TSCA.* EPA has reviewed several MCANs involving intergeneric *T. reesei* QM6a production organisms. More detailed information on MCANs submitted to EPA can be viewed on EPA's TSCA Biotechnology Program Web page: *http://www.epa.gov/oppt/biotech/pubs/submain.htm.*

Intergeneric *T. reesei* QM6a strains could also be used to manufacture industrial chemicals other than enzymes such as surfactants or specialty chemicals.

5. *Studies which indicate the potential for the microorganism to cause adverse effects to health or the environment*—a. *Human health hazards*—i. *Pathogenicity. Trichoderma reesei* QM6a is not pathogenic to humans. Due to its long history of use for production of enzymes used in food

applications, the potential for the fungus and its products to be pathogenic or toxic to humans has been evaluated numerous times. Various studies have been conducted assessing *T. reesei* QM6a's pathogenic potential in healthy and immunocompromised laboratory animals. Most studies have shown a lack of pathogenicity of *T. reesei* QM6a. Pathogenicity studies have been conducted as part of submissions submitted to FDA for GRAS petitions for several different enzymes used in the food industry. Studies using intraperitoneal (ip) injection of *T. reesei* QM6a in rats, using intravenous (IV) injection of *T. reesei* QM6a in both healthy and immunosuppressed rats, and using ip injection of viable and heat-killed cells of *T. reesei* QM6a in rats have all demonstrated a lack of potential pathogenicity to humans.

T. reesei QM6A is not known to possess any virulence factors associated with colonization or disease such as adherence factors, penetration factors, necrotic factors, toxins, or the ability to grow at human body temperature, 37 °C. There are no reports in the literature on infection in healthy humans by *T. reesei* QM6A. There are no reports of harmful effects associated with the use of or exposure to *T. reesei* QM6A strains given decades of commercial use for enzyme production. The body of evidence indicates that *T. reesei* QM6A does not pose concerns regarding human pathogenicity.

ii. *Toxicity.* Available data indicate that *T. reesei* QM6a strains used in submerged standard industrial fermentation operations in which no solid plant material or insoluble substrate is present in the fermentation broth do not present human toxicity concerns. A number of studies have been conducted assessing the potential for *T. reesei* QM6a to produce toxins during submerged fermentation for production of enzymes for food, pharmaceutical, or industrial uses. A cellulase enzyme known as celluclast produced by *T. reesei* QM6a has been tested for general oral toxicity and inhalation toxicity. Acute oral toxicity studies conducted in mice, rats, and dogs showed that *T. reesei* QM6a cellulase was not toxic to any of the test animals. Subchronic toxicity studies showed no evidence of systemic effects in dogs or rats. Additional toxicity studies have been conducted on other enzymes produced by *T. reesei* QM6a, the results of which have been presented in various GRAS petitions. Acute oral toxicity tests on two endoglucanases and a glucoamylase showed a lack of toxins. Subchronic feeding studies conducted on a cellulase, two xylanases, two endoglucanases, a protease, and a glucoamylase also showed a lack of toxicity in rats.

Industrial strains of *T. reesei* QM6a are routinely checked by the enzyme producers to confirm the absence of antibiotic activity and toxins including aflatoxin B, ochratoxin A, sterigmatocystin, T–2 toxin, and zearalenone according to the recommendations of the Joint Food and Agriculture Organization and the World Health Organization (FAO/WHO) Expert Committee on Food Additives. Relying on the data that show *T. reesei* QM6a has a long history of safe use in the production of food enzymes where there is a need to routinely check for the absence of toxins, EPA has preliminarily concluded that strains used industrially would not be expected to produce these compounds under the growth conditions used for enzyme fermentation.

iii. *Mycotoxins and other secondary metabolites.* The only health concern associated with *T. reesei* QM6a is its ability to produce a secondary metabolite called paracelsin, which is a peptaibol. Peptaibols are small linear peptides of 1,000–2,000 daltons characterized by a high content of the non-proteinogenic amino acid α-amino-isobutyric acid (Aib), with an *N*-terminus that is typically acetylated, and a *C*-terminus that is linked to an amino alcohol, which is usually phenylalaninol, or sometimes valinol, leucinol, isoleucinol, or tryptophanol. Peptaibols are associated with a wide variety of biological activities and have antifungal, antibacterial, sometimes antiviral, antiparasitic, and neurotoxic activity. Paracelsin has been shown to have toxicity toward mammalian cells such as hemolytic activity on human erythrocytes and cytotoxicity to rat adrenal medulla PC12 cells. Paracelsin showed toxicity to PC12 cells (a cell line derived from a pheochromocytoma of the rat adrenal medulla) with a CC_{50} (cytotoxicity concentration of 50%) of 21.8 micromolar (μM) (Ref. 6). The *in vitro* hemolytic activity of paracelsin has been reported to be $C_{50} = 3.7 \times 10^{-5}$ mole/liter (mol/L) (Ref. 6).

Paracelsin has not been detected in the use of *T. reesei* QM6a under submerged standard industrial fermentation operations in which no solid plant material or insoluble substrate is present in the fermentation broth; numerous toxicity studies on enzyme products of *T. reesei* QM6a have demonstrated a lack of toxicity to laboratory animals. EPA therefore generally expects that paracelsin production will be of insignificant concern with submerged standard industrial fermentation operations in which no solid plant material or insoluble substrate is present in the fermentation broth.

However, under non-standard conditions of fermentation, such as with extended duration of fermentation, or fermentation in the presence of insoluble carbon sources such as cellulose or in the presence of solid plant material, paracelsin may be produced (Ref. 6). Neither the information submitted with the petition, nor the information that is otherwise available is sufficient to allow EPA to determine the extent of paracelsin formation under these non-standard conditions. Consequently, EPA is unable to determine whether the use of the microbe under these non-standard conditions will pose an unreasonable risk to human health and/or the environment (Ref. 6).

b. *Environmental hazards*—i. *Hazards to animals. T. reesei* QM6a is not pathogenic to domesticated animals or wildlife. However, the secondary metabolite paracelsin produced by *T. reesei* QM6a has been shown to exhibit toxicity to aquatic species. Twenty-four hour exposure of paracelsin to *Artemia salina* (brine shrimp) suggested a lethal concentration of 50% (LC_{50}) of 21.26 μM (40.84 micrograms per milliliter (μg/ml)) which decreased to 9.66 μM (18.56 μg/ml) with a 36-hour (hr) exposure. With *Daphnia magna,* paracelsin was found to be moderately toxic, with an LC_{50} of 7.70 μM (14.79 μg/ml) with a 24-hr exposure, and 5.60 μM (10.76 μg/ml) with a 36-hr exposure.

ii. *Hazards to plants. Trichoderma reesei* QM6a is not a pathogen of plants. Although it is capable of degrading cellulose and hemicellulose due to the copious quantities of the enzymes it can produce, it cannot be a primary colonizer on plant tissue as genetic studies have shown that it does not contain any genes for ligninases that are required for initial breakdown of plant material. This species is known as a wood rot fungus, but it apparently attacks only decaying plant material, not live plants.

iii. *Effects on other organisms.* Peptaibols are toxic to Gram-positive bacteria and various fungi. The inhibitory action of peptaibols on various fungi is the reason that many species of *Trichoderma* are used as biocontrol agents of plant pathogenic fungi. *T. reesei* QM6a, which is known to produce only the peptaibol paracelsin, has been shown to be inhibitory to one particular fungus, *Phoma destructiva.*

Some species of *Trichoderma,* specifically *T. aggressivum, T. pleuotrophilum,* and *T. fulvidum* are pathogens of mushrooms. However, *T. reesei* QM6a is not a pathogen of mushrooms.

6. *Studies which indicate the survival characteristics of the microorganism in the environment.* The species *T. reesei* is known only from the single original isolate QM6a from the Solomon Islands. Therefore, there is little information on its prevalence or behavior in the environment. Microcosm studies have been conducted that suggest it would survive in the environment if inadvertently released in the plant rhizosphere and in bulk soils.

Although *T. reesei* was originally isolated from a tropical climatic region, it would be expected to persist in soils for extended periods of time, even after cold temperatures.

B. Evaluation of Available Information Relevant to the Criteria at § 725.67 for B. amyloliquefaciens as a Recipient Microorganism

1. *Identification and classification of the microorganism using available genotypic and phenotypic information. Bacillus amyloliquefaciens* was initially proposed as a unique species in 1943. The name *Bacillus amyloliquefaciens* lost standing when it was not included on the Approved List of Bacterial Names with Standing in Nomenclature in 1980. Since classical phenotypic tests could not differentiate it as a species unique from *Bacillus subtilis,* it was regarded as a subspecies of *B. subtilis* for several decades. However, molecular evidence from various subsequent studies led to the conclusion that *Bacillus amyloliquefaciens* did indeed deserve independent status. The DNA homology between *B. subtilis* and *B. amyloliquefaciens* is only about 15%. In addition, there were several phenotypic properties that differed between the two species. Chemotaxonomic studies revealed additional capability of separating strains of *B. amyloliquefaciens* from the other related species, *B. subtilis, B. licheniformis,* and *B. pumilus.* The species has remained within the genus *Bacillus sensu stricto* since it was last established as a separate species.

Recently, it has been proposed that there are two subspecies within the species *B. amyloliquefaciens, B. amyloliquefaciens* subsp. *amyloliquefaciens* and *B.* a*myloliquefaciens* subsp. *plantarum.* The former subspecies includes the type strain and likely most, if not all, of the industrial strains of *B. amyloliquefaciens* used for enzyme production. The latter subspecies consists of plant-associated strains used as biocontrol agents since they produce a number of antifungal lipopeptide and antibacterial polyketide toxins. This proposed exemption would be restricted to the subspecies *B. amyloliquefaciens* subsp. *amyloliquefaciens* which contains the industrial strains used for enzyme production. Adequate genotypic and phenotypic information is available to accurately identify *B. amyloliquefaciens* subsp. *amyloliquefaciens.*

2. *Information to evaluate the relationship of the microorganism to any other closely related microorganisms which have a potential for adverse effects on health or the environment.* There are several species in the genus *Bacillus* that are known pathogens. These include *B. anthracis,* which is pathogenic to humans and other animals, and *B. cereus,* which is a common cause of food poisoning. *B. thuringiensis, B. larvae, B. lentimorbus, B. popilliae,* and some strains of *B. sphaericus* are pathogenic or toxigenic to certain insects. The new subspecies *B. amyloliquefaciens subsp. plantarum* has been shown to exhibit toxicity mainly to plant pathogenic fungi, but can also be cytotoxic to mammalian cells. It is possible, using polyphasic approaches, to differentiate between *Bacillus amyloliquefaciens subsp. amyloliquefaciens* and these other species and subspecies that have the potential to adversely affect humans or other organisms. *B. amyloliquefaciens* can be distinguished from the very similar *B. subtilis* by a few phenotypic traits and DNA dissimilarity.

3. *A history of safe commercial use for the microorganism. Bacillus amyloliquefaciens* has been used to produce commercial enzymes for more than 50 years. It produces carbohydrases, proteases, nucleases, xylanases, and phosphatases that have applications in the food, brewing, distilling, and textile industries.

For commercial enzyme production, *B. amyloliquefaciens* is grown in a closed, submerged fermentation system. In submerged fermentation, growth of the microorganism occurs beneath the surface of the liquid growth medium. The fermentation broth is a defined liquid growth medium (with no solid plant material or insoluble substrate) of carbon and nitrogen sources, minerals, salts, and other nutrients that is maintained at optimal pH and temperature. These conditions support the active growth and productivity of the organisms. Submerged fermentation systems reduce the potential for exposure of workers to the production organism and fermentation broth aerosols, reduce the potential for contamination of the culture, and make the collection of extracellular enzyme simpler and less costly. The fermentation process is terminated before the *B. amyloliquefaciens* organisms go into the stationary growth phase (i.e., before secondary metabolism begins). At the end of the fermentation process, the production organisms are separated from the fermentation broth and inactivated. The enzyme preparation may also be subjected to other purification processes.

B. amyloliquefaciens has a long history of safe use for the production of enzymes with both food and industrial uses with no incidences associated with human pathogenicity. In response to a petition from the ETA, FDA affirmed that carbohydrase enzyme preparations and protease enzyme preparations derived from either *B. subtilis* or *B. amyloliquefaciens* are GRAS for use as direct food ingredients. The European Food Safety Authority (EFSA) has put *B. amyloliquefaciens* on their list of bacteria that have a ''qualified presumption of safety'' (QPS) because of a long history of apparent safe use in food and feed production. However, it was put on the list with a qualifier that only strains of *B. amyloliquefaciens* that do not have toxigenic potential be used.

One strain of *B. amyloliquefaciens* also has been used as a biopesticide. A naturally occurring strain of *B. amyloliquefaciens subsp. plantarum* was registered in 2000 as a biopesticide active ingredient under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). It can only be used on certain ornamental, non-food plants in greenhouses and other closed structures.

4. *Commercial uses indicating that the microorganism products might be subject to TSCA.* It is expected that intergeneric strains of *B. amyloliquefaciens* will be used to produce enzymes and to manufacture other industrial chemicals subject to TSCA. Many enzymes produced by *B. amyloliquefaciens,* particularly α-amylase, are used in laundry detergents and in textile processing. *B. amyloliquefaciens* also makes a surfactant known as surfactin which functions as an antibiotic.

5. *Studies which indicate the potential for the microorganism to cause adverse effects to health or the environment*—a. *Human health hazards*—i. *Pathogenicity.*

Bacillus amyloliquefaciens is not pathogenic to humans. There are no reports in the literature associating *B. amyloliquefaciens* with infection or disease in humans. *B. amyloliquefaciens*

has been categorized as a Biosafety 1 microorganism by the Centers for Disease Control and Prevention (CDC). Biosafety 1 microorganisms are well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and which present minimal potential hazard to laboratory personnel and the environment. Animal toxicity studies were performed with *B. amyloliquefaciens* strain FZB24 to support its registration as a biopesticide. Tests for acute oral toxicity/pathogenicity, acute pulmonary toxicity/pathogenicity, and acute injection toxicity/pathogenicity showed little to no adverse effects, which indicated low mammalian toxicity and a lack of pathogenicity/infectivity.

ii. *Toxins and other secondary metabolites.* Although another species in the genus *Bacillus, B.cereus,* has the potential to produce food poisoning toxins which cause both emetic and diarrheal syndromes, and a variety of local and systemic infections, the risk of food-borne disease caused by bacilli other than *B. cereus* is generally considered to be negligible because usually only *B. cereus* has the genes that encode food poisoning toxins. Industrial strains of *Bacillus* species belonging to the *B. subtilis* group, which includes *B. amyloliquefaciens,* do not express *B. cereus* toxins. In addition, there are no reported cases of food poisoning being caused by *B. amyloliquefaciens.*

Some strains of *B. amyloliquefaciens* have been shown to produce bioactive cyclic lipopeptide metabolites such as iturin, surfactin, fengycin, and bacillomycin D. These are cyclical lipoprotein biosurfactants produced by non-ribosomal peptide synthesis. They have a low mammalian toxicity as demonstrated by a lethal dose of 50% (LD_{50}) of >2,500 milligram/kilogram (mg/kg) in an acute toxicity test of surfactin C, and a No Observed Adverse Effect Level (NOAEL) of 500 mg/kg-day in a repeat dose oral gavage study. Some strains of *B. amyloliquefaciens* may also produce the polyketide toxins macrolactin, bacillanene, and difficidin. *B. amyloliquefaciens* also produces the protein toxin barnase and the antifungal protein baciamin.

There are several reports of the isolation of *B. amyloliquefaciens* from water-damaged buildings in which occupants were suffering ill health symptoms. Extracts from biomass of isolated strains of *Bacillus* exhibiting antifungal properties were assessed for the toxicity endpoints. All of the isolated *B. cereus* and *B. amyloliquefaciens* strains studied showed cytotoxicity as evidenced by inhibition of boar spermatozoa motility; however, the *B. amyloliquefaciens* strains affected boar spermatozoa differently from the indoor *B. cereus* isolates and the reference food-poisoning strain.

The isolation of cytotoxic strains of *B. amyloliquefaciens* from water-damaged buildings is of little concern in relation to this exemption of *B. amyloliquefaciens* subsp. *amyloliquefaciens.* It is important to note that all of the *B. amyloliquefaciens* strains studied in water-damaged buildings were specifically selected for further study because the isolates exhibited antifungal activity. Some of the secondary metabolites produced by these biocontrol-type strains of *B. amyloliquefaciens* apparently also exhibit cytotoxicity to mammalian cells (i.e., boar spermatozoa). However, industrial strains of *B. amyloliquefaciens* that would fall into the classification as *B. amyloliquefaciens* subsp. *amyloliquefaciens* have been shown not to produce most, if not all, of the antifungal and antibacterial lipopeptides and polyketides produced by the biocontrol-type strains. The genome of the type strain of *B. amyloliquefaciens* DSM 7^T (now *B. amyloliquefaciens* subsp. *amyloliquefaciens*) is very similar to the genome of the biocontrol strain FZB42 (*B. amyloliquefaciens* subsp. *plantarum*). However, the latter subspecies had genomic islands carrying prophage sequences, transposases, integrases, and recombinases that the DSM 7^T type strain did not have. The DSM 7^T type strain was shown to have a diminished capacity to non-ribosomally synthesize secondary metabolites with antifungal and antibacterial activities. The DSM 7^T type strain could not produce the polyketides difficidin or macrolantin, and could not produce lipopeptide such as iturin, macrolantin, and other compounds except for the compound surfactin.

The only other reported instance of mammalian toxin production by *B. amyloliquefaciens* was during the 1980s with the commercial production of tryptophan, by a genetically engineered strain of *B. amyloliquefaciens,* strain IAM 1521. The consumption of the tryptophan food supplement from various retail lots produced by one specific company resulted in an epidemic of a disease known as eosinophilia-myalgia syndrome (EMS) in which 1,511 were sickened, and 37 people died. Although this disease incidence was widely studied, the cause of the disease was never confirmed. It was thought to be due to the consumption of a chemical constituent that was associated with specific tryptophan manufacturing processes. This included the combination of using reduced quantities of powdered carbon for a purification step with the use of a ''new'' strain of *B. amyloliquefaciens* called Strain V. There purportedly was a chemical substance produced as a result of the genetic engineering of this certain strain, but the toxin was not attributable to the parental strain of *B. amyloliquefaciens* as not all production batches were toxic.

Although there are isolated reports of toxin production in several antifungal, environmental isolates of *B. amyloliquefaciens,* the larger body of studies available on the safety and toxicity of *B. amyloliquefaciens* strains used industrially for enzyme production (Ref. 6) indicate that these strains are safe and non-toxic. For example, the toxicity of industrial strains of *B. amyloliquefaciens, B. subtilis,* and *B. licheniformis* used for large-scale enzyme production has been studied. The industrial strains did not exhibit any cytotoxicity in Chinese hamster ovary tests. In Europe, the toxicity of two strains of *B. amyloliquefaciens* used for the production of α-amylase and bacillolysin for the product Kemzyme W Dry was assessed by the EFSA's Scientific Panel on Additives and Products or Substances used in Animal Feed. The panel concluded that the *B. amyloliquefaciens* production strains DSM9553 and DSM9554 when used as a source of extracellular enzyme do not present a toxigenic risk. Given its widespread distribution in the environment, its long history of safe use in industrial fermentation, the absence of reports on pathogenicity to humans, and the limited reports of cytotoxicity, all indicate that the use of *B. amyloliquefaciens* in fermentation facilities for production of enzymes or specialty chemicals does not present a human health concern.

b. *Environmental hazards*—i. *Hazards to animals.* There are no reports suggesting that *B. amyloliquefaciens* is pathogenic to domesticated animals or wildlife. The cytotoxicity of antifungal secondary metabolites to mammalian cells by biocontrol stains of *B. amyloliquefaciens* is discussed in this unit.

ii. *Hazards to plants. B. amyloliquefaciens* is not pathogenic to plants. There are plant-associated strains of *B. amyloliquefaciens* that are beneficial to plants because they inhibit the growth of fungal plant pathogens. Various antifungal and antibacterial secondary metabolites produced by

strains of *B. amyloliquefaciens* such as various iturins, surfactins, fengycin, bacillomycins, and azalomycin have been shown to inhibit the growth of *Rhizoctonia solani, Xanthomonas campestris* pv. *campestris, Alternaria brassicae, Botyris cinerea, Leptosphaeria maculans, Verticillium longisporum, Pythium ultimatum, Aspergillus* spp., *Fusarium* spp., *Bipolaris sorokiniana,* and *Fusarium oxysporum.*

In addition to the ability of *B. amyloliquefaciens* to produce antifungal and antibacterial compounds, the bacterium is known as a plant growth-promoting rhizobacterium. Some of the biological control strains of *B. amyloliquefaciens* produce the phytohormone indole-3-acetic acid (IAA).

6. *Studies which indicate the survival characteristics of the microorganism in the environment.* Using polymerase chain reaction (PCR) techniques, it has been found that populations of viable *B. amyloliquefaciens* inoculated at high densities to intact soil-core microcosms decreased to below the detection limit within 1 month. Survival was longer for a genetically modified *B. amyloliquefaciens* strain on leaf surfaces; vegetative cells were still detected for over 2 months in the phylloplane. Viable cells were not detectable in plant roots after 1 month or in soils after a few days. Given that the natural habitat for *B. amyloliquefaciens* is typically in soil, on plant roots, or as an endophyte within the roots or stems of plants, the bacterium is likely to survive for a least some period of time if inadvertently released to the environment. However, like other bacilli, survival in soil may occur predominately as the resistant endospore state, whereas in the rhizosphere, it may exist as active vegetative cells.

IV. Physical Containment and Control Technologies

A. Release and Exposure Assessment in Support of Proposed TSCA Section 5(h)(4) Exemption for T. reesei QM6a

The estimated releases of the microorganism from an enzyme manufacturing facility and exposures of the microorganisms to workers, the general population, and the environments are based on a generic scenario developed by EPA for large-scale closed system fermentation. Assumptions in the generic scenario are that the facility operates 350 days/year, produces 100 batches/year, and the maximal cell concentration in the fermentation broth is 1×10^7 colony-forming units (cfu)/ml, and the volume of the fermentation broth is 70,000 L. The process consists of the main steps of laboratory propagation, fermentation and then recovery where filtration operations separate out the biomass from the concentrated desired product. The operations, sources of exposure and release are described in more detail in EPA's Release and Exposure Assessments (Ref. 8).

B. Release and Exposure Assessment in Support of Proposed TSCA 5(h)(4) Exemption for B. amyloliquefaciens

The estimated releases of the microorganism from an enzyme manufacturing facility and exposures of the microorganisms to workers, the general population, and the environments are based on a generic scenario developed by EPA for large-scale closed system fermentation. Assumptions in the generic scenario are that the facility operates 350 days/year, produces 100 batches/year, and the maximal cell concentration in the fermentation broth is 1×10^{11} cfu/ml and the volume of the fermentation broth is 70,000 L. The process consists of the main steps of laboratory propagation, fermentation and then recovery where filtration operations separate out the biomass from the concentrated desired product. The operations, sources of exposure and release are described in more detail in EPA's Release and Exposure Assessments (Ref. 9).

Additionally, containment and control technologies are delineated in the § 725.422 for Tier I and Tier II exemptions.

V. Risk Assessment

A. Risk Assessment for T. reesei QM6a

There is only one potential concern for human health and environmental hazards associated with *T. reesei* QM6a, and that is for paracelsin production. Paracelsin production is not expected to occur in submerged standard industrial fermentation operations in which no solid plant material or insoluble substrate is present in the fermentation broth. There is no concern for potential pathogenicity of *T. reesei* QM6a to humans, plants, domesticated animals, or wildlife. Pathogenicity test data on various industrial strains typically do not show adverse effects. Toxicity testing on a number of enzymes produced by *T. reesei* indicates that the fungus does not produce toxins under the standard conditions used for enzyme production.

T. reesei has a long history of safe use and would be expected to present low hazard to workers, the general public, and the environment. Although direct monitoring data are unavailable, worst-case estimates of potential exposures made by EPA in its assessment of potential risks (Ref. 6) do not indicate high levels of exposure of *T. reesei* to either workers or the public resulting from the submerged industrial enzyme fermentation operations that are standard throughout the industry. Standard industrial hygiene management practices currently used in the fermentation industry reduce the potential for adverse health effects in the workplace. The standard use of engineering controls (closed fermentation systems), appropriate work practices, personal protective equipment, and personal hygiene reduce the potential for worker exposure. Thus, current practices reduce the potential for the dermal and respiratory exposures estimated by EPA.

EPA has made a preliminary determination based on worst-case exposure scenarios and toxicity of the microorganism that the potential risk to workers, the general public, and to the environment resulting from the use of *T. reesei* QM6a in submerged standard industrial fermentation as a recipient microorganism is low, provided the additional criteria of the tiered exemptions for the introduced genetic material and the physical containment conditions are met (Ref. 6).

B. Risk Assessment for B. amyloliquefaciens

Industrial strains of *Bacillus amyloliquefaciens* that would fall into the subspecies *Bacillus amyloliquefaciens* subsp. *amyloliquefaciens* are not pathogenic to humans, plants, domesticated animals, or wildlife, and do not produce many of the toxic secondary metabolites found in biological control strains of *B. amyloliquefaciens* subsp. *plantarum.* The long history of safe use of enzymes produced by industrial strains of *B. amyloliquefaciens* in food is evidence that the bacterium does not produce toxins under standard conditions used for enzyme production.

Current practices in the fermentation industry reduce the potential for adverse health effects in the workplace. The use of engineering controls (closed fermentation systems), appropriate work practices, personal protective equipment, and personal hygiene reduce the potential for worker exposure. Thus, current practices reduce the potential for dermal and respiratory exposures.

Industrial strains of *B. amyloliquefaciens* have a long history of

safe use and would be expected to present low hazard to workers, the general public, and the environment. Although direct monitoring data are unavailable, worst-case estimates do not suggest high levels of exposure of *B. amyloliquefaciens* to either workers or the public resulting from the submerged industrial enzyme fermentation operations that are standard throughout the industry.

EPA has made a preliminary determination based on worst-case exposure scenarios and toxicity of the microorganism, that the potential risk to workers, the general public, and the environment, associated with the use of industrial strains of *B. amyloliquefaciens* subsp. *amyloliquefaciens* in submerged standard industrial fermentation as a recipient microorganism is low provided the additional criteria of the tiered exemptions for the introduced genetic material and the physical containment conditions are met (Ref. 7).

VI. Economic Impacts

EPA's economic assessment (Ref. 10) evaluates the potential for significant economic impacts as a result of the addition of two microorganisms (*Trichoderma reesei* (Strain QM6a) and *Bacillus amyloliquefaciens* subsp. *amyloliquefaciens*) to § 725.420 which lists recipient microorganisms eligible for Tier I and Tier II exemptions. Over the course of the first 10 years after the effective date of the final rule, if finalized as proposed, EPA estimates that the proposed addition of the two microorganisms to the list in § 725.420 would generate a total cost savings to society of $5.68 million. Industry would save approximately $1.98 million and the Agency would save approximately $3.68 million. The equivalent, annualized cost savings are expected to be $552,000 and $535,000 at a 3% and 7% discount rate, respectively. EPA estimates that there will be a net decrease in burden to society of 72,500 hr over this 10-year period.

VII. Rationale for Proposed Regulatory Action

A. Statutory Background

Pursuant to TSCA section 5(h)(4), EPA is authorized to exempt the manufacturer of any new chemical substance from all or part of the requirements of TSCA section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or any combination of such activities, will not present an unreasonable risk of injury to human health or the environment. Section 26(c) of TSCA provides that any action authorized under TSCA for an individual chemical substance may be taken for a category of such chemical substances.

While TSCA does not contain a definition of ''unreasonable risk,'' the legislative history indicates that the determination of unreasonable risk requires a balancing of the considerations of both the severity and the probability that harm will occur against the effect of the final regulatory action on the availability to society of the benefits of the chemical substance (Ref. 11). This analysis can include an estimate of factors such as market potential, the effect of the regulation on promoting or hindering the economic appeal of a chemical substance, environmental effects, and many other factors which are difficult to define and quantify precisely. EPA may rely not only on data available to it, but also on its professional judgment. Congress recognized that the implementation of the unreasonable risk standard ''will vary on the specific regulatory authority which the Administrator seeks to exercise'' [Ibid.].

B. EPA's Approach

In determining whether *T. reesei* QM6a and *Bacillus amyloliquefaciens* subsp. *amyloliquefaciens* will not present an unreasonable risk of injury to human health or the environment, the Agency considers more than just the inherent risks presented by the two microorganisms. The Agency also considers the full range of societal benefits associated with the exemption; for example, as discussed in more detail in Unit V., EPA considers not only the cost savings to the users of the microorganism, but also the societal benefits that flow from promotion of the use of low-risk recipient microorganisms, while allowing the Agency to direct its resources toward higher risk microorganisms.

EPA is only proposing to revise one aspect of the existing tiered exemptions at § 725.420; specifically, EPA is proposing to expand the exemption to apply to two specific microorganisms. EPA is not reconsidering or otherwise reopening any other aspect of those exemptions. The narrow scope of this action necessarily affects the scope of EPA's cost-benefit analysis. This means, for example, that EPA compares the risks and benefits of the two microorganisms being considered for an exemption with the risks that would have resulted if those same two microorganisms remained subject to full MCAN submission requirements and 90-day EPA review. But EPA does not compare the risks and benefits that would result from use of these two microorganisms in the absence of any regulation.

It is also significant that the standard applicable to this proposed rule is that the microorganisms will present ''no unreasonable risk,'' rather than ''no risk.'' It is not possible to eliminate all risks associated with the manufacture, processing, distribution in commerce, use, and disposal of any new microorganism nor was this Congress' intent. The standard embodied by a TSCA section 5(h)(4) exemption does not require the Agency to ensure absolute safety from the activities associated with an exempted chemical substance.

C. Application of No Unreasonable Risk Factors

The following is an explanation of the factors and their analyses relevant to the no unreasonable risk finding.

1. *Risks associated with microorganisms.* EPA's evaluation of the available information concerning *T. reesei* QM6a and *B. amyloliquefaciens* subsp. *amyloliquefaciens* against these criteria is presented in detail in Unit III., and is summarized again here for the readers' convenience.

The Agency developed specific criteria in § 725.67 that the Agency uses in determining the extent of a potential recipient microorganism's risks, and consequently, its eligibility for listing at § 725.420. These criteria were explained in detail in the proposed ''biotech'' rule (Ref. 12) and final ''biotech'' rule (Ref. 13), and are discussed again in Units II. and III. EPA's conclusions regarding the low-risk potential for these two microorganisms are based on the available data and EPA's scientific professional judgment based on 14 years experience reviewing notifications for new intergeneric microorganisms submitted in accordance with the regulations at 40 CFR part 725.

T. reesei QM6a is not pathogenic to humans, plants, domesticated animals, or wildlife and the fungus does not produce toxins under standard industrial conditions used for enzyme production. *T. reesei* QM6a has a long history of safe use and is generally expected to present low risk to workers, the general public, and the environment resulting from submerged standard industrial enzyme fermentation operations that are standard throughout the industry. Under non-standard conditions of fermentation, such as with extended duration of fermentation, or fermentation in the presence of insoluble carbon sources such as

cellulose or other solid surfaces, paracelsin may be produced. The risks associated with the production of paracelsin may be significant due to the toxicity of paracelsin to mammalian cells, aquatic species, Gram-positive bacteria, and various fungi. However, the potential risk associated with any paracelsin production would be significantly reduced by this proposed rule, which proposes to limit the exemption to fermentation operations using submerged standard industrial fermentation operations, and in which no solid plant material or insoluble substrate is present in the fermentation broth.

Industrial strains of *Bacillus amyloliquefaciens* that would fall into the subspecies *Bacillus amyloliquefaciens* subsp. *amyloliquefaciens* are not pathogenic to humans, plants, domesticated animals, or wildlife, and do not produce toxins under standard conditions used for enzyme production. Industrial strains of *B. amyloliquefaciens* subsp. *amyloliquefaciens* used in fermentation facilities for the production of enzymes have a long history of safe use and are expected to present low hazards to human health and the environment resulting from standard industrial submerged fermentation operations. Consistent with the proposed restrictions on *Trichoderma reesei* discussed in Unit II.A., only strains of *Bacillus amyloliquefaciens* that would fall into the subspecies *Bacillus amyloliquefaciens* subsp. *amyloliquefaciens* were considered as the eligible recipient microorganism at § 725.420. EPA is proposing to exclude other strains/subspecies of these two species for which:

- The Agency still has insufficient data and review experience to find that they will not present an unreasonable risk of injury or
- The Agency has found that, under certain conditions, based on data on the species in question, a strain or subspecies may present an unreasonable risk, thereby requiring a closer examination of the conditions of manufacturing, processing, distribution in commerce, use, and disposal during a full 90-day Premanufacture Notice (PMN) review. Consequently, additional information would be necessary to make an appropriate determination about the organisms' potential risks and benefits.

The Agency believes that the requirement for submission of a MCAN followed by a 90-day review period for new intergeneric microorganisms that use *T. reesei* QM6a and *Bacillus amyloliquefaciens* subsp. *amyloliquefaciens* as recipient microorganisms is not necessary to address the risks associated with these microorganisms, and would not result in any additional protection than would be achieved by this proposed rule. In part, this conclusion is based on EPA's preliminary findings regarding the intrinsically low level of hazard that these two organisms pose to human health and the environment. In addition, the existing requirements of the Tier I and Tier II exemptions, taken with the proposed restrictions, would place sufficient constraints to significantly limit the potential risks of injury to human health or the environment that these two microorganisms may present.

In sum, the Agency believes that the criteria set forth in this proposed exemption would be sufficient to mitigate the identified risks associated with these microorganisms.

2. *Costs.* This proposed rule expands an existing exemption, and as discussed in Unit VI., would significantly reduce costs to currently regulated entities. The proposed rule would not otherwise impose any additional cost or other burden on currently regulated entities, or existing fermentation processes.

EPA further believes that limiting the use of this proposed exemption to the identified fermentation conditions would impose no burden on affected entities. The restriction merely codifies existing industrial fermentation procedures that are common practices for manufacturing operations that currently seek to use tiered exemptions. Consequently, EPA expects that most, if not all, manufacturers currently using these microbes will already have the measures in place to qualify for the exemption. Equally important, this limitation would add no burden to any existing fermentation processes. Currently, fermentation operations with either of these microbes are not eligible for the tiered exemption, and thus a MCAN must be submitted. Any company that chooses to use a different fermentation process could continue to operate under the status quo and simply submit a MCAN. This proposed rule would simply offer an additional, less costly option, to facilities that choose to use the fermentation operations discussed in this proposed rule.

3. *Benefits.* The following discussion describes the benefits of this proposed rule in a qualitative manner; for a more quantitative approach, see the economic analysis prepared for this proposed rule (Ref. 10). A summary of that economic analysis is also provided in Unit VI.

The benefits analyzed encompass more than the direct benefits associated with submitting a Tier I or Tier II exemption for a new intergeneric microorganism rather than a MCAN. Rather, EPA's benefit analysis included a consideration of the broader benefits to society. EPA's unreasonable risk determination is based on broader benefits to society as well as those benefits attributable to a reduction in the burden associated with submission of Tier I and Tier II exemptions rather than MCANs.

EPA believes manufacturers of new intergeneric microorganisms based on these low-risk microorganisms currently bear an unnecessary regulatory burden in continuing to file MCANs. By adding *T. reesei* QM6a and *B. amyloliquefaciens* to the list of eligible recipient microorganisms in § 725.420, the Agency removes unnecessary regulatory impediments to the design, manufacture, and commercialization of these low risk new intergeneric microorganisms, and of the chemical substances that can be produced by these safer microorganisms. This action would also substantially reduce the costs associated with industry's reporting burden, including the costs associated with the preparation of the submission, and with the delay in the commercial market introduction of the new intergeneric microorganism. Some of the cost-savings benefits may accrue to small businesses, either as developers of the exempt microorganisms, as producers of fermentation chemicals using the live microorganisms, or as customers for enzymes or other products made using the microorganisms.

There would also be a reduction in the Agency review resources currently allocated to reviews of MCANs for these two microorganisms. These Agency resources would be shifted to the review of new intergeneric microorganisms or chemical substances of greater concern.

There would be cost savings to both the industry and the Agency. The proposed rule is expected to positively impact the rate of innovation in the industry. It is reasonable to assume that a new intergeneric microorganism will either possess a new function or serve an existing function more efficiently or less expensively. The reduction in delay for that new intergeneric microorganism to be introduced into commerce is a benefit to both manufacturers and the general public who will have access to the substance more quickly. The expected benefits to innovation have not been quantified but include: Reduced time to develop and commercialize organisms; decreased cost of some downstream industrial products, such as fuel ethanol; improved consumer appeal of some products, such as certain

textiles; and reduced costs of some consumer products, such as detergent and leather goods.

4. *Risk/benefit balance.* Determining the presence or absence of an unreasonable risk requires balancing of the benefits and risks posed by a regulatory action. EPA has determined that the risks are generally low based on the inherent properties and intended uses of *T. reesei* QM6a and *B. amyloliquefaciens,* and would be adequately managed by the restrictions in the proposed rule, combined with the existing requirements of the Tier I and Tier II exemptions.

As noted in this unit, EPA believes that this proposed rule would impose no costs. This proposed rule expands an existing exemption, and as such, would in fact reduce costs to currently regulated entities. This proposed rule would not otherwise impose any additional cost or other burden on currently regulated entities, or existing fermentation processes. The limitation on the use of the proposed exemption to certain fermentation conditions is not a cost that would be imposed by this proposed rule but rather a limitation on the amount of regulatory relief it would provide. The proposed conditions reflect industrial fermentation procedures that are currently common practices for the affected industry.

EPA also believes that the benefits of this proposed rule are quite significant. This proposed rule would reduce the overall regulatory burden for affected entities by reducing the reporting requirements and by eliminating the delay of these products into commerce. As a consequence, this would benefit both regulated entities and the general public by promoting the expedited manufacture and use of the chemical substances produced using these low-risk organisms and manufacturing processes. There is also the added benefit of concentrating limited EPA resources on regulation of chemical substances which have a greater potential to present significant risks, rather than on these two microorganisms. While this is difficult to quantify, it is considered substantial nonetheless.

In sum, the Agency believes that the criteria set forth in this proposed exemption are sufficient to mitigate the low level of potential risks presented by these organisms, particularly when compared to the benefits, *in toto,* of this proposed exemption, to levels that are consistent with the statutory standard for an exemption. Consequently, EPA has made a preliminary conclusion that adding *T. reesei* QM6a and *B. amyloliquefaciens* as recipient microorganisms to the list of recipient microorganisms at § 725.420 is appropriate, as it would not present an unreasonable risk of injury to human health or the environment when manufactured under the conditions of this proposed exemption.

VIII. Request for Public Comment, Rulemaking Process, and Request for an Informal Public Hearing

A. Rulemaking Process and Request for an Informal Public Hearing

EPA is conducting this rulemaking under the notice and comment rulemaking procedures of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553. Interested persons have the opportunity to submit written comments by the methods identified under **ADDRESSES**. EPA will carefully consider all such comments.

EPA is also providing an opportunity for an informal public hearing on the proposed rule. This hearing will be held only if EPA receives a timely written request for such a hearing.

As a general matter, EPA is not required to hold a public hearing in informal notice and comment rulemaking conducted under APA section 553. However, use of TSCA section 5(h)(4) modifies the APA section 553 rulemaking requirements by referencing TSCA section 6(c)(2) and (c)(3) rulemaking procedures. Under the TSCA section 6 procedures, EPA must hold an informal public hearing, if requested, and, if properly requested and granted by EPA, allow an opportunity to present rebuttal submissions and conduct cross-examinations related to disputed issues of material fact.

EPA does not anticipate that, even if a hearing is held, there will be a need for rebuttal submissions and cross-examination, because the TSCA section 5(h)(4) portion of this proposed rulemaking is based primarily on matters of science policy that do not yield disputed factual issues.

B. Specific Comment Solicitation

EPA is seeking public comment pertaining to several specific issues regarding the proposed rule.

1. Do the proposed rule and supporting documents adequately address:

- The effects of the new microorganism on health and the environment?
- The magnitude of exposure of human beings and the environment to the new microorganism?
- The benefits of the new microorganism for various uses and the availability of substitutes for such uses?
- The reasonably ascertainable economic consequences of granting or denying the exemption, including effects on the national economy, small business, and technological innovation?

2. Does the proposed rule address taxonomy adequately (is the Agency capturing and excluding the correct strains)?

3. Does the proposed rule address the right description of typical conditions for enzyme production (eliminating plant material/solid surfaces)?

4. Are the limitations on the use of *T. reesei* QM6a reasonable for preventing paracelsin production (i.e., having no solid plant material or insoluble substrate with the microorganism)?

IX. References

As indicated under **ADDRESSES**, a docket has been established for this proposed rule under docket ID number EPA–HQ–OPPT–2011–0740. The following is a listing of the documents that have been placed in the docket for this proposed rule. The docket includes information considered by EPA in developing this proposed rule, including the documents listed in this unit, which are physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these referenced documents are physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not physically located in the docket, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**. The docket is available for review as specified under **ADDRESSES**.

1. Genencor International, Inc. Letter of Application to list *Trichoderma reesei* as exempt under subpart G of 40 CFR Part 725—Reporting Requirements and Review Processes for Microorganisms. March 17, 2005.

2. Novo Nordisk BioChem North America, Inc. Letter of Application to list *B.amyloliquefaciens* as exempt under subpart G of 40 CFR Part 725—Reporting Requirements and Review Processes for Microorganisms. November 7, 1997.

3. EPA, OPPT. Email confirming Novo Nordisk BioChem North America, Inc.'s letter of application to list *B.amyloliquefaciens* as exempt under subpart G of 40 CFR Part 725—Reporting Requirements and Review Processes for Microorganisms. August 3, 2009.

4. ETA. Supplemental information on *Trichoderma reesei.* January 29, 2010.

5. ETA. Supplemental information on *Trichoderma reesei.* June 16, 2011.

6. EPA, OPPT. Risk Assessment of *Trichoderma reesei* for Consideration of Addition to the List of Eligible Recipient

Microorganisms for the Tiered 5(h)(4) Exemptions from MCAN Reporting Requirements. October 2011.

7. EPA, OPPT. Risk Assessment of *Bacillus amyloliquefaciens* subsp. *amyloliquefaciens* for Consideration of Addition to the List of Eligible Recipient Microorganisms for the Tiered 5(h)(4) Exemptions from MCAN Reporting Requirements. October 2011.

8. EPA, OPPT. Release and Exposure Assessment in Support of Proposed TSCA 5(h)(4) Exemption for *Trichoderma reesei.* June 2011.

9. EPA, OPPT. Release and Exposure Assessment in Support of Proposed TSCA 5(h)(4) Exemption for *Bacillus amyloliquefaciens.* June 2011.

10. EPA, OPPT. Economic Analysis for the Proposed Biotechnology Exemptions Rule for *Trichoderma reesei* and *Bacillus amyloliquefaciens.* September 2011.

11. Legislative History of the Toxic Substances Control Act, pp. 409–423. House Report 1341, 94th Congress, 2nd Session. 1976.

12. EPA. Microbial Products of Biotechnology; Proposed Regulation under the Toxic Substances Control Act. **Federal Register** (59 FR 45526; September 1, 1994) (FRL–4774–4).

13. EPA. Microbial Products of Biotechnology; Final Regulation under the Toxic Substances Control Act. **Federal Register** (62 FR 17910; April 11, 1997) (FRL–5577–2).

X. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563:

Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). EPA prepared an analysis of the potential costs and benefits associated with this action, which is summarized in Unit VI.

B. Paperwork Reduction Act (PRA)

According to PRA, 44 U.S.C. 3501 *et seq.,* an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information that requires approval by the Office of Management and Budget (OMB) under PRA, unless it has been approved by OMB and displays a valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

The information collection requirements related to the submission of Tier I and Tier II notification are already approved by OMB under PRA, and have been assigned OMB control numbers 2070–0012 and 2070–0038. This proposed rule does not impose any new requirements, or otherwise increase burden such that additional OMB review or approval is necessary. Instead, this proposed rule is expected to reduce the amount of required reporting by allowing firms to submit less information for qualifying microorganisms.

The PRA requires agencies to estimate the potential recordkeeping and reporting burden of a proposed rule. In this context, the term ''burden'' is defined in 5 CFR 1320.3(b). EPA estimates that this proposed rule would result in a reduction of industry burden by 30,695 hr over 10 years. EPA also estimates that the proposed rule would cause a total incremental Agency savings of 41,869 hr over 10 years. Submit any comments related to these estimates to EPA. See **ADDRESSES** for submission of comments.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* the Agency hereby certifies that this proposed rule, if promulgated as proposed, would not have a significant economic impact on a substantial number of small entities. Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this action on small entities, small entity is defined as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201 using either the number of employees or annual receipts for the businesses affected by the regulation, which for this action includes any business that is conducting commercial research and development activities or persons manufacturing, importing or processing products using intergeneric microorganisms for biofertilizers; biosensors; enzyme, commodity, or specialty chemical production; energy applications; waste treatment or pollutant degradation; and other TSCA subject uses.

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

In making this determination, the impact of concern is any significant adverse economic impact on small entities because the primary purpose of regulatory flexibility analysis is to identify and address regulatory alternatives ''which minimize any significant economic impact of the rule on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may certify under RFA when the rule relieves regulatory burden, or otherwise has no expected economic impact on small entities subject to the rule.

This proposed rule is an exemption, and is therefore expected to reduce the existing regulatory burden, which will benefit all submitters regardless of the size of the entity. The factual basis for the Agency's certification under RFA is presented in the small entity impact analysis prepared as part of the Economic Analysis for this proposed rule (Ref. 10), and is briefly summarized in Unit VI.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

EPA has determined that this action does not impose any enforceable duty or contain any unfunded mandate for State, local, or Tribal governments or the private sector, and does not otherwise have any effect on small governments, such that it is subject to the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531–1538. As indicated previously, this action is expected to reduce costs. In addition, based on EPA's experience with past MCANs and Tier I and II exemptions, State, local, and Tribal governments have not been affected by these reporting requirements, and EPA does not have any reason to believe that any State, local, or Tribal government will be affected by this particular rulemaking. A search of past submissions to EPA demonstrated that no State, local, or Tribal government have ever submitted a MCAN, Tier I or Tier II notification to EPA. EPA has no information to indicate that any State, local, or Tribal government commercially manufactures the microorganisms covered by this action.

E. Executive Order 13132: Federalism

For the same reasons presented in Unit X.D., the Agency has determined that this action will not have a substantial direct effect on State or local governments, on the relationship between the national government and the States or local governments, or on the distribution of power and responsibilities among the various

levels of government. Thus, the Agency has determined that Executive Order 13132 (64 FR 43255, August 10, 1999) does not apply to this action.

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

For the same reasons presented in Unit X.D., the Agency has determined that this action will not have a substantial direct effect on tribal governments, on the relationship between the national government and Tribal governments, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13175 (65 FR 67249, November 9, 2000) does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks, nor is it an ''economically significant regulatory action'' as defined by Executive Order 12866.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of NTTAA, 15 U.S.C. 272 note, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, etc.) that are developed or adopted by voluntary consensus standards bodies. This proposed rule does not impose any technical standards that would require EPA to consider any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. Therefore, this action does not involve special consideration of environmental justice-related issues as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 725

Environmental protection, Administrative practice and procedure, Biotechnology, Chemicals, Hazardous substances, Imports, Labeling, Microorganisms, Occupational safety and health, Reporting and recordkeeping requirements.

Dated: August 28, 2012.

James Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 725—[AMENDED]

1. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

2. In § 725.3, add in alphabetical order the definition below to read as follows:

§ 725.3 Definitions.

* * * * *

Submerged standard industrial fermentation for purposes of this part, means a fermentation system that meets all of the following conditions:

(1) Submerged fermentation (i.e., growth of the microorganism occurs beneath the surface of the liquid growth medium).

(2) Any fermentation of solid plant material or insoluble substrate, to which *T. reesei* fermentation broth is added after the standard industrial fermentation is completed, may be initiated only after the inactivation of the microorganism as delineated in § 725.422(d).

* * * * *

3. In § 725.420, add new paragraphs (k) and (l) to read as follows:

§ 725.420 Recipient microorganisms.

* * * * *

(k) *Trichoderma reesei* strain QM6a used only in submerged standard industrial fermentation operations in which no solid plant material or insoluble substrate is present in the fermentation broth, fermentation may only be initiated after the inactivation of T. reesei as delineated in § 725.422(d).

(l) *Bacillus amyloliquefaciens* subsp. *amyloliquefaciens.*

[FR Doc. 2012–21843 Filed 9–4–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 101

[WT Docket No. 10–153; FCC 12–87]

Facilitating the Use of Microwave for Wireless Backhaul and Other Uses and Providing Additional Flexibility To Broadcast Auxiliary Service and Operational Fixed Microwave Licensees

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission seeks more detailed comments on specific proposals made by parties to allow use of smaller antennas and wider channels in other part 101 microwave bands. We also seek comment on a proposal to revise our rules to change our treatment of smaller antennas in the 10.7–11.7 GHz band (11 GHz band). We also seek comment on additional ways to increase the flexibility, capacity, and cost-effectiveness of the microwave bands, while protecting incumbent licensees in these bands. In the *Second Notice of Inquiry,* we seek comment on making additional changes to our antenna standards to reflect advances in technology, accommodate non-parabolic antennas, and harmonize our standards with international standards. By enabling more flexible and cost-effective microwave services, the Commission can help foster deployment of broadband infrastructure across America.

DATES: Submit comments on or before October 5, 2012. Submit reply comments on or before October 22, 2012.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. You may submit comments, identified by FCC 12–87, or by WT Docket No. 10–153, or by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Federal Communications Commission's Web Site: http://

www.fcc.gov/cgb/ecfs/. Follow the instructions for submitting comments.

People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: (202) 418–0530 or TTY: (202) 418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For further information contact John Schauble, Deputy Chief, Wireless Telecommunications Bureau, Broadband Division, at 202–418–0797 or by email to *John.Schauble@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Second Further Notice of Proposed Rulemaking and Second Notice of Inquiry,* FCC 12–87, adopted and released on August 3, 2012. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554. The complete text may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc. (BCPI), Portals II, 445 12th Street SW., Room CY–B402, Washington, DC 20554, (202) 488–5300, facsimile (202) 488–5563, or via email at *fcc@bcpiweb.com.* The complete text is also available on the Commission's Web site at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC–12–87A1.doc.* Alternative formats (computer diskette, large print, audio cassette, and Braille) are available by contacting Brian Millin at (202) 418–7426, TTY (202) 418–7365, or via email to *bmillin@fcc.gov.*

Summary

Second Further Notice of Proposed Rulemaking

1. In this *Second Further Notice of Proposed Rulemaking,* we continue our efforts to improve and modernize our rules and increase the flexibility of our part 101 rules to promote wireless backhaul. We seek more detailed comment on specific proposals made by parties to allow use of smaller antennas and wider channels in other part 101 microwave bands. We also seek comment on a proposal to revise our rules to change our treatment of smaller antennas in the 10.7–11.7 GHz band (11 GHz band).

Allow Smaller Antennas in the 13 GHz Band

2. Comsearch asks that the Commission modify its antenna standards for the 13 GHz band to allow the use of 2 foot antennas under Category B. Comsearch states that a 2.5 foot antenna can satisfy the Standard A suppression requirements, but that 2 foot antennas do not meet the Standard B suppression requirements because the suppression criteria are too tight from 5 to 15 degrees. Comsearch states that 2 foot antennas are commonly used in the 11 GHz band under Standard B, and it anticipates that similar usage would be desirable in the 13 GHz band. Comsearch believes using 2 foot antennas should not be a significant interference concern because paths would be limited to rural areas outside of BAS TV pickup service areas. Comsearch proposes specific antenna standards.

3. We seek comment on modifying our antenna standards to allow use of 2 foot antennas in the 13 GHz band under Category B as proposed by Comsearch. Smaller antennas have a variety of benefits, including savings in purchasing, installing, and renting space for such antennas. We recognize that the proposed use of smaller, lower-gain antennas will result in more radiofrequency energy being transmitted in the side lobes off the main point-to-point link. We therefore wish to ensure that any proposed changes to the Commission's rules appropriately protect other users in the bands from interference due to the operation of these smaller antennas. We seek comment on whether the use of smaller antennas pursuant to the proposed modifications will adversely affect other users in the specific bands by increasing the risk of interference. If so, do the potential benefits of using smaller antennas outweigh the potential risks of interference? We also seek comment on the relative costs and benefits of allowing smaller antennas in the 13 GHz band. Can the benefits be calculated in the same manner as we calculated the benefits of smaller antennas in the 6, 18, and 23 GHz bands?

Revising Antenna Rules for 11 GHz Band

4. We seek comment on revising the circumstances under which licensees in the 11 GHz band can reduce power in order to avoid having to upgrade their antennas. We also propose to amend our rules to ensure that applicants do not specify more power than they need.

5. In 2007, the Commission amended its antenna specifications for the 11 GHz band to allow smaller antennas in that band. In response to a question raised by Comsearch about interference protection, the Commission stated:

> Under the existing rules, a licensee using a Category B antenna must install a Category A antenna meeting Category A standards if necessary to resolve interference. In response to Comsearch's question as to whether a licensee can resolve interference by reducing power, we will allow licensees to resolve interference by reducing EIRP. Specifically, a licensee using a smaller antenna may demonstrate equivalent protection by reducing its EIRP from the maximum by an amount equivalent to the difference between the minimum suppression of a Category A antenna and the suppression of the actual antenna being used, at the relevant angle to the objecting party.

This concept was codified in § 101.115(f) of the Commission's rules.

6. Comsearch argues that allowing a licensee to reduce its EIRP from the maximum allowed by the rule negates the intent of the rule and does not provide proper interference protection. According to Comsearch, most 11 GHz links operate with far less power than the maximum authorized under the rules. Comsearch argues that if a link using a Category B antenna is operating significantly below the maximum power authorized under our rules, it will not have to modify the link because its power is already below the power radiated using a Category A antenna with maximum power. Comsearch asks that § 101.115(f) of the Commission's rules be modified to replace the phrase ''and operating with the maximum EIRP allowed by the rules'' with ''and operating with the authorized EIRP.''

7. The Fixed Wireless Communications Coalition (FWCC) generally supports Comsearch's request for relief. FWCC is concerned, however, that Comsearch's proposed rule change would give applicants incentives to apply for more power they need in case a later applicant raises an interference concern. FWCC offers two proposals for addressing that concern. FWCC's first proposal is to add language to § 101.115(f) limiting the circumstances under which a licensee could reduce EIRP without changing to a Category A antenna. Alternatively, FWCC proposes to amend § 101.113 of the Commission's rules to clarify that a licensee may not hold an authorization for substantially more power than it actually needs.

8. We seek comment on amending §§ 101.103 and 101.115(f) of the Commission's rules to address the concerns raised by Comsearch and FWCC. We note that theoretically, the existing rules could allow licensees using lower EIRP to avoid having to

change antennas to correct interference problems. At the same time, § 101.115(f) has been in effect for several years, and we are unaware of instances where this rule has led to interference disputes or precluded the placement of links in an area. We ask proponents of this change to provide examples of instances where the existing rules have led to interference problems or precluded other users from using 11 GHz spectrum within a given area. We also ask commenters to provide specific data on the costs and benefits associated with this proposed rule change.

9. If rule changes are appropriate, we tentatively conclude that the best method of resolving the issue would be to change the term ''maximum EIRP'' to ''authorized EIRP'' and making the changes to § 101.113 proposed by FWCC. The term ''authorized EIRP'' is subjective since applicants select the power at which they propose to operate. Absent some additional limitations in the rule, we agree with FWCC that merely inserting the term ''authorized EIRP'' into § 101.115(f) would give applicants incentive to propose excessive power. Of the two alternatives offered by FWCC, it appears that the proposed changes to § 101.113 would maximize licensee flexibility to resolve interference issues while clearly stating that applicants must request the minimum power necessary. We seek comment on this tentative conclusion, and any associated benefits or costs of this proposal.

Allowing Intermediate Antenna Upgrades

10. Currently, if a licensee must upgrade its antenna in order to resolve an interference problem, it must upgrade to an antenna meeting the higher Category A standards contained in our rules. We propose to allow licensees to make lesser upgrades (*i.e.,* to an antenna that does not meet Category A standards) if the lesser upgrade would resolve the interference.

11. In general, the Commission's rules require a Category B user to upgrade to a Category A antenna if the antenna causes interference problems that would be resolved by the use of a Category A antenna. Wireless Strategies, Inc. (WSI) suggests that in the 6 GHz and 11 GHz bands, applicants and licensees be allowed to operate any antenna, including an antenna that does not meet the less demanding Category B standard. WSI also proposes that if the applicant or licensee could resolve an interference issue by upgrading to a lesser antenna that does not meet Category A standards, the applicant or licensee would be allowed to use that lesser antenna. WSI claims that its proposed change ''would allow designers and users of FS microwave to minimize the cost and make it easier to comply with local zoning and homeowner association rules and ensure that the use of antennas not meeting Category A requirements does not increase the potential for harmful interference.''

12. We see some merit in the idea of allowing intermediate upgrades if a licensee can resolve an interference issue by upgrading from one Category B antenna to another Category B antenna with better performance characteristics, that still does not meet Category A standard. There may be instances where an applicant or licensee could resolve an interference issue or conflict by upgrading to an antenna that does not meet Category A standards but would resolve the interference problem. An intermediate upgrade may allow a licensee to maintain operations from an existing site or reduce costs to the point where operation remains economically feasible. Furthermore, while licensees may be reluctant to upgrade antennas, the current rules impose a duty to upgrade to a Category A antenna. The proposed change would give licensees additional flexibility by giving them another option to resolve interference issues. Under our proposal, a licensee proposing to make an intermediate upgrade would assume the risk that the intermediate upgrade would not resolve the interference issue and would be required to make a further upgrade to a Category A antenna if the intermediate upgrade failed to resolve the issue or if a Category A antenna was needed to accommodate another link.

13. Accordingly, we seek comment on allowing licensees and applicants to resolve an interference issue by upgrading from one Category B antenna to another Category B antenna with better performance characteristics, but that still does not meet Category A standard. We ask proponents of this proposal to identify specific instances where such intermediate upgrades could facilitate wireless backhaul deployment. Opponents should identify specific harms that they believe would result from allowing intermediate upgrades, keeping in mind that an applicant or licensee who sought to make an intermediate upgrade would be required to make a further upgrade to a Category A antenna if necessary. While WSI makes its proposal with respect to the 6 and 11 GHz bands, we seek comment on allowing intermediate upgrades in all part 101 bands. We also seek specific, quantitative information on the benefits and costs of our proposal.

Notice of Inquiry—Additional Changes to Antenna Standards

14. Several parties argue that the Commission should institute a comprehensive review of its part 101 antenna standards. Comsearch notes that it has been many years since the antenna standards have undergone a comprehensive review. Comsearch asks the Commission ''to revise the standards to make them reflect the proper current balance of manufacturing capabilities, spectral efficiency, and cost.'' It points to standards recently adopted by the European Telecommunications Standards Institute (ETSI), which require significantly greater suppression of the far sidelobes and significantly greater front-to-back ratio. Comsearch argues that manufacturers follow the ETSI standards and that it would therefore be reasonable to tighten the Commission's requirements to meet those standards. Comsearch also asks the Commission to: (1) Change the rules to use breakpoints connected by straight line segments rather than the ranges at a constant suppression level that lead to a ''stairstep'' pattern; (2) introduce standards for suppression of cross-polarized signals; and (3) tighten the Category A and B antenna standards as much as possible consistent with the anticipated size and cost of antennas. FWCC concurs with Comsearch's ideas. Clearwire and FWCC also ask that the Commission adopt standards for antenna configurations other than the traditional parabolic design. Clearwire argues that manufacturers are developing next generation antennas that will introduce a greater array of options for deploying wireless backhaul in an efficient and cost effective manner. It asks that the Commission's rules accommodate such non-parabolic antennas.

15. We believe it would be appropriate to seek input on whether a comprehensive review of our antenna standards is appropriate and what changes would be appropriate as part of that review. We ask commenters to offer specific proposals and rule language so that the Commission and parties can evaluate the proposals and offer meaningful comment. We ask whether we can tighten our antenna standards while still allowing the affordable deployment of wireless backhaul facilities. Are the ETSI standards a useful benchmark for changing our standards? Are there factors unique to the United States market that justify different standards? Does the fact that many microwave bands are shared with other services affect the appropriate standards? Would changing the

standards allow these bands to be used for new and innovative standards? We seek comment on these and other related questions, including any associated costs and benefits.

16. We also seek comment on Comsearch's more specific suggestions. It appears that we would have to replace the existing table in § 101.115 of the Commission's rules with some other means of indicating the appropriate suppression levels. What would be the best means of implementing such a change in our rules? What changes to our rules would be necessary to take into account cross-polarized signals? What would be the costs and benefits of any such rule changes?

17. We note that our rules do not mandate the use of parabolic antennas. Instead, our rules specify certain technical parameters—maximum beamwidth, minimum antenna gain, and minimum radiation suppression—that limit the interference potential. We ask Clearwire, FWCC and others to explain what rule changes would be necessary in order to accommodate non-parabolic antennas. What effect would such changes have on other licensees? Is it possible to establish rules that would include all the possible types of microwave antennas? We seek comment on these questions and related issues, including potential costs and benefits of any rule changes.

18. Finally, we note that our definition of a congested area, for the purpose of requiring antennas to meet Category A standards, is based in part on a 1976 public notice that was last republished in 1983. We seek comment on how we should update or change our standards for defining a congested area. Should we attempt to develop an updated list of congested areas, rely exclusively on location-specific interference analyses, or should we use some other paradigm for determining what areas require the use of Category A antennas? What would be the costs and benefits of other paradigms?

19. By issuing this *Second Notice of Inquiry,* we intend to start a broad discussion of our microwave antenna standards. We invite commenters to raise additional questions and ideas. We also encourage a broad range of affected parties to comment, including current licensees, equipment manufacturers, operators who are interested in using microwave facilities, licensees who share spectrum with microwave operators, frequency coordinators, and other interested parties.

Procedural Matters

Ex Parte Rules—Permit-But-Disclose

20. The proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule § 1.1206(b). In proceedings governed by rule § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Comment Period and Procedures

21. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

▪ *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/*.

▪ *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

▪ All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

▪ Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

▪ U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington D.C. 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Availability of Documents: The public may view the documents filed in this proceeding during regular business hours in the FCC Reference Information Center, Federal Communications Commission, 445 12th Street SW., Room CY–A257, Washington, DC 20554, and on the Commission's Internet Home Page: *http://www.fcc.gov*. Copies of comments and reply comments are also available through the Commission's duplicating contractor: Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, 1–800–378–3160.

Paperwork Reduction Analysis

22. This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain

any new or modified ''information collection burden for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

23. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this *Second Further Notice of Proposed Rulemaking (2nd FNPRM).* Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines specified in the *2nd FNPRM* for comments. The Commission will send a copy of this *2nd NPRM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

Need for, and Objectives of, the Proposed Rules

24. In this *Second Further Notice of Proposed Rulemaking,* we propose five additional changes to our rules involving microwave stations. These changes are described in further detail below. First, we propose to allow the use of smaller antennas in the 12700–13150 MHz band (13 GHz band) fixed service (FS) band. Second, we seek comment on amending our rules for the 11 GHz band to clarify the rules concerning antenna upgrades. Finally, we propose to provide additional flexibility to licensees who must upgrade their antennas to resolve interference issues.

25. With respect to the first proposal, § 101.115(b) of the Commission's rules establishes directional antenna standards designed to maximize the use of microwave spectrum while avoiding interference between operators. The rule on its face does not mandate a specific size of antenna. Rather, it specifies certain technical parameters—maximum beamwidth, minimum antenna gain, and minimum radiation suppression—that, depending on the state of technology at any point in time, directly affect the size of a compliant antenna. Smaller antennas have several advantages. They cost less to manufacture and distribute, are less expensive to install because they weigh less and need less structural support, and cost less to maintain because they are less subject to wind load and other destructive forces. In addition, the modest weight of small antennas makes them practical for installation at sites incapable of supporting large dishes, including many rooftops, electrical transmission towers, water towers, monopoles and other radio towers. Smaller antennas raise fewer aesthetic objections, thereby permitting easier compliance with local zoning and homeowner association rules and generating fewer objections. On the other hand, smaller antennas have increased potential to cause interference because smaller antennas result in more radiofrequency energy being transmitted in directions away from the actual point-to-point link. We seek comment on whether we can allow smaller antennas in the 13 GHz band without producing harmful interference.

26. Second, we seek comment on amending our rules for the 11 GHz band to clarify the circumstances under which a licensee can reduce power to avoid having to upgrade its antenna and to make clear that that a licensee may not hold an authorization for substantially more power than it actually needs. Parties have expressed concern that our existing rules allow licensees using powers below the maximum specified in the rules to avoid upgrading antennas and that the existing rules do not provide proper interference protection.

27. Finally, we propose to allow licensees to make intermediate antenna upgrades to resolve interference issues. Currently, a licensee using an antenna meeting Category B standards must upgrade to an antenna meeting Category A standards if an antenna upgrade is necessary to resolve an interference issue. Currently, under § 101.115(c) of the Commission's rules, if an existing antenna is insufficient to resolve interference, the operator must upgrade to an antenna meeting performance standard A. There may be instances where an applicant or licensee could resolve an interference issue or conflict by upgrading to an antenna that does not meet Category A standards but would resolve the interference problem. An intermediate upgrade may allow a licensee to maintain operations from an existing site or reduce costs to the point where operation remains economic.

Legal Basis

28. The proposed action is authorized pursuant to sections 1, 2, 4(i), 7, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 157, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333 and section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302.

Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

29. The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules and policies, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

30. *Small Businesses, Small Organizations, and Small Governmental Jurisdictions.* Our action may, over time, affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three comprehensive, statutory small entity size standards. First, nationwide, there are a total of approximately 27.5 million small businesses, according to the SBA. In addition, a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of 2007, there were approximately 1,621,315 small organizations. Finally, the term ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' Census Bureau data for 2011 indicate that there were 89,476 local governmental jurisdictions in the United States. We estimate that, of this total, as many as 88,506 entities may qualify as ''small governmental jurisdictions.'' Thus, we estimate that most governmental jurisdictions are small.

31. *Wireless Telecommunications Carriers (except satellite).* The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census Bureau data for 2007, which now supersede data from the 2002 Census, show that there were 3,188 firms in this category that operated for the entire year. Of this total, 3,144 had employment of 999 or fewer, and 44 firms had employment of 1,000 employees or more. Thus under this

category and the associated small business size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities that may be affected by our proposed action.

32. *Fixed Microwave Services.* Microwave services include common carrier, private-operational fixed, and broadcast auxiliary radio services. At present, there are approximately 31,549 common carrier fixed licensees and 89,633 private and public safety operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services. Microwave services include common carrier, private-operational fixed, and broadcast auxiliary radio services. They also include the Local Multipoint Distribution Service (LMDS), the Digital Electronic Message Service (DEMS), and the 24 GHz Service, where licensees can choose between common carrier and non-common carrier status. The Commission has not yet defined a small business with respect to microwave services. For purposes of the IRFA, the Commission will use the SBA's definition applicable to Wireless Telecommunications Carriers (except satellite)—i.e., an entity with no more than 1,500 persons is considered small. For the category of Wireless Telecommunications Carriers (except Satellite), Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year. Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus under this category and the associated small business size standard, the majority of firms can be considered small. The Commission notes that the number of firms does not necessarily track the number of licensees. The Commission estimates that virtually all of the Fixed Microwave licensees (excluding broadcast auxiliary licensees) would qualify as small entities under the SBA definition.

33. *Satellite Telecommunications and All Other Telecommunications.* Two economic census categories address the satellite industry. The first category has a small business size standard of $15 million or less in average annual receipts, under SBA rules. The second has a size standard of $25 million or less in annual receipts.

34. The category of Satellite Telecommunications ''comprises establishments primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' Census Bureau data for 2007 show that 512 Satellite Telecommunications firms operated for that entire year. Of this total, 464 firms had annual receipts of under $10 million, and 18 firms had receipts of $10 million to $24,999,999. Consequently, the Commission estimates that the majority of Satellite Telecommunications firms are small entities that might be affected by our action.

35. The second category, *i.e.* ''All Other Telecommunications'' comprises ''establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing Internet services or voice over Internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry.'' For this category, Census Bureau data for 2007 show that there were a total of 2,383 firms that operated for the entire year. Of this total, 2,347 firms had annual receipts of under $25 million and 12 firms had annual receipts of $25 million to $49,999,999. Consequently, the Commission estimates that the majority of All Other Telecommunications firms are small entities that might be affected by our action.

Description of Projected Reporting, Recordkeeping, and other Compliance Requirements

36. This *2nd FNPRM* proposes no new reporting or recordkeeping requirements.

Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

37. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

38. The actions proposed in the *FNPRM* would provide additional options to all licensees, including small entity licensees. Such actions will serve the public interest by providing additional flexibility for broadcasters to use microwave spectrum. The rules will therefore open up beneficial economic opportunities to a variety of spectrum users, including small businesses. Because the actions proposed in the *FNPRM* will improve beneficial economic opportunities for all businesses, including small businesses, a detailed discussion of alternatives is not required.

39. Generally, the alternative approach would be to maintain the existing rules.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

40. None.

41. It is ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this *Second Further Notice of Proposed Rulemaking,* including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

42. It is further ordered, pursuant to sections 1, 2, 4(i), 7, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 157, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333, and section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302, that this *Second Further Notice of Proposed Rulemaking* is hereby adopted and that comment is sought on these proposals.

43. It is further ordered, pursuant to sections 1, 2, 4(i), 7, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 157, 201, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, and 333, and section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302, that this *Second Notice of Inquiry* is hereby adopted.

List of Subjects in 47 CFR Part 101

Communications equipment, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Sheryl Todd,

Deputy Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 101 as follows:

PART 101—FIXED MICROWAVE SERVICES

1. The authority citation for part 101 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

2. Amend § 101.113 by revising the first sentence of paragraph (a) introductory text and by revising paragraph (b) to read as follows:

§ 101.113 Transmitter power limitations.

(a) On any authorized frequency, the average power requested in an application for authorization and delivered to an antenna in this service must be the minimum amount of power necessary to carry out the communications desired, except as provided in paragraph (b) of this section. * * *

* * * * *

(b) The maximum power of transmitters that use Automatic Transmitter Power Control (ATPC) and the power of non-ATPC transmitters shall not exceed, the power input or output specified in the instrument of station authorization. The power of non-ATPC transmitters shall be maintained as near as practicable to, the power input or output specified in the instrument of station authorization. A licensee that reduces power in order to resolve interference pursuant to § 101.115(f) must update its license to reflect the reduced power level.

* * * * *

3. Amend § 101.115 by revising the entry ''12,200 to 13,250'' in the table in paragraph (b)(2) and paragraphs (c) and (f) to read as follows:

§ 101.115 Directional antennas.

* * * * *

(b) * * *

(2) * * *

Frequency	Category	Maximum beam-width to 3 dB points [1] (included angle in degrees)	Minimum antenna Gain (dBi)	*Minimum radiation suppression to angle in degrees from centerline of main beam in decibels*						
				5° to 10°	10° to 15°	15° to 20°	20° to 30°	30° to 100°	100° to 140°	140° to 180°
*	*	*	*		*		*		*	
12,200 to 13,250 [9]	A	1.0	n/a	23	28	35	39	41	42	50
	B1	2.0	n/a	20	25	28	30	32	37	47
	B2	2.0	n/a	17	24	28	32	35	60	60
*	*	*	*		*		*		*	

* * * * *

[9] Except for Temporary-fixed operations in the band 13200–13250 MHz with output powers less than 250 mW and as provided in § 101.147(q), and except for antennas in the MVDDS service in the band 12.2–12.7 GHz.

* * * * *

(c) The Commission shall require the replacement of any antenna or periscope antenna system of a permanent fixed station operating at 932.5 MHz or higher that does not meet performance Standard A specified in this paragraph (c), at the expense of the licensee operating such antenna, upon a showing that said antenna causes or is likely to cause interference to (or receive interference from) any other authorized or applied for station whereas a higher performance antenna is not likely to involve such interference. Antenna performance is expected to meet the standards of this paragraph (c) for parallel polarization. A licensee may upgrade to an antenna not meeting performance standard A if such upgrade will resolve the interference. A licensee who chooses to upgrade to an antenna not meeting performance standard A will be required to upgrade to an antenna meeting performance standard A in the future if necessary to resolve a subsequent interference issue. For cases of potential interference, an antenna will not be considered to meet Standard A unless the parallel polarization performance for the discrimination angle involved meets the requirements, even if the cross-polarization performance controls the interference.

* * * * *

(f) In the 10,700–11,700 MHz band, a fixed station may employ transmitting and receiving antennas meeting performance standard B in any area. If a Fixed Service or Fixed Satellite Service licensee or applicant makes a showing that it is likely to receive interference from such fixed station and that such interference would not exist if the fixed station used an antenna meeting performance standard A, the fixed station licensee must modify its use. Specifically, the fixed station licensee must either substitute an antenna meeting performance standard A or operate its system with an EIRP reduced so as not to radiate, in the direction of the other licensee, an EIRP in excess of that which would be radiated by a station using a Category A antenna and operating with the authorized EIRP. A licensee or prior applicant using an antenna that does not meet performance Standard A may object to a prior coordination notice based on interference only if such interference would be predicted to exist if the licensee or prior applicant used an antenna meeting performance standard A.

* * * * *

[FR Doc. 2012–21336 Filed 9–4–12; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2012–0067; 4500030114]

RIN 1018–AY63

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Franciscan Manzanita

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for *Arctostaphylos franciscana* (Franciscan manzanita) under the Endangered Species Act of 1973, as amended (Act).

In total, approximately 318 acres (129 hectares) are being proposed for designation as critical habitat. The proposed critical habitat is located in San Francisco County and City, California.

DATES: We will accept comments received or postmarked on or before November 5, 2012. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in the **FOR FURTHER INFORMATION CONTACT** section by October 22, 2012.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter Docket No. FWS–R8–ES–2012–0067, which is the docket number for this rulemaking. Then, click on the Search button to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R8–ES–2012–0067; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see *Public Comments* below for more information).

The coordinates or plot points or both from which the maps are generated are included in the administrative record for this critical habitat designation and are available at *http://www.fws.gov/sacramento, http://www.regulations.gov* at Docket No. FWS–R8–ES–2012–0067, and the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). Any additional tools or supporting information that we may develop for this critical habitat designation will also be available at the Fish and Wildlife Service Web site and Fish and Wildlife Office set out above, and may also be included in the preamble or at *http://www.regulations.gov,* or both.

FOR FURTHER INFORMATION CONTACT: Susan Moore, Field Supervisor, U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, W–2605, Sacramento, CA 95825; telephone 916–414–6600; facsimile 916–414–6612. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. This is a proposed rule to designate critical habitat for *Arctostaphylos franciscana* (Franciscan manzanita). Elsewhere in today's **Federal Register**, we are publishing a final rule to list *Arctostaphylos franciscana* as endangered. Under the Endangered Species Act, any species that is determined to be an endangered or threatened species will, to the maximum extent prudent and determinable, have habitat designated that is considered to be critical habitat. We have determined that designating critical habitat for *Arctostaphylos franciscana* is both prudent and determinable. Designations of and revisions to critical habitat can only be completed by issuing a rule. This proposed designation for Franciscan manzanita includes 11 units in San Francisco County and City, California, totaling 318 acres (129 hectares).

The basis for our action. Section 4(b)(2) of the Endangered Species Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species.

We are preparing a draft economic analysis for the proposed designation. In order to consider the economic impacts of the proposed designation, we are preparing a draft analysis of the economic impacts of the proposed critical habitat designation. We will announce the availability of the draft economic analysis as soon as it is completed.

We will seek peer review. We are seeking the expert opinions of appropriate and independent specialists regarding this proposed rule to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses. We have invited these peer reviewers to comment during the proposed rule's public comment period on our proposed rule to designate critical habitat. We will consider all comments and information we receive during the comment period in our preparation of the final determination. Accordingly, the final decision may differ from this proposal.

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned government agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of designation such that the designation of critical habitat may not be prudent.

(2) Specific information on:

(a) The amount and distribution of historic habitat and the range of *Arctostaphylos franciscana;*

(b) What areas, that are occupied at the time of listing (that is, are currently occupied) and that contain features essential to the conservation of the species, should be included in the designation and why;

(c) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including managing for the potential effects of climate change;

(d) What areas not occupied at the time of listing are essential for the conservation of the species and why; and

(e) The specific information on *A. franciscana* pollinators and their habitat requirements.

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(4) Information on the projected and reasonably likely impacts of climate change on *Arctostaphylos franciscana* and proposed critical habitat.

(5) Whether all the remaining areas containing the physical or biological features essential to the conservation of *Arctostaphylos franciscana* or other areas essential for the conservation of *A. franciscana* should be designated as critical habitat or if additional areas outside the historic range should also be

considered for designation. We have identified several areas outside the area we are considering the species' historic range and have proposed one such area, Unit 11 (Bayview Unit) (see *Proposed Critical Habitat Designation* section below). Additional areas we have not currently proposed but would like public comment on including serpentine or greenstone outcrops in San Francisco (McKinley Park, and Starr King Open Space near Potrero Hill; and Grand View Park, the Rocks, and Golden Gate Heights Park along 14th Avenue) and areas farther south of Mount Davidson into San Mateo County (Milagra Ridge, Sweeney Ridge) or north into Marin County (Angel Island and Golden Gate National Recreation Area along the Marin Peninsula). Because of the limited amount of habitat available within the City and County of San Francisco, these additional areas may provide additional sites for reintroduction, and we would like public input on whether these areas should be considered essential for the conservation of the species.

(6) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation; in particular, any impacts on small entities or families, and the benefits of including or excluding areas that exhibit these impacts.

(7) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act. We have not proposed to exclude any areas from critical habitat, but the Secretary is considering exercising his discretion to exclude areas within the Presidio and City or County Park Lands from final critical habitat designation. We will coordinate with the Presidio Trust, the City, and County and will examine conservation actions for the *A. franciscana,* including current management planning documents, in our consideration of these areas for exclusion from the final designation of critical habitat for *A. franciscana,* under section 4(b)(2) of the Act. We specifically solicit comments on the inclusion or exclusion of these areas.

(8) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We request that you send comments only by the methods described in the **ADDRESSES** section.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* You may request at the top of your document that we withhold personal information such as your street address, phone number, or email address from public review; however, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

It is our intent to discuss only those topics directly relevant to the designation of critical habitat for *Arctostaphylos franciscana* in this proposed rule. For further information on the species' biology and habitat, population abundance and trends, distribution, demographic features, habitat use and conditions, threats, and conservation measures, please see the final listing rule for *A. franciscana,* published elsewhere in today's **Federal Register**; the September 8, 2011, proposed listing for the species (76 FR 55623); or the Recovery Plan for Coastal Plants of the Northern San Francisco Peninsula (Service 2003). These documents are available from the Environmental Conservation Online System (ECOS) (*http://ecos.fws.gov/ecos/indexPublic.do*), the Sacramento Fish and Wildlife Office Web site (*http://www.fws.gov/sacramento/*), or from the Federal eRulemaking Portal (*http://www.regulations.gov*).

Prudency Determination

In our proposed listing rule for *Arctostaphylos franciscana* (76 FR 55623; September 8, 2011), we stated that we concluded that critical habitat was not determinable at the time of the proposal due to a lack of knowledge of what physical or biological features were essential to the conservation of the species, or what areas outside the site that is currently occupied may be essential for the conservation of the species. Subsequently, we requested information from the public during the public comment period and solicited information from peer reviewers on whether the determination of critical habitat was prudent and determinable, what physical or biological features were essential to the conservation of the species, and what areas contained those features or were otherwise essential for the conservation of the species. Based on the information we received on the physical or biological features essential to *A. franciscana,* and information on areas otherwise essential for the species, we have determined that the designation of critical habitat is prudent and determinable, and we are proposing critical habitat at this time. For more information regarding our determination to designate critical habitat, please see our response to comments in the final listing determination for *A. franciscana* published elsewhere in today's **Federal Register**.

Species Information

Arctostaphylos franciscana is a low, spreading-to-ascending evergreen shrub in the heath family (Ericaceae) that may reach 0.2 to 1.5 meters (m) (0.6 to 3 feet (ft)) in height when mature (Chasse *et al.* 2009, p. 5; Eastwood 1905, p. 201). The leaves are smooth, flat, bright green, wider towards the tip, and 1.5–2 centimeters (cm) (0.6–0.8 inches (in)) long and 0.5–1 cm (0.2–0.4 in) wide. The flowering period is from January to April. In the wild, *A. franciscana* is an obligate-seeding species (it reproduces primarily from seed after a fire or other disturbance rather than resprouting from burls) (Vasey 2010, p. 1), although the exact germination requirements for *A. franciscana* have not yet been studied. The fruit and seeds of *Arctostaphylos* are eaten and dispersed primarily by mammals, such as raccoons, coyotes, foxes, deer, and rodents (Service 1950, p. 8; Sampson and Jespersen 1963, p. 123; T. Parker pers. comm., 2011; Vasey 2011a, p. 1), and by various fruit-eating birds such as quail and turkey (NRCS 1999, p. 3; Zornes and Bishop 2009, p. 6).

Distribution and Habitat

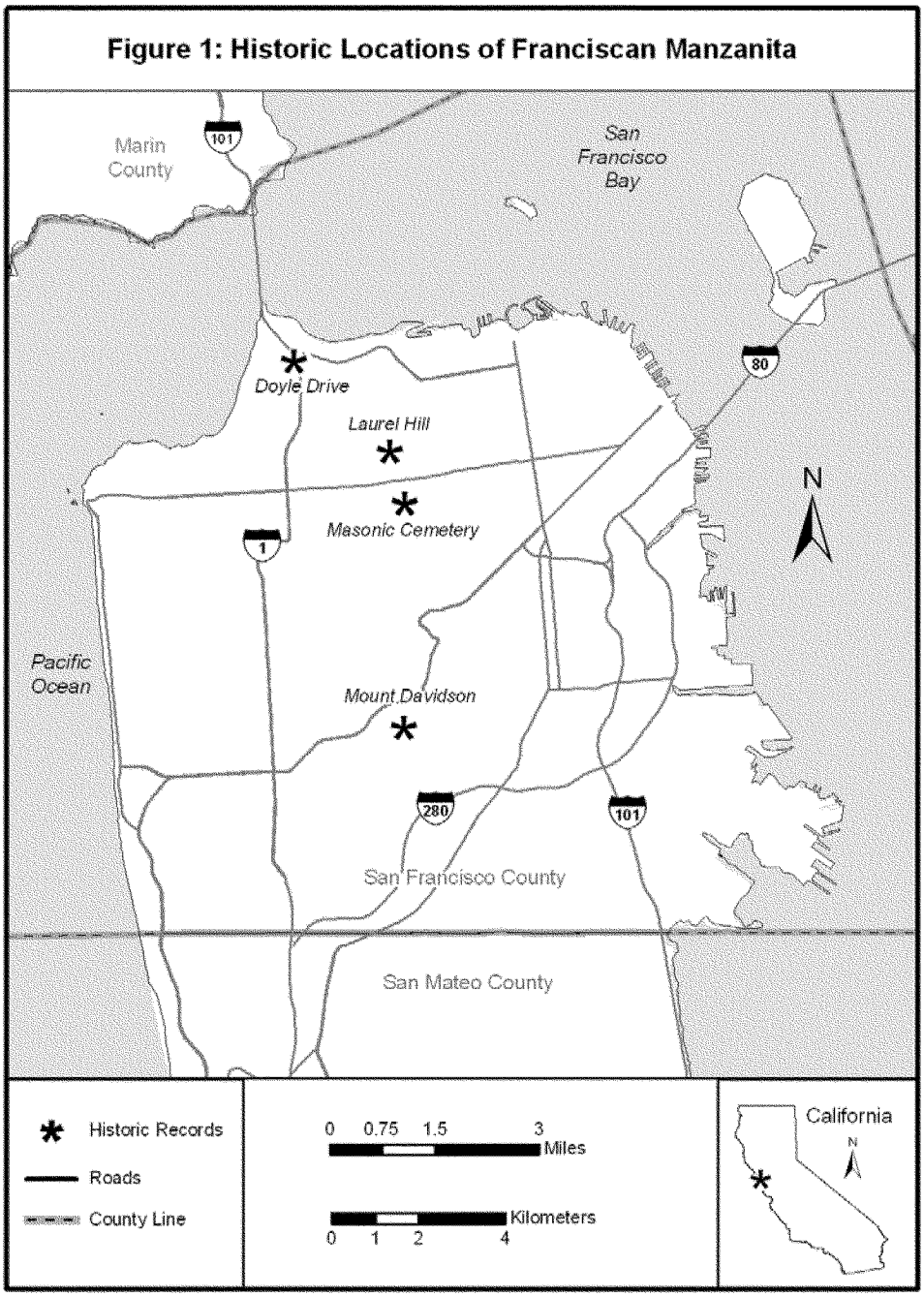
Based on early species occurrence records, voucher specimens, and publications on San Francisco and Bay Area flora, prior to extensive development, *Arctostaphylos franciscana* historically occurred on or near open bedrock outcrops scattered throughout the San Francisco peninsula (Brandegee 1907; Clark 1928; Wieslander 1938; Schlocker 1974, p. 119; Service 1984, pp. 11–12; Service 2003, pp. 15–20, 62).

Portions of the San Francisco peninsula where *Arctostaphylos franciscana* occurs are known as

maritime chaparral, a plant community dominated by shrub species such as *Arctostaphylos* (manzanita) (Vasey 2007b, in litt., p. 1). Maritime chaparral occurs in coastal locations and is characteristic of having small daily and seasonal temperature ranges, summer fog, and high relative humidity (Vasey 2007a, in litt., pp. 1–3). Nearly all historic herbarium collections of *A. franciscana* were from such maritime chaparral locations on or near rock outcrops, which suggests limited historic and prehistoric distribution and only local abundance (Service 2003, p. 62). Locations where *A. franciscana* was found included: (1) The former Laurel Hill Cemetery (Brandegee 1907; Eastwood 1934, p. 114); (2) the former Masonic Cemetery (near the ''base of Lone Mountain'') (Greene 1894, p. 232); (3) Mount Davidson (Stewart 1918); and (4) the ''rediscovery site'' near Doyle Drive (Gluesenkamp *et al.* 2010, p. 6). In addition, there is a historical record of ''*Arctostaphylos pumila*'' (later considered to be *A. franciscana* by species experts) at the former Protestant Orphan Asylum (Laguna at Haight Street, long urbanized by the late 1800s) (Behr 1892, pp. 2–6). The Doyle Drive plant has been transplanted to a locality within the Presidio, and is still surviving (Chasse *et al.* 2009, pp. 17–21; Gluesenkamp *et al.* 2010, pp. 11–14). Chasse *et al.* (2009, pp. 6, 7) have noted that information on the plant community that historically included *A. franciscana* is largely missing from the literature. At the Laurel Hill Cemetery site, *A. franciscana* was associated with *Quercus agrifolia* (coast live oak), *Ceanothus thyrsiflorus* (coast blue blossom), and *Baccharis pilularis* (coyote brush), according to herbarium collections (Wieslander 1938). Several herbarium collections of *A. franciscana* often consist of inadvertent inclusions of *A. hookeri* ssp. *ravenii* (Note: *Arctostaphylos hookeri* ssp. *ravenii* has recently undergone a taxonomic revision to *A. montana* ssp. *ravenii*) (Raven's manzanita) material as the two plants often co-occurred in the same locations (Roof 1976, pp. 21–24, Service 1984, p. 6) (see Figure 1 below).

These observations, along with the geology and climate of historical sites, indicate that the species' community likely consisted of a mosaic of coastal scrub, barren serpentine maritime chaparral, and perennial grassland, with occasional woodland of coast live oak and toyon shrubs and small trees (Chasse 2009, pp. 6, 7). However, native habitats have been largely converted to urban areas of the City of San Francisco, and habitat that might support *A. franciscana* is now mostly lost to development (Chasse 2010, p. 2; Gluesenkamp *et al.* 2010, p. 7).

Figure 1. Historic Locations of Franciscan Manzanita.



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Previous Federal Actions

On December 23, 2009, we received a petition dated December 14, 2009, from the Wild Equity Institute, the Center for Biological Diversity, and the California Native Plant Society, requesting that *Arctostaphylos franciscana* be listed as an endangered species on an emergency basis under the Act and that critical habitat be designated. Included in the petition was supporting information regarding the species' taxonomy and ecology, historical and current distribution, present status, and actual and potential causes of decline. On January 26, 2010, we acknowledged the receipt of the petition in a letter to Wild Equity Institute. On August 10, 2010, we published in the **Federal Register** a 90-day finding indicating that the petition presented substantial information and that we would conduct a status review on the species (75 FR 48294). On September 8, 2011, we published a combined 12-month finding and proposed listing for the species in the **Federal Register** (76 FR 55623). In the proposed listing for the species, we requested information on whether it was prudent to designate critical habitat for the species. After receiving comments from peer reviewers as well as the public, we have determined to the designation of critical habitat is both prudent and determinable. For additional information on previous Federal actions please refer to the September 8, 2011, combined 12-month

finding and proposed listing for the species (76 FR 55623).

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies insure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical and biological features within an area, we focus on the principal biological or physical constituent elements (primary constituent elements such as roost sites, nesting grounds, seasonal wetlands, water quality, tide, soil type) that are essential to the conservation of the species. Primary constituent elements are the specific elements of physical or biological features that provide for a species' life-history processes, and are essential to the conservation of the species.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. We designate critical habitat in areas outside the geographical area occupied by a species only when a designation limited to its range would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34270)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, other unpublished materials, or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. Climate change will be a particular challenge for biodiversity because the interaction of additional stressors associated with climate change and current stressors may push species beyond their ability to survive (Lovejoy 2005, pp. 325–326). The synergistic implications of climate change and habitat fragmentation are the most threatening facet of climate change for biodiversity (Hannah *et al.* 2005, p.4). Current climate change predictions for terrestrial areas in the Northern Hemisphere indicate warmer air temperatures, more intense precipitation events, and increased summer continental drying (Field *et al.* 1999, pp. 1–3; Hayhoe *et al.* 2004, p. 12422; Cayan *et al.* 2005, p. 6; Intergovernmental Panel on Climate Change (IPCC) 2007, p. 1181). Climate change may lead to increased frequency and duration of severe storms and droughts (McLaughlin *et al.* 2002, p. 6074; Cook *et al.* 2004, p. 1015; Golladay *et al.* 2004, p. 504).

We anticipate these changes could affect a number of native plants and their habitats, including *Arctostaphylos franciscana* occurrences and habitat. For example, if the amount and timing of precipitation changes or the average temperature increases in northern California, the following changes may affect the long-term viability of *A. franciscana* in its current habitat configuration:

(1) Drier conditions or changes in summer fog may result in additional stress on the transplanted plant.

(2) Drier conditions may also result in lower seed set, lower germination rate, and smaller population sizes.

(3) A shift in the timing of annual rainfall may favor nonnative species that impact the quality of habitat for this species.

(4) Warmer temperatures may affect the timing of pollinator life-cycles causing pollinators to become out-of-sync with timing of flowering *A. franciscana.*

(5) Drier conditions may result in increased fire frequency, making the ecosystems in which *A. franciscana* currently grows more vulnerable to the initial threat of burning, and to subsequent threats associated with erosion and nonnative or native plant invasion.

However, currently we are unable to specifically identify the ways that climate change may impact *Arctostaphylos franciscana;* therefore, we are unable to determine if any additional areas may be appropriate to include in this proposed critical habitat designation.

We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of a species. Areas that are important to the conservation of *Arctostaphylos franciscana,* both inside and outside a critical habitat designation, would continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) the prohibitions of section 9 of the Act if actions occurring in these areas may affect the species.

Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Physical or Biological Features

In accordance with section 3(5)(A)(i) and 4(b)(1)(A) of the Act and regulations at 50 CFR 424.12, in determining which areas within the geographical area occupied by the species at the time of listing to designate as critical habitat, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical, geographical, and ecological distributions of a species.

We derive the specific physical or biological features required for *Arctostaphylos franciscana* from studies of this species' habitat, ecology, and life history as described below. Additional information can be found in the August 10, 2010, 90-day finding published in the **Federal Register** (75 FR 48294); the September 8, 2011, combined 12-month finding and proposed listing for the species published in the **Federal Register** (76 FR 55623); the 2003 Recovery Plan for Coastal Plants of the Northern San Francisco Peninsula (Service 2003); and the Raven's Manzanita Recovery Plan (Service 1984). We have determined that the physical or biological features discussed below are essential to *A. franciscana.*

Space for Individual and Population Growth and for Normal Behavior

Historically, the 46-mi^2 (119-km^2) tip of the San Francisco peninsula contained a diversity of habitat types including dunes, coastal scrub, maritime chaparral, grasslands, salt and fresh water marsh, oak woodlands, rocky outcrops, and serpentine habitats (Holland 1986, pp. 1–156; National Park Service 1999, pp. 18–26; Sawyer and Keeler-Wolf 1997, p. 211). The vegetation of the area is influenced by coastal wind, moisture, and temperature (Service 1984, pp. 11–16; Chasse *et al.* 2009, p. 4). The maritime chaparral and open grassland plant communities, of which *Arctostaphylos franciscana* is a part, may have been present historically to a greater extent (even before habitat loss through development), but the cumulative effects of periodic burning by native Americans, grazing during the mid-1800s to early 1900s, gathering of firewood during the U.S. military period, and fire suppression actions during the 1900s to the present may have converted many of the areas to nonnative grassland or depauperate coastal scrub (Sweeney 1956, pp. 143–250; Schlocker 1974, pp. 6–7; Christensen and Muller 1975, pp. 29–55; Keeley and Keeley 1987, pp. 240–249; Greenlee and Langenheim 1990, pp. 239–253; Tyler 1996, pp. 2182–2195; Keeley 2005, pp. 285–286; Chasse 2010, p. 2).

The current geographic distribution of *Arctostaphylos franciscana* has been greatly reduced by habitat loss in San Francisco. In 2009, the single remaining wild plant was discovered along the freeway access to the Golden Gate Bridge during construction activities and was transplanted to a natural area within the Presidio of San Francisco (Chasse *et al.* 2009, pp. 3–4, 10–11; Gluesenkamp *et al.* 2010, pp. 10–15). Historic populations of *A. franciscana,* as identified from herbarium records, occurred locally, often with the endangered *A. montana* ssp. *ravenii.* A single individual of *A. montana* ssp. *ravenii* exists in the wild today within the Presidio (44 FR 61910; October 26, 1979). Both manzanitas occurred on or near scattered exposures of bedrock outcrops (Behr 1892, pp. 2–6; Greene 1894, p. 232; Stewart 1918; Service 1984, pp. 11–12; McCarten 1993, pp. 4–5).

Most bedrock outcrops of the interior parts of San Francisco are characterized by areas often at ridges with steep topography, thin dry soils, and bare rock, conditions that maintain permanently sparse vegetative cover, at least locally (Service 2003, p. 16). Many persist as undevelopable knobs on the crests of hills up to 281 m (922 ft) above sea level, or as high, unstable, coastal bluffs subject to frequent landslides. They are composed mostly of serpentine and greenstone or other mafic and ultramafic rocks (Schlocker 1974, pp. 8–16, Plate 3). These serpentine and rocky areas are often harsh and contain unproductive soils with poor nutrient levels and reduced water-holding capacity (Holland 1986, p. 8; Sawyer and Keeler-Wolf 1997, p. 211; Chasse *et al.* 2009, pp. 12–13). McCarten (1993, pp. 4–5) identified some of the rock outcrops within the area as being sparsely vegetated with open barrens that may have historically contained *Arctostaphylos* species such as *A. montana* ssp. *ravenii* and "*A. hookeri* ssp. *franciscana* [*A. franciscana*]." He referred to the serpentine areas on the

Presidio as ''Decumbent Manzanita Serpentine Scrub'' and stated that the plant community is one of the rarer plant communities in the area. Historically, these areas included plant associations classified as coastal grassland (prairie) and variations of coastal scrub. Historic voucher specimens and observations cited *A. franciscana* occurring with *Quercus agrifolia* (coast live oak), *Ceanothus thyrsiflorus* (coast blue blossom), *Baccharis pilularis* (coyote brush), *Heteromeles arbutifolia* (toyon), *Ericameria* sp. (mock heather), *Eriogonum* sp. (buckwheat), and *Achillea* sp. (yarrow) (Eastwood 1905, pp. 201–202). The bedrock outcrop vegetation in San Francisco is variable today, including elements of remnant native vegetation as well as naturalized nonnative vegetation (National Park Service 1999, pp. 1, 17–18).

Some knowledge of the habitat requirements of *Arctostaphylos franciscana* can be inferred from historic locations and information on voucher specimens. The historic sites were mostly underlain by serpentine or greenstone substrates (Roof 1976, pp. 20–24). Sites which were occupied by *A. franciscana* historically were characterized as bare stony or rocky habitats often along ridges and associated with bedrock outcrops and other areas with thin soils on the San Francisco peninsula (Eastwood 1905, pp. 201–202; Brandegee 1907). Rowntree (1939, p. 121) observed *A. franciscana* ''forming flat masses over serpentine outcroppings and humus-filled gravel and flopping down over the sides of gray and chrome rocks.'' In a study to determine potential restoration sites for *A. montana* ssp. *ravenii,* the general site conditions identified included open exposures with mild slopes of shallow rocky soils with some coastal fog (McCarten 1986, pp. 4–5). These rocky outcrops within the San Francisco peninsula occur in the geologic strata known as the Franciscan formation. The Franciscan formation, which has contributed to the characteristic appearance and distribution of flora on portions of the peninsula, is a result of fault zones occurring in the area. These faults have uplifted and folded various geologic strata and formed the characteristic ''islands'' of rock outcrops and soils associated with *A. franciscana.* The thrust-fault shear zone runs across San Francisco from Potrero Hill in the southeast to the Presidio in the northwest (Schlocker 1974, pp. 1–2). Figure 2, below, identifies bedrock outcrops occurring in the San Francisco peninsula.

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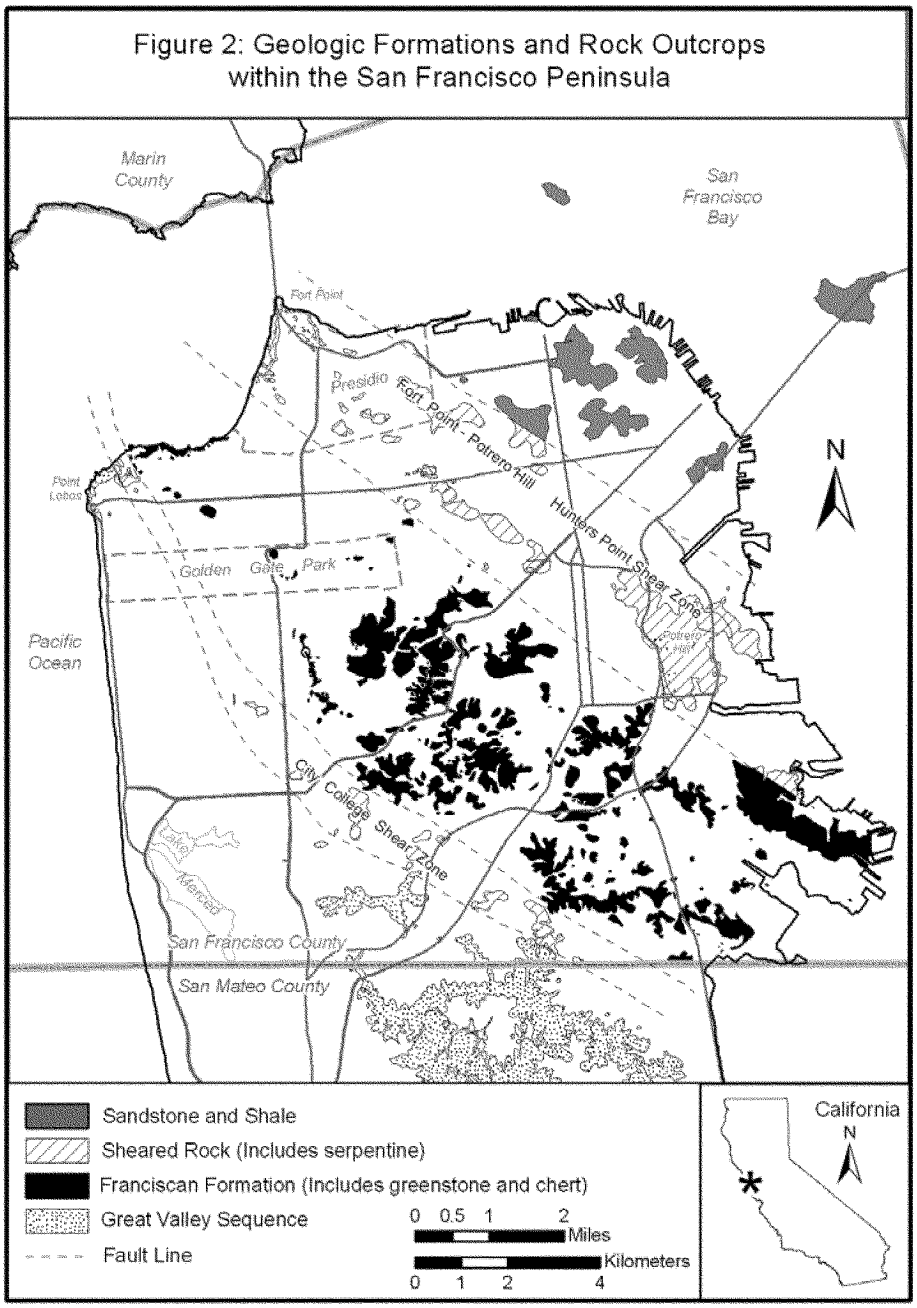
Figure 2. Geologic Formations and Rock Outcrops within the San Francisco Peninsula



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Franciscan formation rocks include sandstones, shale, chert, greenstone (mostly basalts), serpentinite, gabbro-diabase, and mixed sheared rocks along fault zones. The outcrops range from erosion-resistant basalt and chert, to serpentine rocks that are hard and dense to soft, friable, and plastic (Schlocker 1974, pp. 56–65). The soils surrounding the rock outcrops are often thin. Serpentine rocks and soils derived from them are particularly low in calcium and high in magnesium and heavy metals, and greatly influence local vegetation. The majority of sites where *A. franciscana* was historically found occurred on serpentine outcrops, except at Mount Davidson, which is comprised of greenstone and mixed Franciscan rocks. The characteristics of serpentine soils or rock outcrops often result in exclusion or growth suppression of many plant species, creating open or barren areas that are not as subject to plant competition for light, moisture, and nutrients, which often causes selection for a narrow range of endemic plant species such as *A. franciscana* (Raven and Axelrod 1978, pp. 24–26; Kruckeberg 1984, pp. 11–17, Service 1984, pp. 11–12; McCarten 1993, pp. 4–5; Service 1998, pp. 1–1, 1–2, 1–10—1–12; Service 2003, pp. 15–16). Therefore, based on the above information, we identify sites with open rocky bedrock associated with serpentine or greenstone outcrops to be an essential physical or biological feature for this species.

Cover or Shelter

As stated above, *Arctostaphylos franciscana* historically occurred in open or semi-open areas associated with

rock outcroppings in coastal scrub or serpentine maritime chaparral. Although *A. franciscana* is considered to be endemic to serpentine soils (Kruckeberg 1984, pp. 11–17; Safford *et al.* 2005, p. 226), its historic occurrence at Mount Davidson on greenstone and at other locations on mixed Franciscan rocks, and its ability to grow at nursery locations (with management), calls into question such a strict edaphic affinity. McCarten (1993, p. 8) stated that the species most likely evolved in these open to semi-open, thin-soiled, nutrient-poor locations due to a response to lack of competition from nearby plants in better soil locations rather than a specific plant-serpentine soil relationship. Being more open, these sites are exposed to direct sun with little shading from nearby vegetation and are often dry. The nutrient-poor soils of these outcroppings also limit the number of other species able to tolerate these locations. Disturbance of these areas through introduction of additional nutrients (soil disturbance, nitrogen deposition, erosion) may lead to increased tolerance of these sites by native and nonnative species, and lead to competition and shading, thereby preventing natural growth and reproduction of *A. franciscana* (Weiss 1999, pp. 1479–1485). Therefore, based on the information above, we identify areas with mostly full to full sun, that are open, barren, or sparse with minimal overstory or understory of vegetation to be an essential physical or biological feature for this species.

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Summer Fog

Summer fog is a climatic condition that characterizes many areas within the San Francisco Bay area, including the Presidio (Schlocker 1974, p. 6; Null 1995, p. 2). Summer fog increases humidity, moderates drought pressure, and provides for milder summer and winter temperature ranges than occur in interior coastal areas. Summer fog is a major influence on the survival and diversity of manzanitas and other vegetation within this zone (Patton 1956, pp. 113–200; McCarten 1986, p. 4; McCarten 1993, p. 2; Service 2003, p. 66; Chasse *et al.* 2009, p. 9; Johnstone and Dawson 2010, p. 5). The cooler temperatures and additional moisture availability during the summer may lessen the harsh site conditions of the thin-soiled, nutrient-poor, rock outcrops (Raven and Axlerod 1978, pp. 1, 25–26; Kruckeberg 1984, pp. 11–17). As a result, we have identified areas influenced by coastal summer fog to be an essential physical or biological feature for *Arctostaphylos franciscana.*

Fungal Mycorrhizae Relationship

Arctostaphylos species form strong symbiotic relationships with over 100 different fungal mycorrhizae species (McCarten 1986, p. 4; Bruns *et al.* 2005, p. 33; Chase *et al.* 2009, p. 12). These fungi are located in the soil and form an ectomycorrhizal sheath around the host plant's roots (Salisbury and Ross 1985, pp. 116–118). The presence of these fungal mycorrhizae is essential for the plant because they assist in water and nutrient absorption (Bruns *et al.* 2002, pp. 352–353). The fungi form a network of connections within the soil to other plants (of the same or other species) and may play a major role in ecosystem sustainability, thereby leading to increased plant germination and vigor (Horton *et al.* 1999, p. 94; Simard and Durall 2004, pp. 1140–1141). As a result, we identify areas with a healthy fungal mycorrhizae component to be an essential physical or biological feature for *A. franciscana.*

Pollinators

We are currently unaware of any studies that have specifically documented which insect or animal species pollinate *Arctostaphylos franciscana;* however, the species is most likely visited by numerous bees, butterflies, and even hummingbirds. In a study on *A. patula* in northern California, 3 solitary bees (Halictidae and Andrenidae), 2 long-tongued bees (Anthophoridae), 1 honey bee (Apidae), and 4 bumble bees (Apidae) were observed pollinating that species (Valenti *et al.* 1997, p. 4), which is in addition to the 27 other hymenopteran species previously documented by species experts (Krombein *et al.* 1979). These pollinators are important as they are able to travel long distances and cross fragmented landscapes to pollinate *A. franciscana.* Conserving habitat where these pollinators nest and forage will sustain an active pollinator community and facilitate mixing of genes within and among plant populations, without which inbreeding and reduced fitness may occur (Widen and Widen 1990, p. 191).

Native bees typically are more efficient pollinators than introduced European honeybees (*Apis mellifera*) (Javorek *et al.* 2002, p. 345). Therefore, plant populations visited by a higher proportion of native pollinator species are likely to maintain higher reproductive output and persist for more generations than populations served by fewer native pollinators or with pollination limitations of any kind (Javorek *et al.* 2002, p. 350).

Pollinators also require space for individual and population growth, so adequate habitat should be available for pollinators in addition to the habitat necessary for *A. franciscana* plants.

In this proposed critical habitat rule, we acknowledge that healthy pollinator populations provide conservation value to *A. franciscana.* However, we do not currently include areas for pollinators and their habitats within this designation, because: (1) Meaningful data on specific pollinators and their habitat needs are lacking; and (2) we were not able to quantify the amount of habitat needed for pollinators, given the lack of information on the specific pollinators of *A. franciscana.* We are seeking input from the public and peer reviewers on the specific information on pollinators for input into our final critical habitat designation.

Habitats Representative of the Historical, Geographical, and Ecological Distribution of the Species

The type locality for *Arctostaphylos franciscana* is the former Laurel Hill Cemetery (Eastwood 1905, pp. 201–202), an area south of the Presidio between California Street and Geary Boulevard. Voucher specimens for *A. franciscana* also exist from exposed slopes of Mount Davidson (Roof 1976, pp. 21–24), and reliable observations are recorded from the former Masonic Cemetery (bounded by Turk Street, Masonic Avenue, Park Avenue, and Fulton Street near Lone Mountain) (Roof 1976, pp. 21–24). Behr (1892, pp. 2–6) observed a possible fourth historic occurrence near the former Protestant Orphan Asylum near Laguna and Haight Streets. All these sites have been lost due to development, except for the Mount Davidson location, which has mostly been altered and converted to nonnative habitat. The ''rediscovery site'' at Doyle Drive near the Golden Gate Bridge has also been lost due to freeway construction (Gluesenkamp *et al.* 2010, pp. 9–10; Park Presidio 2012, pp. 1–2). The lone ''wild'' *A. franciscana* shrub has been transplanted to a site within the Presidio (Gluesenkamp *et al.* 2010, pp. 10–15). Development and habitat alteration from human activities and nonnative plant species have greatly altered the majority of remaining habitat for the species, although some appropriate habitat for the species still remains within the San Francisco peninsula. As a result, we have identified the species' general range to include only the area within the San Francisco peninsula from the Presidio of San Francisco south to

Mount Davison (see Figure 1, above). Although additional sites outside the peninsula, but within the Bay Area, contain appropriate habitat characteristics, these areas are outside the known historic range of the species, and we are not considering these areas for critical habitat at this time.

Primary Constituent Elements for *Arctostaphylos franciscana*

Under the Act and its implementing regulations, we are required to identify the physical and biological features essential to the conservation of *Arctostaphylos franciscana* in areas occupied at the time of listing (i.e., areas that are currently occupied), focusing on the features' primary constituent elements. We consider primary constituent elements (PCEs) to be the elements of physical and biological features that provide for a species' life-history processes and that are essential to the conservation of the species.

Based on our current knowledge of the physical or biological features and habitat characteristics required to sustain the species' life-history processes, we determine that the primary constituent elements specific to self-sustaining *Arctostaphylos franciscana* populations are:

(1) Areas on or near bedrock outcrops often associated with ridges of serpentine or greenstone, mixed Franciscan rocks, or soils derived from these parent materials.

(2) Areas having soils originating from parent materials identified above in PCE 1 that are thin, have limited nutrient content or availability, or have large concentrations of heavy metals.

(3) Areas within a vegetation community consisting of a mosaic of coastal scrub, serpentine maritime chaparral, or serpentine grassland characterized as having a vegetation structure that is open, barren, or sparse with minimal overstory or understory of trees, shrubs, or plants that contain and exhibit a healthy fungal mycorrhizae component.

(4) Areas that are influenced by summer fog, which limits daily and seasonal temperature ranges, provides moisture to limit drought stress, and increases humidity.

With this proposed designation of critical habitat, we intend to identify the physical and biological features essential to the conservation of the species, through the identification of the appropriate quantity and spatial arrangement of the features' primary constituent elements sufficient to support the life-history processes of the species.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing (in the case of *Arctostaphylos franciscana,* areas that are currently occupied) contain features which are essential to the conservation of the species and which may require special management considerations or protection. Special management considerations or protection may be necessary to eliminate or reduce the magnitude of threats that affect these species. Threats identified in the final listing rule for the species include: (1) Loss, degradation, or alteration of habitat due to development or other human activities; (2) competition from nonnative plants; (3) small population size and curtailment of the species' range, which restrict the species' current and future ability to naturally reproduce and expand its range; and (4) soil compaction, potential overutilization, disease introduction, or vandalism from visitor use at the transplantation site.

Loss and degradation of habitat from development are cited in the final listing rule as a primary cause for the decline of *Arctostaphylos franciscana.* The single ''wild'' plant is located in the Presidio of San Francisco on one of the limited open rocky sites remaining. These areas are frequently near or bounded by urbanized areas, roadways, trails, or other developed sites, and continue to have impacts from increasing human populations and development pressure. Urban development removes the plant community's components and associated rocky substrate and mycorrhizal relationship within the soil, which eliminates or fragments the remaining habitat of *A. franciscana.* Conservation and management of *A. franciscana* habitat is needed to address the threat of development. Adjacent development may introduce nonnative, invasive plant species that alter the vegetation composition or the open physical structure, to such an extent that the area would not support or would greatly affect *A. franciscana* or the surrounding plant community that it inhabits. Additionally, nitrogen or other nutrient deposition from human activities may assist excessive plant growth from other species that would compete with *A. franciscana* for space and resources that would otherwise be available to the species. Management activities including (but not limited to) removal and control of nonnative, or excessive native, plants are needed to reduce this threat. Unauthorized recreational activities or visitor use may impact the vegetation composition, increase soil compaction, or introduce soil-borne disease to *A. franciscana* habitat to such an extent that the area will no longer support the species.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. We review available information pertaining to the habitat requirements of the species. In accordance with the Act and its implementing regulations at 50 CFR 424.12(e), we consider whether designating additional areas—outside those currently occupied as well as those occupied at the time of listing, if listing occurs before the designation of critical habitat—are necessary to ensure the conservation of the species. We are proposing to designate critical habitat in areas within the geographical area currently occupied by the species (see final listing determination published elsewhere in today's **Federal Register**). We also are proposing to designate specific areas outside the geographical area occupied by the species at the time of listing (in this case, the geographic area currently occupied by the species), which were historically occupied but are presently unoccupied, because such areas are essential for the conservation of the species.

This section provides details of the criteria and process we used to delineate the proposed critical habitat for *Arctostaphylos franciscana.* The areas being proposed for critical habitat within this rule are based largely on habitat characteristics identified from the ''rediscovery site'' near Doyle Drive, the currently occupied transplantation site, and historically occupied areas identified in voucher specimens and historical records. We also used the Recovery Plan for Coastal Plants of the Northern San Francisco Peninsula (Service 2003, pp. 1–322); the Conservation Plan for *Arctostaphylos franciscana* (the Franciscan Manzanita) (Chasse *et al.* 2009, pp. 1–44); the Raven's Manzanita Recovery Plan (Service 1984, pp. 1–73), which provide habitat characteristics of the historically co-occurring species; and information received from peer reviewers and the public on our proposed listing for *A. franciscana* (76 FR 55623; September 8, 2011). Due to the rapid development of the San Francisco peninsula and limited historical information on plant location and distribution, it is difficult to determine the exact range of the species. Given the amount of remaining habitat available with the appropriate

characteristics, we looked at all areas within San Francisco that met our criteria as potential habitat. Based on this information, we are proposing to designate critical habitat in areas within the geographical area currently occupied by *A. franciscana* (which is the same as the geographical area occupied by the species at the time of listing) and unoccupied areas that are essential for the conservation of the species (see the Distribution and Habitat section above for more information on the range of the species).

Although a recovery plan for *Arctostaphylos franciscana* has not been developed, the species is discussed along with the endangered *A. montana* ssp. *ravenii* in the Recovery Plan for Coastal Plants of the Northern San Francisco Peninsula (Service 2003). The recovery plan calls for a three part strategy in conserving *A. montana* ssp. *ravenii,* as well as additional recommendations for establishment in areas outside the Presidio at historic and other rock outcrop sites in conjunction with *A. franciscana* (Service 2003, pp. 75–77). The strategy includes: (1) Protecting the existing plant and surrounding habitat; (2) increasing the number of independent populations throughout suitable habitat within the Presidio; and (3) restoring the natural ecological interactions of the species with its habitat, including allowing gene flow with *A. franciscana.* As mentioned above, the recovery plan also identifies establishing additional areas within rock outcrops throughout suitable habitat along with populations of *A. franciscana.* We believe that a recovery strategy for *A. franciscana* would have many aspects similar to the recovery plan for *A. montana* ssp. *ravenii* based on the two species being limited to one ''wild'' individual, their co-occurrence in similar habitat within the Presidio and elsewhere at historical locations, and the seeming dependence of *A. montana* ssp. *ravenii* on *A. franciscana* to produce viable seed and maintain gene flow with *A. franciscana* in the absence of more than the single individual or clones of *A. montana* ssp. *ravenii.* In order to accomplish portions of this strategy, we have identified areas we believe are essential to the conservation of *A. franciscana* through the following criteria:

(1) Determine, in accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, the physical or biological habitat features essential to the conservation of the species and which may require special management considerations or protection, as explained in the previous section.

(2) Identify multiple independent sites for *A. franciscana.* These sites should be throughout the historic range of the species (generally on the San Francisco peninsula north of Mount Davidson) within or near rock outcrops of various origins but especially on ridges or slopes within serpentine or greenstone formations along the Franciscan fault zone between Potrero Hills and the Golden Gate (see Figure 2, above).

(3) In accordance with section 2(b) of the Act, select areas which would conserve the ecosystem upon which the species depends. This includes areas that contain the natural ecological interactions of the species with its habitat or areas with additional management that may be enhanced. The conservation of *A. franciscana* is dependent on several factors including, but not limited to, selection of areas of sufficient size and configuration to sustain natural ecosystem components, functions, and processes (such as full sun exposure, summer fog, natural fire and hydrologic regimes, intact mycorrhizal or edaphic interactions); protection of existing substrate continuity and structure; connectivity among groups of plants of this species within geographic proximity to facilitate gene flow among the sites through pollinator activity and seed dispersal; and sufficient adjacent suitable habitat for vegetative reproduction and population expansion.

(4) In selecting areas to propose as critical habitat, consider factors such as size, connectivity to other habitats, and rangewide recovery considerations. We rely upon principles of conservation biology, including: (a) Resistance and resiliency, to ensure sufficient habitat is protected throughout the range of the species to support population viability (e.g., demographic parameters); (b) redundancy, to ensure multiple viable populations are conserved throughout the species' range; and (c) representation, to ensure the representative genetic and life history of *A. franciscana* are conserved.

Methods

In order to identify the physical or biological features on the ground based on our criteria outlined above, we used the following methods to delineate the proposed critical habitat:

(1) We compiled and reviewed all available information on *Arctostaphylos franciscana* habitat and distribution from historic voucher specimens, literature, and reports; (2) we also compiled and reviewed all available information on *A. montana* ssp. *ravenii* habitat and distribution from similar sources, as these two species have similar habitat requirements and often occurred together historically; (3) we reviewed available information on rock outcrops, bedrock, and areas identified as serpentine, greenstone, or of Franciscan formation within the San Francisco peninsula and surrounding areas south of Mount Davidson and north into Marin County to determine the extent of these features on the landscape; (4) we compiled species occurrence information including historic record locations, the current occupied site within the Presidio, and information on the ''rediscovery site'' near Doyle Drive; (5) we then compiled all this information into a GIS database using ESRI ArcMap 10.0; and (6) we screen digitized and mapped the specific areas on which are found those physical or biological features essential to the conservation of the species or other areas determined to be essential for the conservation of the species.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical and biological features for *Arctostaphylos franciscana.* The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands, especially within such an urbanized area as San Francisco. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical and biological features in the adjacent critical habitat.

We are proposing for designation of critical habitat lands that we have determined are currently occupied (which, in this case, is the same as occupied at the time of listing) and contain sufficient elements of physical and biological features to support life-history processes essential to the conservation of the species, and lands outside of the geographic area currently occupied that we have determined are essential for the conservation of *Arctostaphylos franciscana.*

The units of critical habitat are proposed for designation based on sufficient elements of physical or

biological features being present to support *Arctostaphylos franciscana*'s life-history processes. Some units contain all of the identified elements of physical or biological features and support multiple life-history processes. Some units contain only some elements of the physical or biological features necessary to support the use of that habitat by *A. franciscana.*

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document in the rule portion. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *http://www.regulations.gov* at Docket No. FWS–R8–ES–2012–0067, on our Internet site at *http://www.fws.gov/sacramento*, and at the Fish and Wildlife office responsible for the designation (see **FOR FURTHER INFORMATION CONTACT** above).

Proposed Critical Habitat Designation

We are proposing 11 units as critical habitat for *Arctostaphylos franciscana.* The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for *A. franciscana.* The areas we propose as critical habitat are identified below. Table 1 shows the occupancy status of each unit.

TABLE 1—OCCUPANCY OF ARCTOSTAPHYLOS FRANCISCANA BY PROPOSED CRITICAL HABITAT UNITS

Unit	Occupied at time of listing?	Currently occupied?
1. Fort Point	No	No.
2. Fort Point Rock.	No	No.
3. World War II Memorial.	No	No.
4. Immigrant Point.	No	No.
5. Inspiration Point.	Yes	Yes.
6. Corona Heights.	No	No.
7. Twin Peaks	No	No.
8. Mount Davidson.	No	No.
9. Diamond Heights.	No	No.
10. Bernal Heights.	No	No.
11. Bayview Park.	No	No.

The approximate area of each proposed critical habitat unit is shown in Table 2.

TABLE 2—PROPOSED CRITICAL HABITAT UNITS FOR ARCTOSTAPHYLOS FRANCISCANA

[Area estimates reflect all land within critical habitat unit boundaries.]

Critical habitat unit	Land ownership by type	Acres (hectares)
1. Fort Point	Federal	12 (5)
	State	0
	Local	0
	Private	0
2. Fort Point Rock	Federal	36 (15)
	State	0
	Local	0
	Private	0
3A. World War II Memorial	Federal	1 (0.6)
	State	0
	Local	0
	Private	0
3B. World War II Memorial	Federal	2 (0.7)
	State	0
	Local	0
	Private	0
4A. Immigrant Point	Federal	0.7 (0.3)
	State	0
	Local	0
	Private	0
4B. Immigrant Point	Federal	6 (3)
	State	0
	Local	0
	Private	0
5A. Inspiration Point	Federal	21 (9)
	State	0
	Local	0
	Private	0
5B. Inspiration Point	Federal	3 (1)
	State	0
	Local	0
	Private	0
6. Corona Heights	Federal	0
	State	0
	Local	10 (4)
	Private	0
7. Twin Peaks	Federal	0
	State	0
	Local	62 (25)

TABLE 2—PROPOSED CRITICAL HABITAT UNITS FOR ARCTOSTAPHYLOS FRANCISCANA—Continued

[Area estimates reflect all land within critical habitat unit boundaries.]

Critical habitat unit	Land ownership by type	Acres (hectares)
8. Mount Davidson	Private	9 (4)
	Federal	0
	State	0
	Local	11 (4)
9. Diamond Heights	Private	1 (0.5)
	Federal	0
	State	0
	Local	34 (14)
10. Bernal Heights	Private	0.3 (0.1)
	Federal	0
	State	0
	Local	24 (10)
11. Bayview Park	Private	0.3 (0.1)
	Federal	0
	State	0
	Local	56 (23)
Total	Private	29 (12)
	Federal	83 (34)
	State	0
	Local	196 (79)
	Private	40 (16)
	Total	318 (129)

Note: Area sizes may not sum due to rounding.

We present brief descriptions of the proposed critical habitat units for *Arctostaphylos franciscana* and the reasons why they meet the definition of critical habitat, below. Acreage or hectare totals may not sum due to rounding.

Unit 1: Fort Point

Unit 1 consists of 12 acres (ac) (5 hectares (ha)) and is located within the Presidio east of the Golden Gate Bridge and north of Doyle Drive (Dr.) along Long Avenue (Ave.) and Marine Dr. This unit is currently unoccupied. The unit is within an area that experiences summer fog, and contains serpentine and Franciscan Complex bedrock outcrops, soils derived from these formations, and native maritime chaparral habitat. The unit represents one of the northern-most areas identified for the species. We have determined that the area is essential for the conservation of the species, because it provides one of multiple independent sites for *A. franciscana* and contains some of the last remaining appropriate habitat within the area.

Unit 2: Fort Point Rock

Unit 2 consists of 36 ac (15 ha) and is located within the Presidio west of the Golden Gate Bridge and west of Lincoln Boulevard (Blvd.). The unit extends from the Toll Plaza south to Kobbe Ave. This unit is currently unoccupied. The unit is within an area that experiences summer fog, and contains serpentine and Franciscan Complex bedrock outcrops, soils derived from these formations, and native maritime chaparral habitat along the coastal bluffs. The unit represents one of the northern-most areas identified for the species. We have determined that the area is essential for the conservation of the species, because it provides one of multiple independent sites for *A. franciscana* and contains some of the last remaining appropriate habitat within the area.

Unit 3: World War II Memorial

Unit 3 consists of a total of 3 ac (1 ha). The unit is located within the Presidio at the intersection of Lincoln Blvd. and Kobbe Ave. The unit is comprised of two subunits. Subunit 3A (1 ac (0.6 ha)) is located west of Lincoln Blvd., and subunit 3B (2 ac (0.7 ha)) is located east of Lincoln Blvd. This unit is currently unoccupied. The unit is along the coastal bluffs within an area that experiences summer fog, and contains serpentine and Franciscan Complex bedrock outcrops, soils derived from these formations, and native maritime chaparral habitat. We have determined that the area is essential for the conservation of the species, because it provides for one of multiple independent sites for *A. franciscana* and contains some of the last remaining appropriate habitat within the area.

Unit 4: Immigrant Point

Unit 4 consists of a total of approximately 7 ac (3 ha). The unit is located within the Presidio along Washington Blvd. east of Lincoln Blvd. and north of Compton Road. The unit is comprised of two subunits. Subunit 4A (0.7 ac (0.3 ha)) is located west of Washington Boulevard, and subunit 4B (6 ac (3 ha)) is located east of Washington Blvd. This unit is currently unoccupied. The unit is located along the coastal bluffs within an area that experiences summer fog, and contains serpentine and Franciscan Complex bedrock outcrops, soils derived from these formations, and native maritime chaparral habitat. We have determined that the area is essential for the conservation of the species, because it provides for one of multiple independent sites for *A. franciscana* and contains some of the last remaining appropriate habitat within the area.

Unit 5: Inspiration Point

Unit 5 consists of a total of approximately 24 ac (10 ha). The unit is within the Presidio and is located north of Pacific Ave. and east of Arguello Blvd. The unit is comprised of two subunits, which are adjacent to each other. Subunit 5A (21 ac (9 ha)) and subunit 5B (3 ac (1 ha)) are located east of Arguello Blvd., but the two areas are separated by an access road. This unit is currently occupied. The unit contains the physical or biological features

essential to the conservation of the species. The unit is within an area that experiences summer fog (PCE 4), and is located on sloping terrain containing serpentine and Franciscan Complex bedrock outcrops (PCE 1), soils derived from these formations (PCE 2), and native maritime chaparral habitat (PCE 3). We have determined that the area is essential to the conservation of the species, because it contains the last remaining wild *A. franciscana* individual and contains some of the last remaining appropriate habitat within the area.

The physical and biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats from habitat loss, degradation, or alteration due to development or other human activities; competition from nonnative plants; small population size and curtailment of the species' range; and various other human induced factors such as soil compaction, potential overutilization, disease, or vandalism from visitor use. Please see the *Special Management Considerations or Protection* section of this proposed rule for a discussion of the threats to *A. franciscana* habitat and potential management considerations.

Unit 6: Corona Heights

Unit 6 consists of 10 ac (4 ha) and is located northwest of Castro and 17th Streets adjacent to Roosevelt and Museum Way. This unit is currently unoccupied. The unit is within an area that experiences summer fog, and is located on sloping terrain that contains Franciscan Complex (greenstone) bedrock outcrops of chert or volcanic materials, soils derived from these formations, and open grassland habitat. The unit represents one of several areas identified for the species within the Mount Davidson area. The units in this area would assist in establishing populations of *A. franciscana* outside the Presidio. As a result, we have determined that the area is essential for the conservation of the species, because it provides for one of multiple independent sites for *A. franciscana* and contains some of the last remaining appropriate habitat within the area.

Unit 7: Twin Peaks

Unit 7 consists of approximately 71 ac (29 ha) along the hilltop of Twin Peaks along Twin Peaks Blvd. west of Market Street. This unit is currently unoccupied. The unit is within an area that experiences summer fog; is located on sloping terrain; and contains Franciscan Complex (greenstone) bedrock outcrops of chert or volcanic materials, soils derived from these formations, and open grassland habitat. The unit represents one of several areas identified for the species within the Mount Davidson area. The units in this area would assist in establishing populations of *A. franciscana* outside the Presidio. As a result, we have determined that the area is essential for the conservation of the species, because it provides for one of multiple independent sites for *A. franciscana* and contains some of the last remaining appropriate habitat within the area.

Unit 8: Mount Davidson

Unit 8 consists of approximately 12 ac (5 ha) and is located on the eastern slope of Mount Davidson near Myra Way and Molimo Drive. This unit is currently unoccupied. The unit is within an area that experiences summer fog, and is located on sloping terrain containing Franciscan Complex (greenstone) bedrock outcrops of chert and sedimentary materials, soils derived from these formations, and open grassland habitat. Mount Davidson is the only known site still remaining that was previously occupied by the species (see Figure 1, above). The reestablishment of populations of *A. franciscana* at this and surrounding units would assist in establishing multiple populations of *A. franciscana* outside the Presidio. As a result, we have determined that the area is essential for the conservation of the species, because it provides for one of multiple independent sites for *A. franciscana* and contains the last remaining historic for the species.

Unit 9: Diamond Heights

Unit 9 consists of approximately 34 ac (14 ha) and is located near Diamond Heights Blvd. south of Turquoise Way. This unit is currently unoccupied. The unit is within an area that experiences summer fog; is located on sloping terrain; and contains Franciscan Complex (greenstone) bedrock outcrops of chert, volcanic, and sedimentary materials, soils derived from these formations, and open grassland habitat. The unit represents one of several areas identified for the species within the Mount Davidson area. Mount Davidson is the only known site still remaining that was previously occupied by the species. The units in this area would assist in establishing populations of *A. franciscana* outside the Presidio. As a result, we have determined that the area is essential for the conservation of the species, because it provides for one of multiple independent sites for *A. franciscana* and contains some of the last remaining appropriate habitat within the area.

Unit 10: Bernal Heights

Unit 10 consists of approximately 24 ac (10 ha), is located north of Cortland Avenue and west of U.S. Highway 101, and is surrounded by Bernal Heights Blvd. This unit is currently unoccupied. The unit is within an area that experiences summer fog; is located on sloping terrain; and contains Franciscan Complex (greenstone) and Franciscan bedrock outcrops of chert, volcanic, and sedimentary materials, soils derived from these formations, and open grassland habitat. This unit would assist in establishing an additional population of *A. franciscana* outside the Presidio and Mount Davidson areas. As a result, we have determined that the area is essential for the conservation of the species, because it provides for one of multiple independent sites for *A. franciscana* and contains some of the last remaining appropriate habitat for the species within the area.

Unit 11: Bayview Park

Unit 11 consists of approximately 85 ac (35 ha) and is located at Bayview Park west of Candlestick Park and east of U.S. Highway 101. This unit is currently unoccupied. This unit is considered outside the range of the species but still within the same Franciscan fault zone as historic populations and as proposed critical habitat for the species. The unit is within an area that experiences summer fog; is located on sloping terrain; and contains Franciscan Complex (greenstone) bedrock outcrops of chert, volcanic, and sedimentary materials, soils derived from these formations, and open grassland habitat. The unit represents one site identified for the species outside the Presidio and Mount Davidson area. Due to the rapid development of the San Francisco peninsula and limited historical information on plant location and distribution, it is difficult to determine the exact range of the species. Given the amount of remaining habitat available with the appropriate characteristics, we looked at all areas within San Francisco that met our criteria as potential habitat. Including this unit would assist in establishing an additional population of *A. franciscana* outside the Presidio and Mount Davidson areas. As a result, we have determined that the area is essential for the conservation of the species, because it provides for one of multiple independent sites for *A. franciscana* and contains some of the last remaining appropriate habitat for the species within the area. We are

seeking public input on whether it would be appropriate to designate this area as critical habitat. Please see the *Public Comments* section above for additional information.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

Decisions by the 5th and 9th Circuit Courts of Appeals have invalidated our regulatory definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service,* 378 F. 3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service et al.,* 245 F.3d 434, 442 (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the statutory provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of section 7 consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy, or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies may sometimes need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species. Activities that may destroy or adversely modify critical habitat are those that alter the physical and biological features to an extent that appreciably reduces the conservation value of critical habitat for *Arctostaphylos franciscana.* As discussed above, the role of critical habitat is to support life-history needs of the species and provide for the conservation of the species. Generally, the conservation role of the *A. franciscana* proposed critical habitat units is to support multiple viable populations in appropriate habitat areas within the historic range of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for *Arctostaphylos franciscana.* These activities include, but are not limited to:

(1) Actions that result in ground disturbance. Such activities could include (but are not limited to) residential or commercial development, dumping, OHV activity, pipeline construction, new road construction or widening, and existing road maintenance. These activities potentially impact the habitat and PCEs of *A. franciscana* by damaging, disturbing, and altering soil composition through direct impacts, increased erosion, and increased nutrient content. Additionally, changes in soil composition may lead to changes in the vegetation composition, thereby changing the overall habitat type.

(2) Actions that result in alteration of the hydrological regimes typically associated with *A. franciscana* habitat. Such activities could include residential or commercial development, which may increase summer watering. These activities could alter natural plant populations adapted to summer drought, disrupt mycorrhizal interactions, increase disease, and promote establishment of nonnative vegetation.

(3) Actions that increase nutrient deposition to the point at which nutrient-loving plants not adapted to serpentine or rocky outcrops become established and compete with *A. franciscana* and adjacent vegetation communities. Such activities could include (but are not limited to) use of chemical fertilizers within the areas, increased nitrogen deposition from atmospheric sources (vehicles, industry), and unauthorized dumping.

Exemptions

Application of Section 4(a)(3) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resources management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

(1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;

(2) A statement of goals and priorities;

(3) A detailed description of management actions to be implemented to provide for these ecological needs; and

(4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) now provides: ''The Secretary shall not designate as critical habitat any lands or other geographic areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.''

There are no Department of Defense lands within the proposed critical habitat designation; as a result no lands are exempted under section 4(a)(3) of the Act.

Exclusions

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

Under section 4(b)(2) of the Act, we may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we must identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and determine whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise his discretion to exclude the area only if such exclusion would not result in the extinction of the species.

Exclusions Based on Economic Impacts

Under section 4(b)(2) of the Act, we consider the economic impacts of specifying any particular area as critical habitat. In order to consider economic impacts, we are preparing an analysis of the economic impacts of the proposed critical habitat designation and related factors.

During the development of the final listing rule and this proposed critical habitat determination, we have identified certain sectors and activities that may potentially be affected by a designation of critical habitat for *Arctostaphylos franciscana.* These sectors include commercial development and urbanization, along with the accompanying infrastructure associated with such projects such as road, storm water drainage, bridge, and culvert construction and maintenance. We also identified recreational use as a potential sector that may experience economic impacts from the designation. We recognize that not all of these sectors may qualify as small business entities. However, while recognizing that these sectors and activities may be affected by this designation, we are collecting information and initiating our analysis to determine which of these sectors may potentially be impacted and to what extent the economic impacts are related to *A. franciscana* being listed as an endangered species under the Act. As such, we are requesting any specific economic information related to small business entities that may be affected by this designation and how the designation may impact small businesses.

We will announce the availability of that draft economic analysis as soon as it is completed. At that time, copies of the draft economic analysis will be available for downloading from the Internet at *http://www.regulations.gov,* or by contacting the Sacramento Fish and Wildlife Office directly (see **FOR FURTHER INFORMATION CONTACT** section). During the development of a final designation, we will consider economic impacts, public comments, and other new information, and areas may be excluded from the final critical habitat designation under section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19.

Exclusions Based on National Security Impacts

Under section 4(b)(2) of the Act, we consider whether there are lands owned or managed by the Department of Defense where a national security impact might exist. In preparing this proposal, we have determined that the lands within the proposed designation of critical habitat for *Arctostaphylos franciscana* are not owned or managed by the Department of Defense, and, therefore, we anticipate no impact on national security. Consequently, the Secretary does not intend to exercise his discretion to exclude any areas from the final designation based on impacts on national security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. We consider a number of factors, including whether the landowners have developed any habitat conservation plans (HCPs)

or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any tribal issues, and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

We are not considering any exclusions at this time from the proposed designation under section 4(b)(2) of the Act based on partnerships, management, or protection afforded by cooperative management efforts. Some areas within the proposed designation are included in management plans or agreements in which the Service is not a signatory, such as with the National Park Service, the Presidio Trust, or local government entities such as the City or County of San Francisco. In this proposed rule, we are seeking input from the public as to whether or not the Secretary should exercise his discretion to exclude such areas under management plans or agreements that benefit *Arctostaphylos franciscana* or its habitat from the final critical habitat designation (see the *Public Comments* section of this proposed rule for instructions on how to submit comments). Should we receive information during public comment that leads us to believe that such exclusions based on partnerships, management, or protection afforded by cooperative management efforts would outweigh the benefits of designating these areas from critical habitat, then these areas may be excluded from the final designation.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses. We have invited these peer reviewers to comment during this public comment period (see **DATES**) on proposed designation of critical habitat.

We will consider all comments and information we receive during the comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in the **FOR FURTHER INFORMATION CONTACT** section. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

At this time, we lack the available economic information necessary to provide an adequate factual basis for the required RFA finding. Therefore, we defer the RFA finding until completion of the draft economic analysis prepared under section 4(b)(2) of the Act and Executive Order 12866. This draft economic analysis will provide the required factual basis for the RFA finding. Upon completion of the draft economic analysis, we will announce availability of the draft economic analysis of the proposed designation in the **Federal Register** and reopen the public comment period for the proposed designation. We will include with this announcement, as appropriate, an initial regulatory flexibility analysis or a certification that the rule will not have a significant economic impact on a substantial number of small entities accompanied by the factual basis for that determination.

Potential land use sectors and small businesses potentially affected by the designation may include entities associated with commercial development and urbanization, along with the accompanying infrastructure associated with such projects such as road, storm water drainage, bridge, and culvert construction and maintenance. We also identified recreational use as a potential sector that may experience economic impacts from the designation. However, while recognizing that these sectors and activities may be affected by this designation, we are collecting information and initiating our analysis to determine which of these sectors may potentially be impacted and to what extent the economic impacts are related to *Arctostaphylos franciscana* being listed as an endangered species under the Act.

We have concluded that deferring the RFA finding until completion of the draft economic analysis is necessary to meet the purposes and requirements of the RFA. Deferring the RFA finding in this manner will ensure that we make a sufficiently informed determination based on adequate, current economic information and provide the necessary opportunity for public comment.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. We do not expect that the proposed critical

habitat designation for *Arctostaphylos franciscana* would significantly affect energy supplies, distribution, or use, as the areas identified as proposed critical habitat are surrounded by highly urbanized areas with their energy supplies, distribution, or infrastructure already in place. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment as warranted.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)-(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments because it will not produce a Federal mandate of $100 million or greater in any year, that is, it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments. In addition, adjacent upland properties are owned by private entities or State partners. Therefore, a Small Government Agency Plan is not required. However, we will further evaluate this issue as we conduct our economic analysis and revise this assessment if appropriate.

Takings—Executive Order 12630

In accordance with Executive Order 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), this rule is not anticipated to have significant takings implications. As discussed above, the designation of critical habitat affects only Federal actions. Critical habitat designation does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. Due to current public knowledge of the protections for the species and the prohibition against take of the species both within and outside of the proposed areas, we do not anticipate that property values would be affected by the critical habitat designation. However, we have not yet completed the economic analysis for this proposed rule. Once the economic analysis is available, we will review and revise this preliminary assessment as warranted, and prepare a Takings Implication Assessment.

Federalism—Executive Order 13132

In accordance with Executive Order 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of, this proposed critical habitat designation with appropriate State resource agencies in California. The designation of critical habitat in areas currently occupied by *Arctostaphylos franciscana* imposes no additional restrictions to those currently in place and, therefore, has little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments because the areas that contain the physical and biological features essential to the conservation of the species are more clearly defined, and the elements of the features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist local governments in long-range planning (rather than having them wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. This proposed rule uses standard property descriptions and identifies the elements of physical and biological

features essential to the conservation of *Arctostaphylos franciscana* within the proposed designated areas to assist the public in understanding the habitat needs of the species.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes.

We have determined that there are no tribal lands that are currently occupied (which, in this case, also means occupied at the time of listing) by the *Arctostaphylos franciscana* that contain the features essential to the conservation of the species, and no tribal lands that are unoccupied by *Arctostaphylos franciscana* that are essential for the conservation of the species. Therefore, we are not proposing to designate any critical habitat for the *Arctostaphylos franciscana* on tribal lands.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this package are the staff members of the Sacramento Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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 § 17.12(h) by revising the entry for ''*Arctostaphylos franciscana*'' under FLOWERING PLANTS in the List of Endangered and Threatened Plants to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*	*	*		*
Arctostaphylos franciscana.	Franciscan manzanita.	U.S.A. (CA)	Ericaceae	E	809	17.96(a)	NA
*	*	*	*	*	*		*

3. Amend § 17.96(a) by adding an entry for ''*Arctostaphylos franciscana* (Franciscan manzanita)'' in alphabetical order under family Ericaceae, to read as follows:

§ 17.96 Critical habitat—plants.

* * * * *

(a) *Flowering plants.*

* * * * *

Family Ericaceae: *Arctostaphylos franciscana* (Franciscan manzanita)

(1) Critical habitat units are depicted for San Francisco County, California, on the maps below.

(2) Within these areas, the primary constituent elements of the physical or biological features essential to the conservation of *Arctostaphylos franciscana* consist of the following four components:

(i) Areas on or near bedrock outcrops often associated with ridges of serpentine or greenstone, mixed Franciscan rocks, or soils derived from these parent materials.

(ii) Areas having soils originating from parent materials identified above in paragraph (2)(i) of this entry that are thin, have limited nutrient content or availability, or have large concentrations of heavy metals.

(iii) Areas within a vegetation community consisting of a mosaic of coastal scrub, serpentine maritime chaparral, or serpentine grassland as characterized as having a vegetation structure that is open, barren, or sparse with minimal overstory or understory of trees, shrubs, or plants that contain and exhibit a healthy fungal mycorrhizae component.

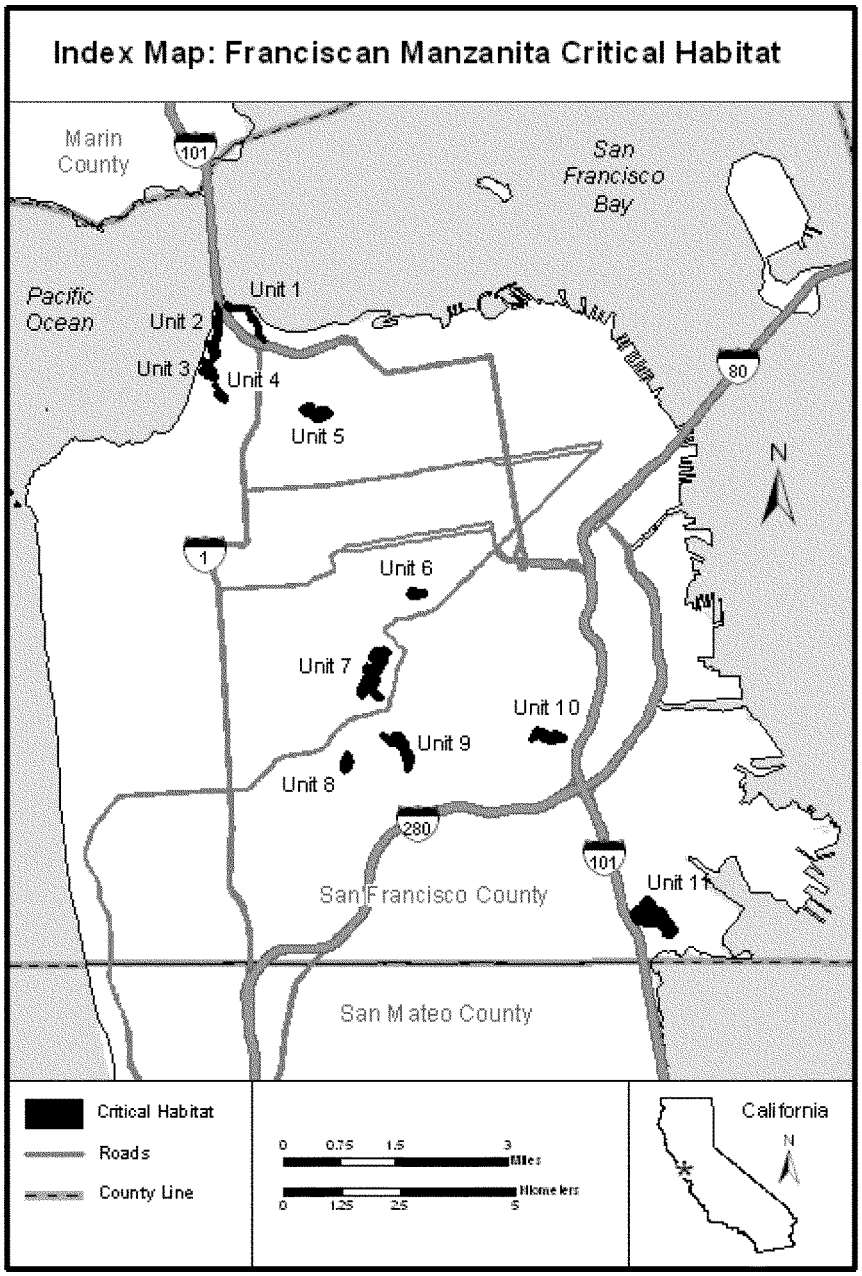
(iv) Areas that are influenced by summer fog, which limits daily and seasonal temperature ranges, provides moisture to limit drought stress, and increases humidity.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

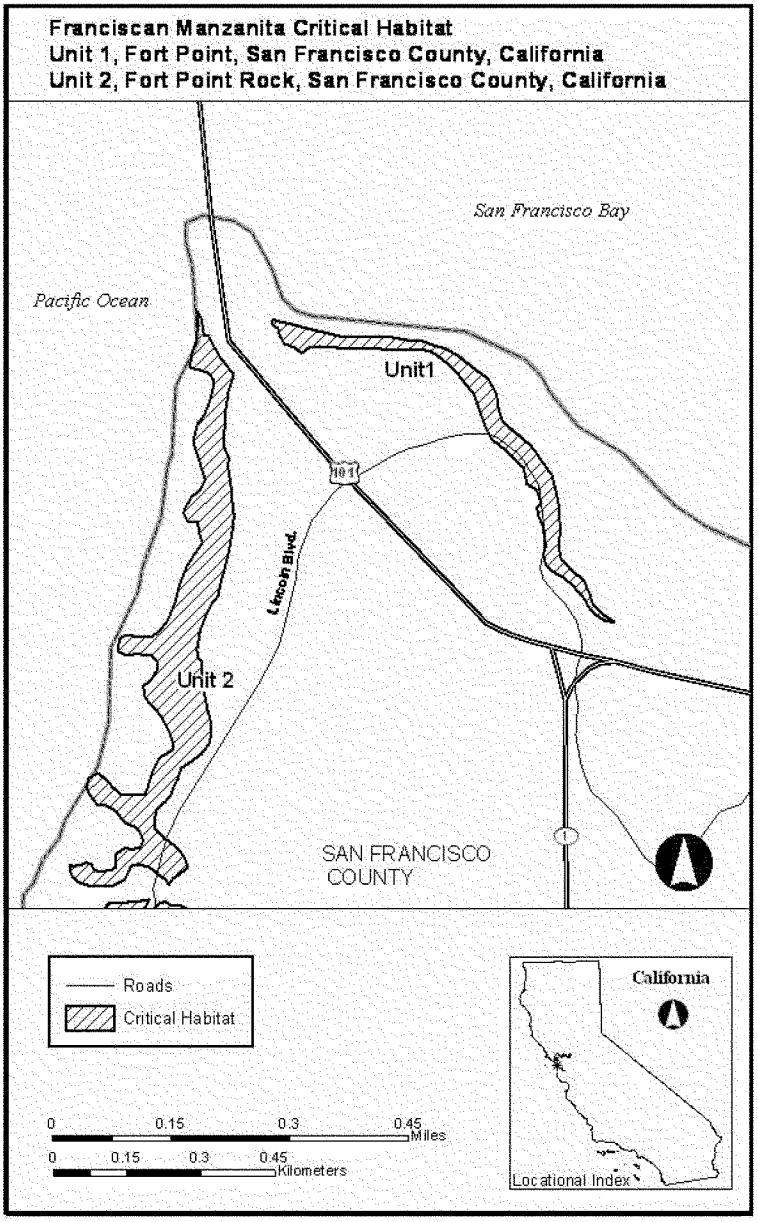
(4) *Critical habitat map units.* Data layers defining map units were created on a base of the Natural Resource Conservation Service National Agriculture Imagery Program (NAIP 2011), and critical habitat was then mapped using North American Datum (NAD) 83, Universal Transverse Mercator Zone 10N coordinates. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the field office internet site (*http://www.fws.gov/sacramento*), *http://www.regulations.gov* at Docket No. FWS–R8–ES–2012–0067, and at the Service's Sacramento Fish and Wildlife Office. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Index map follows:

BILLING CODE 6560–55–P

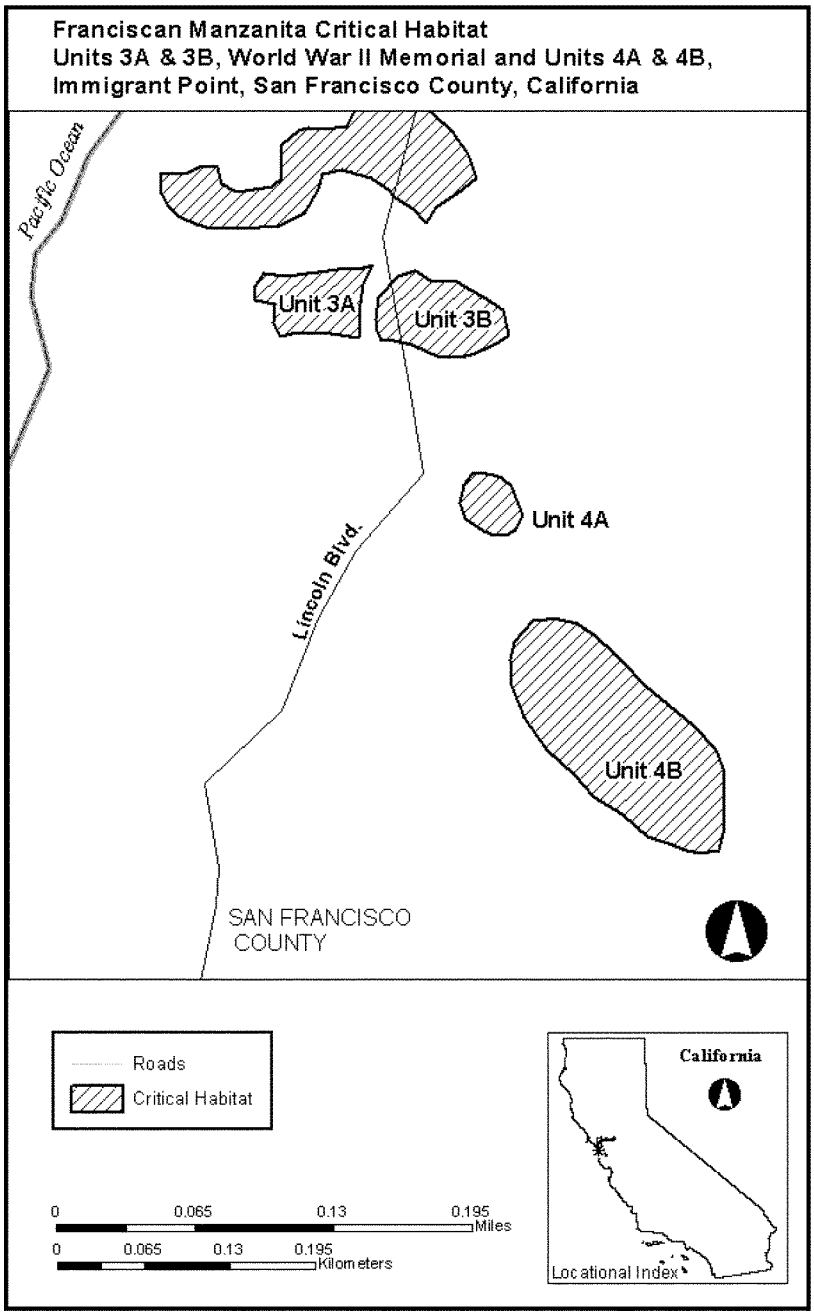

Index Map: Franciscan Manzanita Critical Habitat
Marin County
101
San Francisco Bay
Pacific Ocean
Unit 1
Unit 2
Unit 3
Unit 4
Unit 5
80
N
1
Unit 6
Unit 7
Unit 10
Unit 9
Unit 8
280
101
Unit 11
San Francisco County
San Mateo County
Critical Habitat
Roads
County Line
0 0.75 1.5 3
Miles
0 1.25 2.5 5
Kilometers
California
N

(6) Unit 1: Fort Point, San Francisco County, California. Map of Unit 1 and Unit 2 follows:



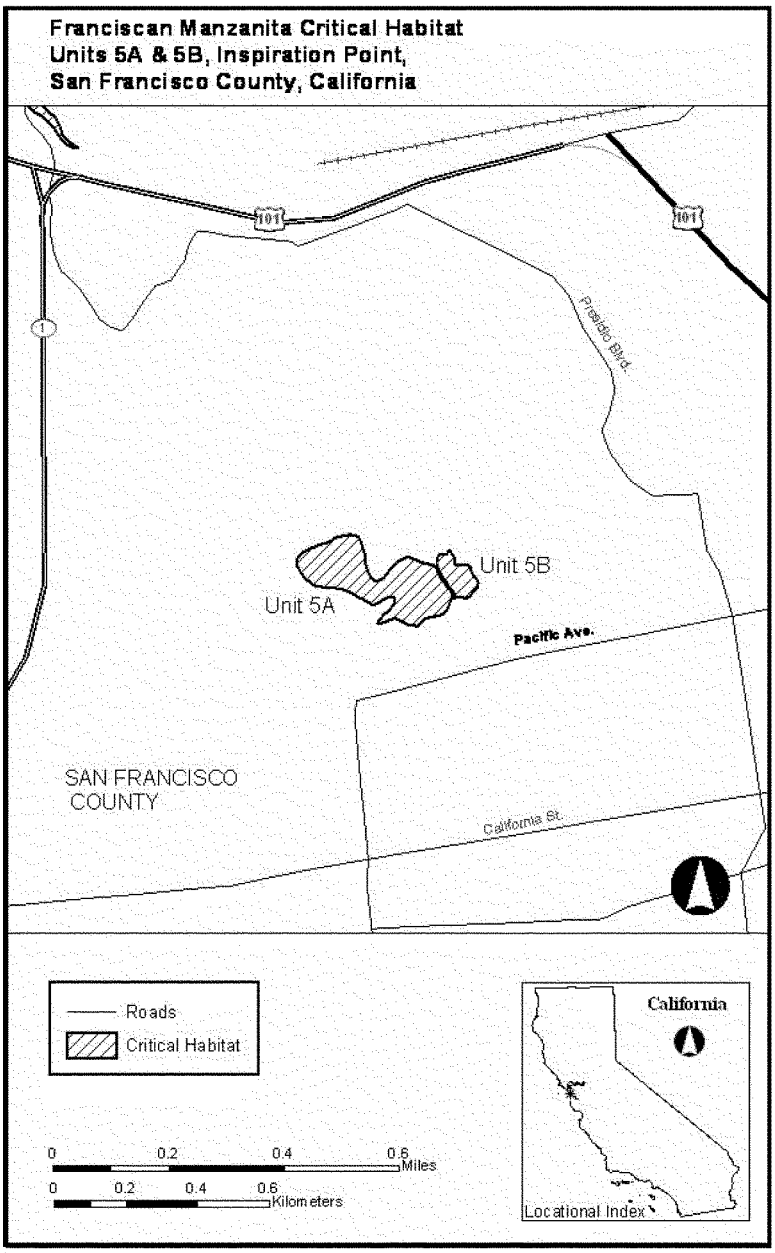
(7) Unit 2: Fort Point Rock, San Francisco County, California. Map of Unit 2 is provided at paragraph (6) of this entry.

(8) Unit 3: World War II Memorial, San Francisco, California. Map of Unit 3 and Unit 4 follows:

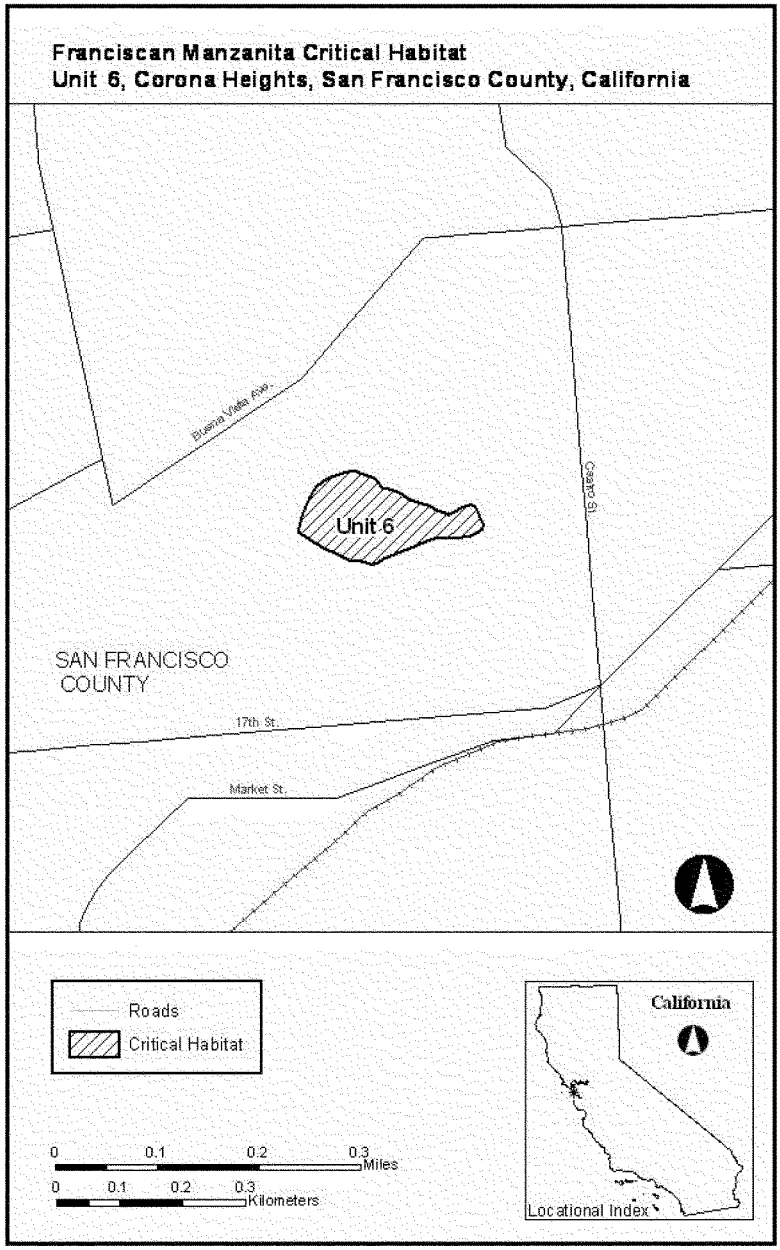


(9) Unit 4: Immigrant Point, San Francisco County, California. Map of Unit 4 is provided at paragraph (8) of this entry.

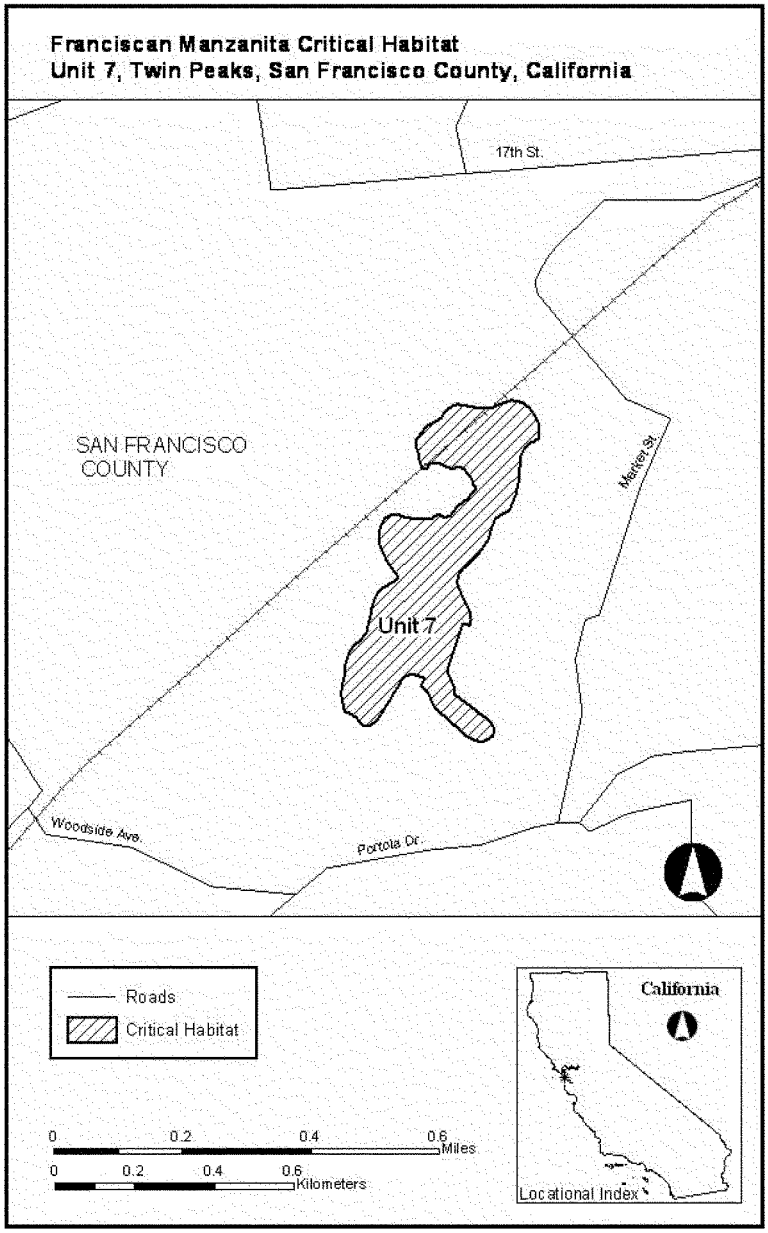
(10) Unit 5: Inspiration Point, San Francisco, California. Map of Unit 5 follows:



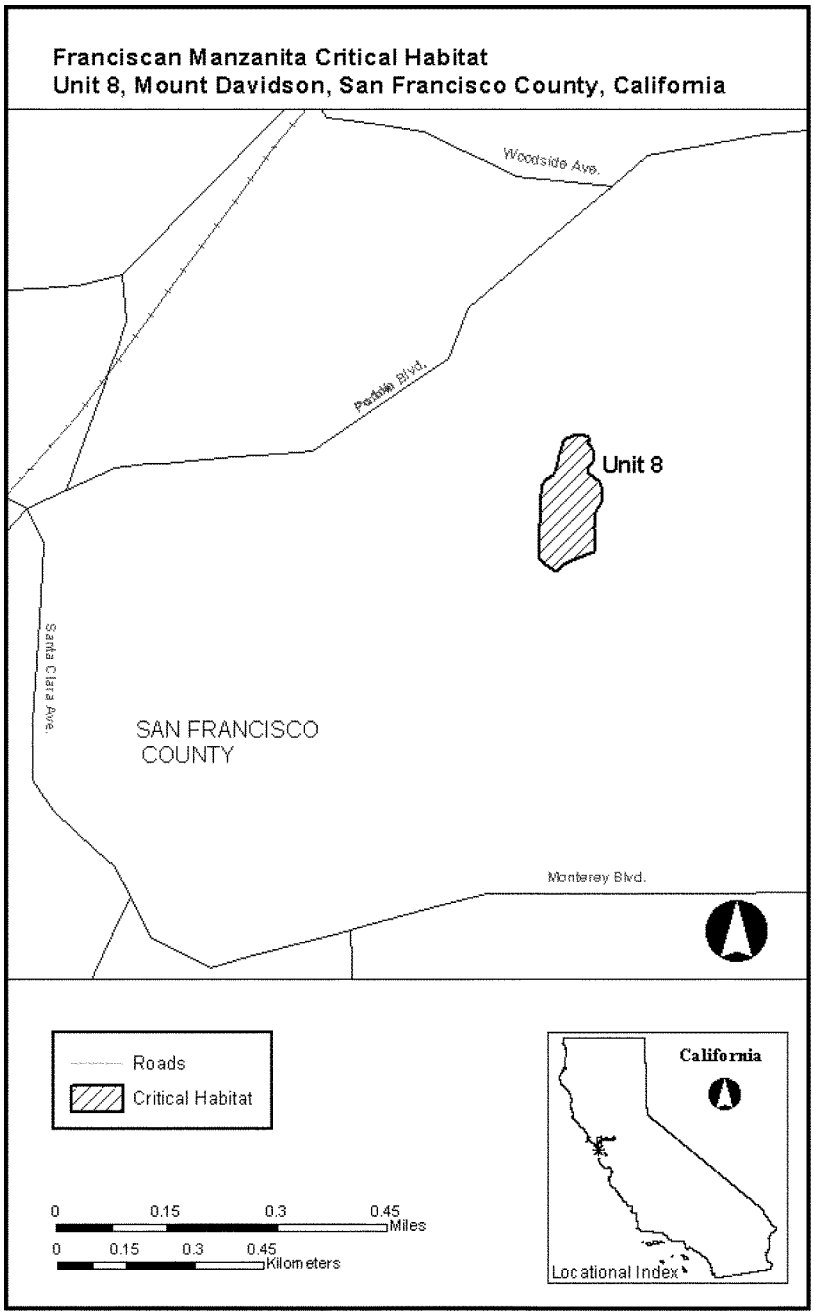
(11) Unit 6: Corona Heights, San Francisco County, California. Map of Unit 6 follows:



(12) Unit 7: Twin Peaks, San Francisco, California. Map of Unit 7 follows:

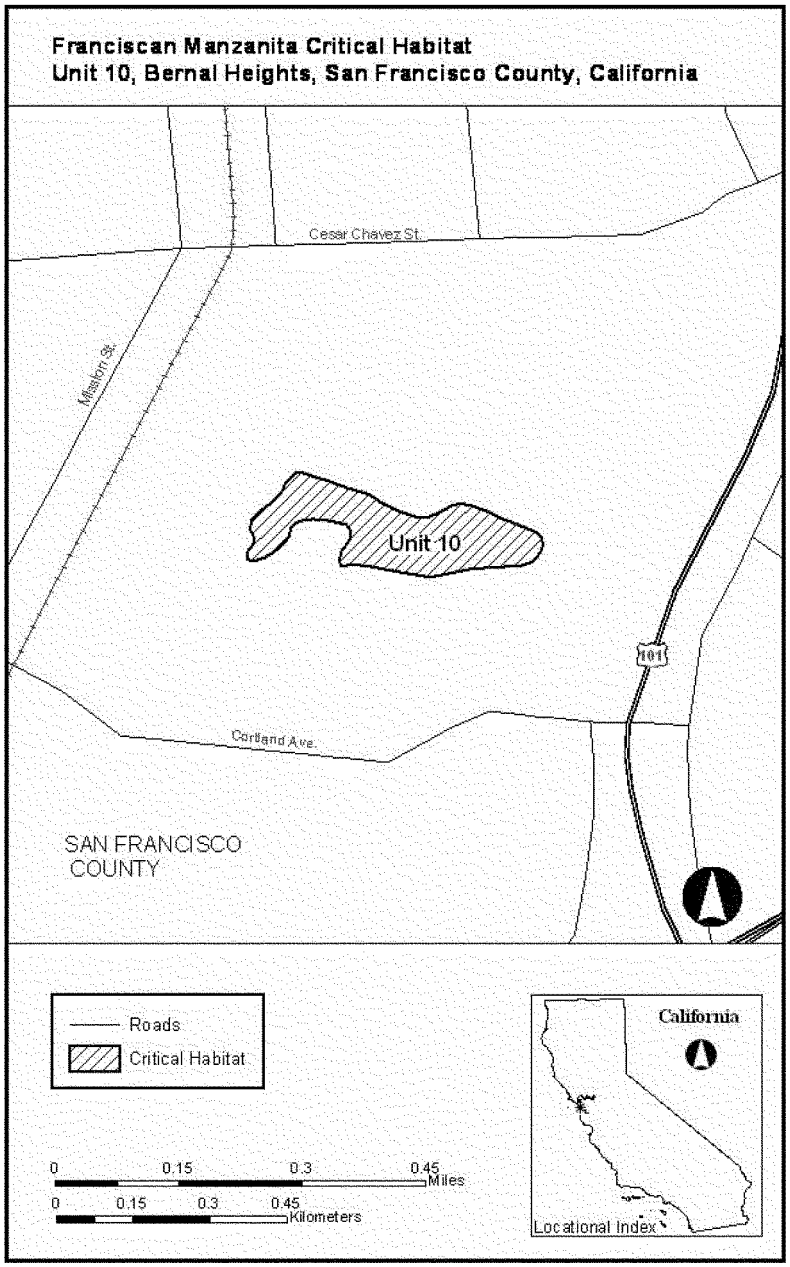


(13) Unit 8: Mount Davidson, San Francisco County, California. Map of Unit 8 follows:

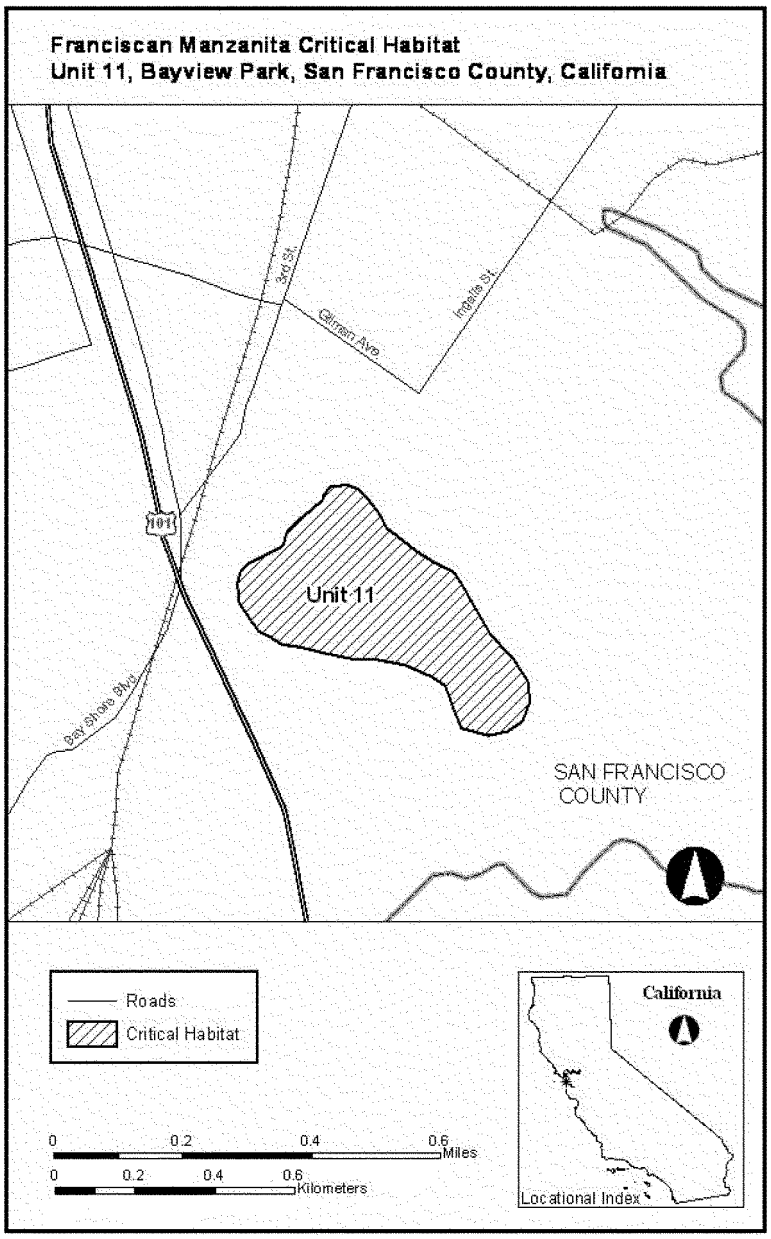


(14) Unit 9: Diamond Heights, San Francisco, California. Map of Unit 9 follows:

(15) Unit 10: Bernal Heights, San Francisco County, California. Map of Unit 10 follows:



(16) Unit 11: Bayview Park, San Francisco County, California. Map of Unit 11 follows:



* * * * *

Dated: August 27, 2012

Rachel Jacobson,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2012–21744 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–55–C

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2012–0072: 4500030113]

Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List the Eagle Lake Rainbow Trout as an Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 90-day petition finding and initiation of status review.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce a 90-day finding on a petition to list the Eagle Lake rainbow trout (*Oncorhynchus mykiss aquilarum*) as an endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). Based on our review, we find that the petition presents substantial scientific or commercial information indicating that listing the Eagle Lake rainbow trout may be warranted. Therefore, with the publication of this notice, we are initiating a review of the status of the subspecies to determine if listing the Eagle Lake rainbow trout is warranted. To ensure that this status review is comprehensive, we are requesting scientific and commercial data and other information regarding this subspecies. Based on the status review, we will issue a 12-month finding on the petition, which will address whether the petitioned action is warranted, as provided in section 4(b)(3)(B) of the Act.

DATES: We request that we receive information on or before November 5, 2012. The deadline for submitting an electronic comment using the Federal eRulemaking Portal (see **ADDRESSES** section, below) is 11:59 p.m. Eastern Time on this date. After November 5, 2012, you must submit information directly to the Division of Policy and Directives Management (see **ADDRESSES** section below). Please note that we might not be able to address or incorporate information that we receive after the above requested date.

ADDRESSES: You may submit information by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter Docket No. FWS–R8–ES–2012–0072, which is the docket number for this action. Then click on the Search button. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R8–ES–2012–0072; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We will not accept email or faxes. We will post all information we receive on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Request for Information section, below, for more details).

FOR FURTHER INFORMATION CONTACT: Susan Moore, Field Supervisor, Sacramento Fish and Wildlife Office, telephone at 916–414–6600; or facsimile at 916–414–6712. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Request for Information

When we make a finding that a petition presents substantial information indicating that listing a species may be warranted, we are required to promptly review the status of the species (status review). For the status review to be complete and based on the best available scientific and commercial information, we request information on Eagle Lake rainbow trout from governmental agencies, Native American tribes, the scientific community, industry, and any other interested parties. We seek information on:

(1) The species' biology, range, and population trends, including:

(a) Habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) The factors that are the basis for making a listing determination for a species under section 4(a) of the Act (16 U.S.C. 1531 *et seq.*), which are:

(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; and

(e) Other natural or manmade factors affecting its continued existence.

If, after the status review, we determine that listing the Eagle Lake rainbow trout is warranted, we will propose critical habitat (see definition in section 3(5)(A) of the Act) under section 4 of the Act, to the maximum extent prudent and determinable at the time we propose to list the species. Therefore, we also request data and information on:

(1) What may constitute ''physical or biological features essential to the conservation of the species,'' within the geographical range currently occupied by the species;

(2) Where these features are currently found;

(3) Whether any of these features may require special management considerations or protection;

(4) Specific areas outside the geographical area occupied by the species that are ''essential for the conservation of the species''; and

(5) What, if any, critical habitat you think we should propose for designation if the species is proposed for listing, and why such habitat meets the requirements of section 4 of the Act.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your information concerning this status review by one of the methods listed in **ADDRESSES**. If you submit information via *http://www.regulations.gov*, your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public

review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov*.

Information and supporting documentation that we received and used in preparing this finding is available for you to review at *http://www.regulations.gov*, or by appointment during normal business hours at the U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

Section 4(b)(3)(A) of the Act requires that we make a finding on whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information indicating that the petitioned action may be warranted. We are to base this finding on information provided in the petition, supporting information submitted with the petition, and information otherwise available in our files. To the maximum extent practicable, we are to make this finding within 90 days of our receipt of the petition, and publish our notice of the finding promptly in the **Federal Register**.

Our standard for substantial scientific or commercial information within the Code of Federal Regulations (CFR) with regard to a 90-day petition finding is ''that amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted'' (50 CFR 424.14(b)). If we find that substantial scientific or commercial information was presented, we are required to promptly conduct a species status review, which we subsequently summarize in our 12-month finding.

The ''substantial information'' standard for a 90-day finding differs from the Act's ''best scientific and commercial data'' standard that applies to a status review to determine whether a petitioned action is warranted. A 90-day finding does not constitute a status review under the Act. In a 12-month finding, we will announce our determination as to whether a petitioned action is warranted after we have completed a thorough status review of the species, which is conducted following a substantial 90-day finding. Because the Act's standards for a 90-day finding and the status review conducted for a 12-month finding on a petition are different, as described above, a substantial 90-day finding does not mean that our status review and resulting determination will result in a warranted finding.

Petition History and Previous Federal Actions

On April 28, 1994, we received a petition, dated April 25, 1994, from Mr. John F. Bosta of Susanville, California, requesting that the Eagle Lake rainbow trout be listed as an endangered or threatened species, with critical habitat, under the Act. On August 7, 1995, we published our 90-day finding in the **Federal Register** (60 FR 40149) that the petition did not present substantial scientific or commercial information to indicate the petitioned action may be warranted. We based the finding on the lack of supporting information included with the petition, and on the existence of significant conservation efforts then underway.

On August 15, 2003, we received a new petition, dated August 14, 2003, again from Mr. John Bosta of Amargosa Valley, Nevada, requesting that the Eagle Lake rainbow trout be listed as an endangered or threatened species under the Act. The petition clearly identified itself as such and included the requisite identification information for the petitioner, as required by 50 CFR 424.14(a). On October 6, 2003, we received a similar petition from Mr. Chuck Sanford, of Loomis, California, dated September 23, 2003. As explained in our 1996 Petition Management Guidance (Service 1996, p. 5), subsequent petitions are treated separately only when they are greater in scope or broaden the area of review of the first petition. Mr. Sanford's petition repeated the same information provided earlier in Mr. Bosta's August 14, 2003, petition and will, therefore, be treated as a comment on the first petition we received.

In a February 24, 2004, letter to Mr. Bosta, we responded that we reviewed the information presented in the petition and determined that issuing an emergency regulation temporarily listing the species under section 4(b)(7) of the Act was not warranted. We also stated that, due to court orders and judicially approved settlement agreements for other listing and critical habitat determinations under the Act, which required nearly all of our listing and critical habitat funding, we would not be able to further address the petition at that time but would complete the action when workload and funding allowed. Delays in responding to the petition continued due to the high priority of responding to court orders and settlement agreements. In response to litigation brought on behalf of petitioned and candidate species, we reached two settlement agreements on May 10, 2011, and July 12, 2011, that establish a 6-year work schedule for reaching final listing determinations for all petitioned and candidate species (*http://www.fws.gov/endangered/improving_ESA/listing_workplan.html*). The agreements were approved by the Federal District Court of the District of Columbia on September 9, 2011 (*WildEarth Guardians* v. *Salazar,* Nos. 10–377). This notice constitutes our 90-day finding on the August 14, 2003, petition to list the Eagle Lake rainbow trout and is in keeping with the Multi-District Litigation (MDL) 6-year work schedule as ordered by the Court.

In our development of this finding, we attempted to contact both petitioners regarding the information they presented and to obtain documents cited in their petitions. The petitioners did not respond to our requests, or we were unable to contact them due to the timeframe between receiving the petitions and our ability to review them, and thus, we were unable to confirm or clarify the intent of some of the petitions' claims or issues raised or to specifically review the information. As a result, we have used information available at the time of the petition in our files to assist in our review of the petitions.

Species Information

The Eagle Lake rainbow trout is a recognized subspecies of rainbow trout (*Oncorhynchus mykiss*) that is native only to Eagle Lake in Lassen County, California (Snyder 1918; Busack *et al.* 1980, pp. 418–424; Moyle *et al.* 1995, p. 85; Moyle 2002, pp. 274–275). Eagle Lake, the second largest natural lake located entirely within California, is located approximately 15 miles (mi) (24 kilometers (km)) north of Susanville, and supports a popular recreational fishery (Moyle *et al.* 1995, pp. 85–87). The Eagle Lake rainbow trout can grow to approximately 24 inches (in) (60 centimeters (cm)) and weigh up to 10 pounds (lbs) (4.6 kilograms (kg)) and can tolerate high alkaline conditions (up to pH 9.6), which is more than any other rainbow trout (Platts and Jensen 1991, pp. 2–3; Moyle *et al.* 1995, p. 86; Moyle 2002, p. 277). Eagle Lake rainbow trout is distinguished by having 58 chromosomes, instead of the 60 chromosomes of most rainbow trout (Busack *et al.* 1980, p. 421). The subspecies is unusually late maturing (3 years) and can be long-lived (up to 11 years) (Moyle 2002, p. 278), although Eagle Lake rainbow trout older than 5 years are rare (McAfee 1966, p. 223).

The Eagle Lake rainbow trout's alkalinity tolerance helps it to survive the unusual conditions of Eagle Lake. Because the lake has no natural outlet,

it is highly alkaline, with pH levels ranging from 8.4 to 9.6 (Platts and Jensen 1991, pp. 2–3; Moyle 2002, p. 277). With the exception of the Lahontan cutthroat trout (*Oncorhynchus clarki henshawi*), the Eagle Lake rainbow trout is the only trout that can tolerate pH levels above about 8.4. Similarly, the longer lifespan of this fish likely is an adaptation to the dry climate in which Eagle Lake is located, which makes natural spawning impossible during some years due to lack of water in the main spawning areas of Pine Creek (the primary tributary to Eagle Lake) and Bogard Springs Creek (an upper tributary to Pine Creek). Pine Creek has a total length of approximately 40 miles (Young 1989, p. 1). Pine Creek flows into the northwestern portion of the lake and currently has perennial flow for only the first 5 to 10 mi (8 to 16 km) of the 30- to 40-mi (48- to 64-km) creek (Platts and Jensen 1991, p. 4). The rest of the creek is intermittent, flowing in most years from March through about mid-June (Young 1989, p. 1).

Historically, Eagle Lake rainbow trout spawned primarily in the headwaters of Pine Creek (Moyle *et al.* 1995, p. 86). After spending 1 to 2 years in the headwaters of Pine Creek, juveniles made their way downstream to the lake, where they lived the rest of their lives except for spawning trips in the spring (Moyle *et al.* 1995, p. 86). Some spawning activity has also been observed along gravelly shores of Eagle Lake, but it is unknown if spawning has been successful or if it has contributed to recruitment to the population (Moyle *et al.* 1995, p. 86). A riverine population also may have remained in perennial portions of Pine Creek, rather than migrating to the Lake (Platts and Jensen 1991, pp. 19, 22).

Prior to 1917, population levels of Eagle Lake rainbow trout within the lake were high enough to support a commercial fishery, but harvesting of the fish was extremely high, leading to concerns the fish would be driven to extinction (Snyder 1917, p. 78; Moyle *et al.* 1995 p. 87). In 1917, the State of California banned commercial trout fishing in Eagle Lake, but the population of the Eagle Lake rainbow trout remained low (Moyle *et al.* 1995, p. 87). According to researchers, the probable reasons for the continued low population numbers included drought, water diversions, logging, heavy grazing, barriers to upstream and downstream movement, introduced predatory brook trout (*Salvelinus fontinalis*) in the headwaters of Pine Creek, and road and railroad construction across Pine Creek that restricted the creek's flow and channelized the streambed (Platts and Jensen 1991, p. 1; Moyle *et al.* 1995, p. 87). Water from Eagle Lake was being diverted through the Bly Tunnel to agricultural operations south of Susanville between 1923 to 1935; however, this diversion has been plugged and is no longer in use (Platts and Jensen 1991, p. 2).

Since 1950, reproduction in the Eagle Lake rainbow trout population has depended largely on a hatchery program run by the California Department of Fish and Game (CDFG) (Platts and Jensen 1991, pp. 20–22; Moyle *et al.* 1995, p. 88). Fish are captured to collect their eggs and milt in order to produce offspring to release in Eagle Lake, and in more recent times, hatchery-produced trout have been released throughout the western United States and Canada for sport fishery purposes (Moyle *et al.* 1995, p. 87; Behnke 2002, p. 103; Moyle 2002, p. 275). In the late-1940s into the mid-1950s, collection traps on Pine Creek as well as additional artificial barriers at the mouths of other creeks were constructed (Platts and Jensen 1991, p. 21; Moyle *et al.* 1995, p. 87). These barriers were installed as part of an effort to protect the fish from being stranded in the creeks by insufficient flows and to assist in the collection of fish for the hatchery program.

Between 1959 and 1994, Eagle Lake rainbow trout were known to pass above the weir at Pine Creek during years of high water flow. The structure at Pine Creek was rebuilt in 1995 to address erosion problems and to prevent upstream migration because some individuals were being stranded, resulting in their death during years of low water levels. Construction modifications on the weir in 1995, and installation of an Alaskan style fish weir at the site in 2002, have made it highly unlikely that fish attempting to move upstream have been able to pass the weir to reach the headwaters of the creek to spawn, even in high flow years.

The CDFG traps fish as they enter Pine Creek from Eagle Lake. The fish are then collected and artificially spawned to produce 2 to 3 million eggs, which are shipped to Crystal Lake and Darrah Springs State Fish Hatcheries (Platts and Jensen 1991, pp. 20–23; Moyle *et al.* 1995, p. 87). Some of the collected eggs are sent to other State hatcheries for stocking in waters across the country (Moyle *et al.* 1995, p. 87). Eggs from fish collected at the mouth of Pine Creek are hatched, and the hatchery-spawned trout are returned and released into Eagle Lake (Moyle *et al.* 1995, pp. 87, 88). Approximately 90,000 half-pound fish produced at the hatcheries are released into Eagle Lake each fall near Pine Creek, while another 90,000 half-pound fish are released at the south end of the Lake annually. Another 1,000 young fish are also stocked in the Pine Creek headwaters, with the hope that they will prey on and outcompete the smaller nonnative brook trout that spawn there. Portions of each release group are freeze-marked to allow mark-recapture estimates of the population in the Lake.

In 1987, a Coordinated Resource Management Planning (CRMP) group met to identify goals and implement a course of action for habitat and ecosystem restoration for Pine Creek. The initial goals for restoring Pine Creek included: (1) Improve streambank stability; (2) improve vegetation cover in watershed; (3) raise the streambed and watertable in the drainage and spread out peak flows of Pine Creek; (4) restore the natural Eagle Lake rainbow trout fishery in Pine Creek; (5) improve wildlife habitat along Pine Creek; (6) reduce nutrient and sediment loading into Eagle Lake from Pine Creek; (7) maintain grazing and timber management; and (8) meet goals in a coordinated effort with all affected parties (Platts and Jensen 1991, p. 1). The CRMP group includes membership by the U.S. Forest Service (USFS), the University of California Cooperative Extension for Lassen County, the CDFG, and local landowners and interested parties. The Service has been occasionally involved in the planning efforts of the CRMP group since 1995. Numerous restoration efforts have been implemented since 1987 or are planned for the Pine Creek watershed.

Evaluation of Information for This Finding

Section 4 of the Act and its implementing regulations at 50 CFR 424 set forth the procedures for adding a species to, or removing a species from, the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act:

(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.

In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the

factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat and we then attempt to determine how significant a threat it is. If the threat is significant, it may drive or contribute to the risk of extinction of the species such that the species may warrant listing as an endangered or threatened species as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively may not be sufficient to compel a finding that listing may be warranted. The information shall contain evidence sufficient to suggest that these factors may be operative threats that act on the species to the point that the species may meet the definition of endangered or threatened under the Act.

In making this 90-day finding, we evaluated whether information regarding the threats to the Eagle Lake rainbow trout, as presented in the petition and other information available in our files at the time the petition was received, is substantial, thereby indicating that the petitioned action may be warranted. Our evaluation of this information is presented below.

A. Present or Threatened Destruction, Modification, or Curtailment of the Species' Habitat or Range

Information Provided in the Petition: The petition asserts that past habitat modification, coupled with uncompleted habitat restoration projects, and the establishment of a barrier (weir) on Pine Creek for fish collection and hatchery purposes has eliminated natural spawning for the Eagle Lake rainbow trout and that the CRMP group established to coordinate habitat improvement efforts has not met in over 2 years (prior to 2003) and should be considered a failure.

Evaluation of Information Provided in the Petition and Available in Service Files: Under the guidance of the CRMP group, numerous habitat improvement projects for Pine Creek were completed or were nearing completion at the time the petition was received. The restoration efforts that had been implemented by 2003 within the Pine Creek watershed by the CRMP group included but were not limited to actions such as stream fencing, old channel restoration, and removal of upstream barriers (Highway 44 and the Burlington Northern Railroad crossing) (Platts and Jensen 1991, pp. 1–2; Moyle 2002, p. 282). In addition, the grazing regimes along Pine Creek were modified and channel restoration projects were completed to encourage increased flows over longer time periods and to improve stream bank conditions. However, access to Pine Creek and its spawning grounds by Eagle Lake rainbow trout have been for the most part blocked since the late 1950's by a barrier (weir). The barrier was initially established to assist spawning as a result of low population numbers and to prevent fish from becoming stranded in Pine Creek during low flow periods. Even though some experts have stated that the trapping and collection of fish at the barrier most likely prevented the species from becoming extinct, the petitioners expressed concern with the hatchery program because fish in the early life-history stages are gradually being selected for survival in a hatchery environment, rather than in the wild (Moyle et al. 1995, p. 88), and this may increase the difficulty of reestablishing a naturally spawning population (Moyle 2002, p. 282). Fortunately, the present management strategy for Eagle Lake rainbow trout by the CDFG is to reestablish a self-sustaining wild population, but this has not yet occurred and hatchery operations are regarded as being an ongoing necessity in maintaining the trophy fishery for Eagle Lake (Platts and Jensen 1991, pp. 19–25; Moyle et al. 1995, p. 88).

Factor A Summary: Available information in our files (Platts and Jensen 1991; Moyle *et al.* 1995; Moyle 2002) indicates that the CRMP group had been and continues to make appreciable progress in addressing past habitat alterations and detrimental land use practices including the restoration of Pine Creek habitat and streamflows and development of plans for fish passage within Pine Creek. However, the presence of the weir on Pine Creek was preventing fish passage and access to spawning grounds and therefore, has most likely prevented and continues to prevent any natural spawning from occurring. As a result, we find that the present or threatened destruction, modification, or curtailment of the species' habitat or range may be a threat. We will further investigate the threatened destruction, modification, or curtailment of the species' habitat or range in our status review for this subspecies.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The information provided in the petition and in our files does not indicate that any impact from overutilization is occurring to Eagle Lake rainbow trout. Commercial fishing for the fish was stopped in 1917 (Snyder 1917, p. 78). However, we will further investigate overutilization for commercial, recreational, scientific, or educational purposes in our status review for this subspecies.

C. Disease or Predation

Information Provided in the Petition: The petition states that Eagle Lake rainbow trout were subject to outbreaks of ''strawberry disease'' in 2000 and 2003. Strawberry disease is a skin disorder of unknown origin that occurs in rainbow trout and is identified by bright red lesions on the skin. The petition attributes these outbreaks to stress, and describes symptoms such as weight loss and a tube-like appearance. The petition cites the following items in support: (1) An article from the Washington Department of Fish and Wildlife; (2) two CDFG fish pathologist reports from 2000, one of which positively identifies the disease on a single fish; and (3) low-resolution photocopies of pictures of Eagle Lake rainbow trout with the disease.

Evaluation of Information Provided in the Petition and Available in Service Files: Strawberry disease is a skin disease that occurs sporadically in rainbow trout (*Oncorhynchus* sp.) and is a subchronic, nondebilitating, and nonfatal disease that has been recognized since the late 1950s (Olsen *et al.* 1985, p. 104). The disease goes into remission when water conditions improve, and untreated fish usually recover in 8 weeks (Olson *et al.* 1985, p. 105). We were unable to obtain a copy of the undated Washington Department of Fish and Wildlife article by Oman, and as a result, could not review the document for this finding. We are not aware of, and the petition did not provide any additional information regarding, the impacts associated with disease to the Eagle Lake rainbow trout or the extent to which disease may affect the subspecies.

The petition did not provide any information regarding predation. However, information in our files does include information on potential predation by introduced trout species. As stated in the *Species Information* section, a permanent population of Eagle Lake rainbow trout occupy upper

Pine Creek in small numbers and may spawn (Platts and Jensen 1991, pp. 19, 22). Pine Creek, like other streams and lakes in California, was stocked indiscriminately with nonnative trout in the 1940s and 1950s. On Pine Creek, brook trout (*Salvelinus fontinalis*) and other rainbow trout of unknown origin were stocked heavily until about 1950. Cutthroat trout may have also been planted in the 1940s. However, since the early 1950s, it appears that only Eagle Lake rainbow trout have been stocked in Pine Creek. Surveys in 1989 found brook trout to be dominant in the upper Pine Creek watershed including the Bogard Springs reach, Pine Valley, and Stephens Meadow. The dense brook trout populations most likely have had a negative effect on Eagle Lake rainbow trout populations in Pine Creek by keeping them unnaturally low (through predation of young or competition for resources) and may be preventing significant reestablishment (Platts and Jensen 1991, p. 24; Moyle *et al.* 1995, p. 88).

Summary of Factor C: The information provided in the petition and in our files does indicate that strawberry disease may affect individual Eagle Lake rainbow trout, but the extent and degree of the impacts are most likely small, short term, and isolated in nature. Predation in the main spawning habitat of Pine Creek from introduced brook trout most likely is occurring and may be having a negative effect on the stream population by keeping numbers artificially low. As a result, we find that predation by introduced brook trout may be a threat. We will further investigate disease or predation in our status review for this subspecies.

D. The Inadequacy of Existing Regulatory Mechanisms

The petition does not discuss or provide any information on how an inadequacy of existing regulatory mechanisms under Factor D may threaten the Eagle Lake rainbow trout, and we do not have any information in our files suggesting that existing regulatory mechanisms are inadequate. However, we will further investigate whether the existing regulatory mechanisms are inadequate in our status review for the subspecies.

E. Other Natural or Manmade Factors Affecting the Species' Continued Existence

The petition lists two potential threats relevant to Factor E: (1) Mortality of Eagle Lake rainbow trout in 2000 during CDFG trout-stocking activities; and (2) hatchery practices that have reduced Eagle Lake rainbow trout's survival in the wild and affected their genetics through gene pool alteration and species contamination.

Issue 1; Information Provided in the Petition: The petition claims that in November 2000, approximately 2,000 Eagle Lake rainbow trout were accidentally killed by CDFG when they were put into water that was too cold when they were stocked into Eagle Lake.

Evaluation of Information in the Petition and Available in Service Files: At the time of the petition we were not aware of any fish kills due to stocking activities. However, the information provided in the petition does not indicate that the loss of approximately 2,000 Eagle Lake rainbow trout due to stocking operations may be a factor that threatens the status of the subspecies. As stated earlier in the *Species Information* section, approximately 180,000 trout are stocked annually in Eagle Lake. The loss of 2,000 fish during a single event would not significantly affect the population of Eagle Lake rainbow trout as a whole. However, we will further investigate whether the loss of fish from stocking operations is a significant loss in our status review for the subspecies.

Issue 2; Information Provided in the Petition: The petition states that hatchery rearing is breeding out the ''wildness'' in the Eagle Lake rainbow trout and causing them to be less aggressive during spawning or be able to make the 40-mi (64-km) trip to the spawning grounds on Pine Creek. No information is provided specifically to support this claim, although other information provided relevant to the additional genetics arguments discussed below may have been intended for consideration with this argument as well. The petition argues that hatchery rearing has genetically altered the ''Eagle Lake trout'' into the Eagle Lake rainbow trout, and that these changes have altered the fish's ability to live in the higher alkaline water of the lake. The petition also states that these changes, brought about or abetted by stocking of ''domestic'' Eagle Lake rainbow trout from the Mount Shasta hatchery, have changed the native ''March through May'' spawning cycle to June through August. The petition cites a series of papers indicating that hatchery-rearing affects the long-term viability of the subspecies by genetic selection, alterations, and lowering their survival in the wild (Muir and Howard 1999, pp. 13853–13856; Marchetti and Nevitt 2003, pp. 9–14). The petition also cites an article by Robb Leary and Fred Allendorf, and another by M. Walker, but the journal titles and publication dates were not provided. As a result, we were unable to review the information. However, we did find a similarly titled article by Robb Leary, which may have been a prepublication version (see further discussion below).

Evaluation of Information in the Petition and Available in Service Files: Eagle Lake rainbow trout was originally called Eagle Lake trout (Snyder 1917, p. 77). Although the petition implies taxonomic changes have occurred regarding the subspecies because of hatchery operations and mixing with other rainbow trout, the name revision merely reflects a name change and not genetic manipulation or behavioral differences. However, Moyle *et al.* (1995) did cite concerns that the hatchery program may be resulting in fish that are gradually being selected for survival in the early life-history stages in a hatchery environment, rather than in the wild. They further state that the dependence on hatcheries for maintaining the Eagle Lake rainbow trout is undesirable because the survival of the species becomes dependent on the vagaries of hatchery funding and management and may be exposed to threats from disease and genetic disorders (Moyle *et al.* 1995, p. 88).

Moyle *et al.* (1995, p. 86) does support the petition's assertion that stocking procedures at one time involved placement of 25,000 ''wild'' and 150,000 ''domestic'' fish in the lake, and also notes that the ''domestic'' fish came from broodstock maintained at the Mount Shasta Hatchery. However, they do not suggest the domestic fish differed in any appreciable way, and they go on to explain that the ''domestic'' fish were marked so as to prevent their use in spawning, even if trapped at Pine Creek (Moyle *et al.* 1995, p. 86). The CDFG no longer stocks fish taken from broodstock maintained at the Mount Shasta Hatchery but only uses reproductively mature Eagle Lake rainbow trout that move into Pine Creek from Eagle Lake in order to spawn. The paper by Marchetti and Nevitt (2003) cited by the petition does not provide strong support for the petition's implied assertion that hatchery rearing may be altering the brain structure of Eagle Lake rainbow trout individuals. The hatchery-raised trout in the study were descended from a long line (50 to 90 years) of solely hatchery-reared broodstock (Marchetti and Nevitt 2003, p. 10). Serious genetic changes capable of altering brain development are much more likely under such conditions due to the unintentional selection of traits promoting survival under hatchery conditions (Marchetti and Nevitt 2003, p. 11). In contrast, trout stocked in Eagle Lake come from eggs collected in the

wild. While it is possible that at least some of the developmental brain differences noted by Marchetti and Nevitt (2003) result from environmental factors in the hatchery rather than from genetic differences, the petition presents no evidence to support that idea, nor to demonstrate how it might apply to Eagle Lake rainbow trout. Eagle Lake rainbow trout seem to have retained their basic biological traits and their migratory life history, as evidenced by their annual attempt to spawn in Pine Creek.

Muir and Howard (1999, entire) used modeling based on the Japanese medaka (*Oryzias latipes*), which were transgenic, meaning they had had portions of their genome deliberately spliced with genes from another species (genetically modified). Transgenic fish and their impacts are not relevant to the situation of the Eagle Lake rainbow trout.

Because the petition did not include reference information for the Leary and Allendorf paper, it is difficult for us to assess its content. We did find a study by Leary that we believe may be the paper referenced by the petition (Leary 1996); however, it does not appear to provide strong support for the petition's conclusions. While the study did find differences between hatchery and naturally spawning stocks, the author also emphasized that the differences were of ''little or no biological significance'' (Leary 1996, pp. 11–13).

Summary of Factor E: We agree that a potential genotype and phenotypic shift in an ongoing hatchery system due to changed selection pressures can be an issue of concern for wild fish populations. Therefore, we find that the hatchery practices may be a threat. We will further investigate whether the hatchery operations and any other natural or manmade factors have significant effects on Eagle Lake rainbow trout in our status review for the subspecies.

Finding

We have reviewed the petition, literature cited in the petition, and information in our files and evaluated that information in relation to the information available to us at the time we received the petition. After this review and evaluation, we find that the petition does present substantial scientific information that listing the Eagle Lake rainbow trout may be warranted at this time.

We evaluated each of the five listing factors individually, and because the potential threats to the Eagle Lake rainbow trout may not be mutually exclusive, we also evaluated the collective effect of these potential threats. The petition focused on three of the five listing factors; habitat modification (Factor A), disease (Factor C), and ''other natural or manmade factors'' (Factor E). Based on information we had at the time of the petition, the placement of the weir on Pine Creek has all but eliminated access to the spawning grounds, and although habitat conditions on Pine Creek had significantly improved through implementation of measures by the CRMP group, habitat conditions were still a concern and it was uncertain if fish are able to traverse the distance between the lake and spawning grounds.

The petition raised several concerns regarding potential genetic threats to the subspecies. Although many of these arguments were either unsupported, or supported by incomplete citations to articles that we were unable to locate, the information we did have or were able to find did raise concerns and supported less dependence on hatchery rearing.

On the basis of our determination under section 4(b)(3)(A) of the Act, we determine that the petition and the information in our files presents substantial scientific or commercial information indicating that listing the Eagle Lake rainbow trout throughout its range may be warranted. This finding is based on information provided under Factors A (the present or threatened destruction, modification, or curtailment of its habitat or range), C (predation), and E (other natural or manmade factors affecting the subspecies' continued existence). Although information provided under Factors C (disease), B (overutilization for commercial, recreational, scientific, or educational purposes), and D (inadequacy of existing regulatory mechanisms) do not support the petition's assertions, we will further consider information relating to these factors in the status review.

Because we have found that the petition presents substantial information indicating that listing Eagle Lake rainbow trout may be warranted, we are initiating a status review to determine whether listing Eagle Lake rainbow trout under the Act is warranted. We will fully evaluate these potential threats during our status review, pursuant to the Act's requirement to review the best available scientific information when making our 12-month finding. Accordingly, we encourage the public to consider and submit information related to these and any other threats that may be operating on the Eagle Lake rainbow trout (see ''Request for Information'').

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this notice are the staff member(s) of the Sacramento Fish and Wildlife Office (see **ADDRESSES**).

Authority

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

Dated: August 24, 2012.

Rowan W. Gould,

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

[FR Doc. 2012–21745 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register

Vol. 77, No. 172

Wednesday, September 5, 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.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Notice of Public Meetings of Committees of the Administrative Conference of the United States

AGENCY: Administrative Conference of the United States.

ACTION: Notice of public meetings.

SUMMARY: Notice is hereby given of eight public meetings: two meetings each for the Committee on Administration and Management, Committee on Collaborative Governance, Committee on Judicial Review, and Committee on Regulation of the Assembly of the Administrative Conference of the United States. At these meetings, the committees will consider reports by Conference consultants and work on preparing recommendations.

DATES: Committee on Administration and Management: Tuesday, September 25, 2012 from 9:30 a.m. to 12:30 p.m. and Wednesday, October 24, 2012, from 2 p.m. to 5 p.m. Committee on Collaborative Governance: Thursday, September 20, 2012 from 3 p.m. to 5 p.m. and Monday, October 15, 2012, from 2 p.m. to 4:30 p.m. Committee on Judicial Review: Wednesday, October 3, 2012 from 2 p.m. to 5 p.m. and Wednesday, October 17, 2012 from 2 p.m. to 5 p.m. Committee on Regulation: Monday, September 24, 2012 from 2 p.m. to 5 p.m. and Monday, October 22, 2012 from 2 p.m. to 5 p.m.

ADDRESSES: The meetings will be held at 1120 20th Street NW., Suite 706 South, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Emily Bremer (Committee on Administration and Management), David Pritzker (Committee on Collaborative Governance), Stephanie Tatham (Committee on Judicial Review), or Reeve Bull (Committee on Regulation), Designated Federal Officers, Administrative Conference of the United States, 1120 20th Street NW., Suite 706 South, Washington, DC 20036; Telephone 202–480–2080; Email *ebremer@acus.gov,dpritzker@acus.gov, statham@acus.gov,* or *rbull@acus.gov*.

SUPPLEMENTARY INFORMATION: Complete details regarding the committee meetings, the nature of the projects, how to attend (including information about remote access and obtaining special accommodations for persons with disabilities), and how to submit comments to each committee can be found on the Conference's Web site, at *http://www.acus.gov*. Click on ''Research,'' then on ''Committee Meetings.''

Comments may be submitted by email to *Comments@acus.gov,* with the name of the appropriate committee in the subject line, or by postal mail to the appropriate committee at the address given above.

Committee on Administration and Management

The Committee on Administration and Management will meet to discuss a draft report on the Inflation Adjustment for Civil Penalties Project. The report, prepared by Professor Jim Chen (University of Louisville Louis D. Brandeis School of Law), presents the findings of a study on the Federal Civil Penalties Inflation Adjustment Act and the general issue of inflation adjustments to federal civil monetary penalties. At its meetings, the Committee on Administration and Management will also consider a draft recommendation based on the consultant's report. Emily S. Bremer is the Designated Federal Officer for this committee. More information can be found in the ''Research'' section of the Conference's website, at *http://www.acus.gov*. Click on ''Research,'' then on ''Conference Projects,'' and then on ''Inflation Adjustment for Civil Penalties.''

Committee on Collaborative Governance

The Committee on Collaborative Governance will meet to consider a draft report and recommendations on agency use of third-party inspections and certification (sometimes known as ''third-party verification''). The Conference's consultant for this study is Professor Lesley K. McAllister (University of San Diego School of Law). A brief presentation may also be made in connection with the Conference's project to examine, describe and catalogue the agencies and other organizational entities of the federal executive establishment, including independent agencies. David M. Pritzker is the Designated Federal Officer for this committee. More information can be found in the ''Research'' section of the Conference's Web site, at *http://www.acus.gov*. Click on ''Research,'' then on ''Conference Projects,'' and then on ''Third-Party Inspections and Certification'' or ''Federal Executive Establishment.''

Committee on Judicial Review

The Committee on Judicial Review will meet to discuss a revised draft report and recommendations for its project examining 28 U.S.C. 1500. The report, prepared by Emily S. Bremer (Administrative Conference Staff) and Jonathan R. Siegel (George Washington University), presents the findings of a study on the barrier to litigation imposed by Section 1500 as applied by federal courts. Stephanie J. Tatham is the Staff Counsel for this committee. At its meetings, the Committee on Judicial Review will also review a draft discussion outline and potential agency survey for the Conference's project on the ''Administrative Record and Judicial Review of Informal Agency Proceedings.'' Leland E. Beck (Federal Regulations Advisor) is the Conference's consultant on the project. More information on these projects can be found in the ''Research'' section of the Conference's Web site, at *http://www.acus.gov*. Click on ''Research,'' then on ''Conference Projects,'' and then on ''Need for Reform of 28 U.S.C. 1500'' or ''Administrative Record and Judicial Review of Informal Agency Proceedings.'' The Committee will also discuss an in-house research project by Stephanie J. Tatham examining the use of remand without vacatur in judicial review of agency decision-making.

Committee on Regulation

At the September 24 and October 22 meetings, the Committee on Regulation will consider a set of draft recommendations dealing with the Science in the Administrative Process project. The committee will consider recommendations proposed in a consultant report by Professor Wendy Wagner (University of Texas Law

School) and additional input received at a September 10, 2012 workshop on agencies'' use of science on which the Conference is collaborating with the National Academies. Reeve T. Bull is the Designated Federal Officer for this committee. More information can be found in the ''Research'' section of the Conference's Web site, at *http://www.acus.gov*. Click on ''Research,'' then on ''Conference Projects,'' and then on ''Science in the Administrative Process.''

Dated: August 31, 2012.

Shawne C. McGibbon,

General Counsel.

[FR Doc. 2012–21965 Filed 9–4–12; 8:45 am]

BILLING CODE 6110–01–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

August 29, 2012.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Business-Cooperative Service

Title: Renewable Energy System Feasibility Study Grant Assistance under the Rural Energy for America Program (REAP).

OMB Control Number: 0570–0061.

Summary of Collection: This grant program, authorized under the 2008 Farm Bill (Pub. L. 110–246, Food, Conservation, and Energy Act of 2008), makes grants to eligible entities to conduct feasibility studies for renewable energy development systems that are eligible for financial assistance under the REAP. Agricultural producers and rural small businesses would be required to pay at least 75 percent of the cost of the feasibility study.

Need and Use of the Information: The agency will collect the information from applicants using a variety of forms and an application package that includes specific information about the applicant and the proposed feasibility study (e.g., the renewable energy project for which the study will be conducted; matching funds), statements of intent to seek REAP funds for the renewable energy system, and the experience of the entity that will be conducting the feasibility study. The Agency will use this information to determine applicant and project eligibility to ensure that funds are used for authorized purposes and to help ensure that an acceptable feasibility study is conducted under the grant.

Description of Respondents: Business or other for-profit; farms.

Number of Respondents: 354.

Frequency of Responses: Reporting: Annually and on occasion.

Total Burden Hours: 4,811.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2012–21788 Filed 9–4–12; 8:45 am]

BILLING CODE 3410–XT–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

August 29, 2012.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Supplemental Nutrition Assistance Program—Supplemental Nutrition Assistance for Victims of Disasters.

OMB Control Number: 0584–0336.

Summary of Collection: The authority to operate the Disaster Supplemental Nutrition Assistance Program (D–SNAP) is found in section 5(h) of the Food and Nutrition Act of 2008, formerly the Food Stamp Act of 1977, as amended and the Disaster Relief Act of 1974, as amended by the Robert T. Stafford Disaster Relief and Assistance Act of 1988 authorizes the Secretary of Agriculture to establish temporary emergency standards of eligibility for victims of a disaster if the commercial channels of food distribution have been disrupted, and subsequently restored. D–SNAP is a program that is separate from the Supplemental Nutrition Assistance Program (SNAP) and is conducted for a

specific period of time. In order for a State to request to operate a D–SNAP, an affected area in the State must have received a Presidential Declaration of ''Major Disaster'' with Individual Assistance.

Need and Use of the Information: This information collection concerns information obtain from State welfare agencies seeking to operate D–SNAP. A State agency request to operate a D–SNAP must contain the following information: Description of incident; geographic area; application period; benefit period; eligibility criteria; ongoing household eligibility; affected population; electronic benefit card issuance process; logistical plans for Disaster SNAP rollout; staffing; public information outreach; duplicate participation check process; fraud prevention strategies; and employee application procedures. The Food and Nutrition Service reviews the request to ensure that all the necessary requirements to conduct a D–SNAP are met. If this collection is not conducted, D–SNAP would not be available to help meet the nutritional needs of disaster victims.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 14.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 140.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2012–21791 Filed 9–4–12; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Lassen County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Lassen County Resource Advisory Committee will meet in Susanville, CA. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 112–141) and in compliance with the Federal Advisory Committee Act. The meeting is to review and recommend projects authorized under Title II of the Act.

DATES: The meeting will be held September 27, 2012 from 8 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Lassen National Forest Supervisor's Office in the Caribou Conference Room at 2550 Riverside Drive, Susanville, CA.

FOR FURTHER INFORMATION CONTACT: Heidi Perry, Public Affairs Officer for the Lassen National Forest at 530–252–6604 or *hperry@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public.

Dated: August 28, 2012.

Jerry Bird,

Forest Supervisor.

[FR Doc. 2012–21813 Filed 9–4–12; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Dixie Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting date and location change.

SUMMARY: The Dixie Resource Advisory Committee will now meet in Cedar City, Utah. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 112–141) and in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is to review and recommend projects authorized under title II of the Act.

DATES: Friday, September 28, 2012, 9 a.m.

ADDRESSES: The meeting will be held at Dixie National Forest Supervisor's Office, 1789 North Wedgewood Lane, Cedar City, Utah.

Written comments may be submitted as described under Supplementary Information. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at 1789 North Wedgewood Lane, Cedar City, Utah. Please call ahead to (435) 865–3700 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Janice Minarik, RAC Coordinator, Dixie National Forest, (435) 865–3794; email: *jminarik@fs.fed.us.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The following business will be conducted: (1) Welcome and committee introductions; (2) Review the purpose of the Act and re-authorization; (3) RAC project presentations and general discussion; and (4) Caucus discussions and final vote. The full agenda and additional information may be previewed at *http://www.fs.usda.gov/dixie/.* Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments must be sent to the RAC Coordinator, 1789 North Wedgewood Lane, Cedar City, Utah 84721, or by email to *jminarik@fs.fed.us,* or via facsimile to (435) 865–3791. A summary of the meeting will be posted at *http://www.fs.usda.gov/dixie/* within 21 days of the meeting.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility for proceedings by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: August 29, 2012.

Kevin R. Schulkoski,

Acting Forest Supervisor.

[FR Doc. 2012–21819 Filed 9–4–12; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Central Montana Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Central Montana Resource Advisory Committee will meet in Stanford, MT. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 112–141) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations

to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is to review and approve project proposals for Fiscal Year 2013.

DATES: The meeting will be held September 20, 2012, 7 p.m.

ADDRESSES: The meeting will be held at the Judith Ranger District, 109 Central Ave., Stanford, MT. VTC/Telephone will be available. Written comments may be submitted as described under Supplementary Information. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Judith Ranger District in Stanford. Please call ahead to (406) 566–2292 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Ron Wiseman, District Ranger, (406) 566–2292 or *rwiseman@fs.fed.us.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The following business will be conducted:

1. Status and review of 2012 projects.
2. Review and approval of FY13 projects.
3. Other matters raised at meeting.

Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 14, 2012 to be scheduled on the agenda. Written comments and requests for time for oral comments must be sent to Judith Ranger District, 109 Central Ave., Stanford, MT 59479, or by email to *rwiseman@fs.fed.us,* or via facsimile to (406) 566–2408. A summary of the meeting will be posted at *http://www.fs.usda.gov/lcnf* within 21 days of the meeting.

Meeting Accommodations: If you require sign language interpreting, assistive listening devices or other reasonable accommodation please request this in advance of the meeting by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: August 29, 2012.

Ron B. Wiseman,

Designated Federal Officer.

[FR Doc. 2012–21809 Filed 9–4–12; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Eastern Idaho Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Easern Idaho Resource Advisory Committee will meet in Idaho Falls, ID. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 112–141) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is to elect new officers and to review and recommend projects authorized under title II of the Act.

DATES: The meeting will be held September 21, 2012 at 9 a.m.

ADDRESSES: The meeting will be held at Caribou-Targhee National Forest Headquarters at 1405 Hollipark Drive, Idaho Falls, ID.

Written comments may be submitted as described under Supplementary Information. All comments, including names and addresses when provided, are placed in the record available for public inspection and copying.

The public may inspect comments received at Headquarter, Caribou-Targhee National Forest, 1405 Hollipak Drive, Idaho Falls, ID. Please call ahead to Lynn Ballard 208–557–5765 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Lynn Ballard, RAC Coordinator, Caribou-Targhee National Forest, 208–557–5765, *lballard@fs.fed.us.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The following business will be conducted: Welcome and introduction of new members, update previous years projects, changes and new information since the last meeting, election of chairperson, review and recommendation of new projects. The full agenda may be previewed at the forest Web site at: *http://www.fs.usda.gov/ctnf.* Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 17, 2012 to be scheduled on the agenda. Written comments and requests for time for oral comments must be sent to 1405 Holipark Drive, Idaho Falls, Idaho 83420, or by email to *lballard@fs.fed.us,* or via facsimile to 1–208–557–5827. A summary of the meeting will be posted at *http://www.fs.usda.gov/ctnf* within 21 days of the meeting.

Meeting Accommodations: If you are a person requiring resonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodations for access to the facility or procedings by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: August 23, 2012.

Brent L. Larson,

Forest Supervisor.

[FR Doc. 2012–21807 Filed 9–4–12; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Suspend the 2012 Census of Agriculture Content Testing

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice of suspension of data collection.

SUMMARY: This notice announces the intention of the National Agricultural Statistics Service (NASS) to suspend a currently approved information collection, the 2012 Census of Agriculture Content Testing.

FOR FURTHER INFORMATION CONTACT: Joseph T. Reilly, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333.

SUPPLEMENTARY INFORMATION:

Title: 2012 Census of Agriculture Content Testing.

OMB Control Number: 0535–0243.

Expiration Date of Approval: January 31, 2013.

Type of Request: To suspend a currently approved information collection.

Abstract: The primary objective of the National Agricultural Statistics Service is to prepare and issue State and national estimates of crop and livestock production, disposition, and prices. The Census of Agriculture is conducted every five years and is the primary source of statistics concerning the nation's agricultural industry and provides the only basis of consistent, comparable data.

Prior to the census, NASS conducts content tests to evaluate factors impacting the census program: questionnaire format and design, new items, changes to question wording and location, respondent burden, ease of completion, and processing methodology such as edit and summary.

With the 2012 Census of Agriculture questionnaires being finalized, NASS will be suspending the content testing. NASS will reinstate the content testing docket in 2015 to prepare for the 2017 Census of Agriculture.

NASS will suspend this information collection (2012 Census of Agriculture Content Testing) as of September 5, 2012 due to the completion of the survey.

Authority: These data were collected under authority of 7 U.S.C. 2204g. Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents.

Estimate of Burden: There will be no further public reporting burden for this collection of information.

Signed at Washington, DC, August 22, 2012.

Joseph T. Reilly,

Associate Administrator.

[FR Doc. 2012–21740 Filed 9–4–12; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended), the Rural Utilities Service (RUS) invites comments on this information collection for which approval from the Office of Management and Budget (OMB) will be requested.

DATES: Comments on this notice must be received by November 5, 2012.

FOR FURTHER INFORMATION CONTACT: Michele L. Brooks, Director, Program Development and Regulatory Analysis, USDA–RUS, 1400 Independence Ave. SW., STOP 1522, Room 5162 South Building, Washington, DC 20250–1522. Telephone: (202) 690–1078. Fax: (202) 720–8435.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that RUS is submitting to OMB for extension.

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 of the proposed collection of information including the validity of the methodology and assumptions used; (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 those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Michele L. Brooks, Director, Program Development and Regulatory Analysis, USDA–RUS, STOP 1522, 1400 Independence Ave. SW., Washington, DC 20250–1522. Fax: (202) 720–8435.

Title: 7 CFR Part 1744–C, Advance and Disbursement of Funds—Telecommunications.

OMB Control Number: 0572–0023.

Type of Request: Extension of a currently approved information collection package.

Abstract: The RUS manages the Telecommunications loan program in accordance with the Rural Electrification Act (RE Act) of 1936, 7 U.S.C. 901 et seq., as amended, and as prescribed by OMB Circular A–129, Policies for Federal Credit Programs and Non-Tax Receivables. In addition, the Farm Security and Rural Investment Act of 2002 (Pub. L. 101–171) amended the RE Act to add Title VI, Rural Broadband Access, to provide loans and loan guarantees to fund the cost of construction, improvement, or acquisition of facilities and equipment for the provision of broadband service in eligible rural communities. RUS therefore requires Telecommunications and Broadband borrowers to submit Form 481, Financial Requirement Statement. This form implements certain provisions of the standard Rural Utilities Service loan documents by setting forth requirements and procedures to be followed by borrowers in obtaining advances and making disbursements of loan funds.

Estimate of Burden: Public reporting for this collection of information is estimated to average 1 hour per response.

Respondents: Business or other for profit, not-for-profit institutions.

Estimated Number of Respondents: 177.

Estimated Number of Responses per Respondent: 6.3.

Estimated Total Annual Burden on Respondents: 1,223 hours.

Dated: August 29, 2012.

Jonathan Adelstein,

Administrator, Rural Utilities Service.

[FR Doc. 2012–21783 Filed 9–4–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1846]

Reorganization of Foreign-Trade Zone 189 Under Alternative Site Framework, Kent, Ottawa, and Muskegon Counties, MI

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (74 FR 1170, 01/12/09; correction 74 FR 3987, 01/22/09; 75 FR 71069–71070, 11/22/10) as an option for the establishment or reorganization of general-purpose zones;

Whereas, the Kent-Ottawa-Muskegon Foreign-Trade Zone Authority, grantee of Foreign-Trade Zone 189, submitted an application to the Board (FTZ Docket 12–2012, filed 03/1/2012) for authority to reorganize under the ASF with a service area of Kent, Ottawa and Muskegon Counties, Michigan, within and adjacent to the Grand Rapids

Customs and Border Protection port of entry, and FTZ 189's existing Sites 1–9 would be categorized as magnet sites;

Whereas, notice inviting public comment was given in the **Federal Register** (77 FR 14000, 3/8/2012) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied, and that the proposal is in the public interest;

Now, therefore, the Board hereby orders:

The application to reorganize FTZ 189 under the alternative site framework is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard 2,000-acre activation limit for the overall general-purpose zone project, and to a five-year ASF sunset provision for magnet sites that would terminate authority for Site 1–8 if not activated by August 31, 2017.

Signed at Washington, DC, this 17th day of August 2012.

Ronald K. Lorentzen,

Acting Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2012–21865 Filed 9–4–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Proposed Information Collection; Comment Request; Offsets in Military Exports

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before November 5, 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: Requests for additional information or copies of the information collection instrument and instructions should be directed to Larry Hall, BIS ICB Liaison, (202) 482–4895, *Lawrence.Hall@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection of information is required by the Defense Production Act (DPA). The DPA requires U.S. firms to furnish information (15 CFR 701) to the Department of Commerce regarding offset agreements exceeding $5,000,000 in value associated with sales of weapon systems or defense-related items to foreign countries or foreign firms. Offsets are industrial or commercial compensation practices required as a condition of purchase in either government-to-government or commercial sales of defense articles and/or defense services as defined by the Arms Export Control Act and the International Traffic in Arms Regulations. Such offsets are required by most major trading partners when purchasing U.S. military equipment or defense related items. An annual report based on offset agreements and offset transactions data reported to BIS by industry is submitted to Congress on the impact of offsets in defense trade on the United States.

II. Method of Collection

Submitted electronically or on paper.

III. Data

OMB Control Number: 0694–0084.

Form Number(s): N/A.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 30.

Estimated Time per Response: 12 hours.

Estimated Total Annual Burden Hours: 360.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 30, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–21847 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

Proposed Information Collection; Comment Request; Interim Procedures for Considering Requests and Comments From the Public for Textile and Apparel Safeguard Actions on Imports From Korea

AGENCY: International Trade Administration.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before November 5, 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: Requests for additional information or copies of the information collection instrument and instructions should be directed to Maria D'Andrea, Office of Textiles and Apparel, U.S. Department of Commerce, Tel. (202) 482–4058, *maria_dandrea@ita.doc.gov,* Fax. (202) 482–0667.

SUPPLEMENTARY INFORMATION:

I. Abstract

Article 4.1 of the U.S.-Korea Free Trade Agreement (the ''Agreement'') provides for a textile and apparel safeguard mechanism. This safeguard mechanism applies when, as a result of the reduction or elimination of a customs duty under the Agreement, a Korean textile or apparel article is being imported into the United States in such increased quantities, in absolute terms or relative to the domestic market for that article, and under such conditions as to cause serious damage or actual threat thereof to a U.S. industry producing a like or directly competitive article. In these circumstances, Article 4.1 permits the United States to (a) suspend any further reduction in the rate of duty provided for under Annex 2–B of the Agreement in the duty imposed on the article; or (b) increase duties on the imported article from Korea to a level that does not exceed the lesser of the prevailing U.S. normal trade relations (''NTR'')/most-favored-nation (''MFN'') duty rate for the article or the U.S. NTR/MFN duty rate in effect on the day before the Agreement enters into force.

The Statement of Administrative Action accompanying the U.S.-Korea Free Trade Agreement Implementation Act (the ''Act'') provides that the Committee for the Implementation of Textile Agreements (CITA) will issue procedures for requesting such safeguard measures, for making its determinations under section 332(a) of the Act, and for providing relief under section 332(b) of the Act.

In Proclamation No. 8783 (77 FR 14265, March 9, 2012), the President delegated to CITA his authority under Subtitle C of Title III of the Act with respect to textile and apparel safeguard measures.

The textile and apparel safeguard mechanism will be of considerable benefit to firms manufacturing textile and apparel goods in the United States in the event that an industry finds itself to be adversely impacted by preferential duty or duty-free imports of textiles and apparel from Korea.

CITA must collect information in order to determine whether a domestic textile or apparel industry is being adversely impacted by imports of these products from Korea, thereby allowing CITA to take corrective action to protect the viability of the domestic textile and apparel industry, subject to section 332(b) of the Act.

An interested party in the U.S. domestic textile and apparel industry may file a request for a textile and apparel safeguard action with CITA. Consistent with longstanding CITA practice in considering textile and apparel safeguard actions, CITA will consider an interested party to be an entity (which may be a trade association, firm, certified or recognized union, or group of workers) that is representative of either: (A) A domestic producer or producers of an article that is like or directly competitive with the subject Korean textile or apparel article; or (B) a domestic producer or producers of a component used in the production of an article that is like or directly competitive with the subject Korean textile or apparel article.

In order for a request to be considered, the requestor must provide the following information in support of a claim that a textile or apparel article from Korea is being imported into the United States in such increased quantities, in absolute terms or relative to the domestic market for that article, and under such conditions as to cause serious damage or actual threat thereof, to a U.S. industry producing an article that is like, or directly competitive with, the imported article: (1) Name and description of the imported article concerned; (2) import data demonstrating that imports of a Korea origin textile or apparel article that are like or directly competitive with the articles produced by the domestic industry concerned are increasing in absolute terms or relative to the domestic market for that article; (3) U.S. domestic production of the like or directly competitive articles of U.S. origin indicating the nature and extent of the serious damage or actual threat thereof, along with an affirmation that to the best of the requester's knowledge, the data represent substantially all of the domestic production of the like or directly competitive article(s) of U.S. origin; (4) imports from Korea as a percentage of the domestic market of the like or directly competitive article; and (5) all data available to the requester showing changes in productivity, utilization of capacity, inventories, exports, wages, employment, domestic prices, profits, and investment, and any other information, relating to the existence of serious damage or actual threat thereof caused by imports from Korea to the industry producing the like or directly competitive article that is the subject of the request. To the extent that such information is not available, the requester should provide best estimates and the basis therefore

If CITA determines that the request provides the information necessary for it to be considered, CITA will publish a notice in the **Federal Register** seeking public comments regarding the request. The comment period shall be 30 calendar days. The notice will include a summary of the request. Any interested party may submit information to rebut, clarify, or correct public comments submitted by any interested party.

CITA will make a determination on any request it considers within 60 calendar days of the close of the comment period. If CITA is unable to make a determination within 60 calendar days, it will publish a notice in the **Federal Register**, including the date it will make a determination.

If a determination under section 322(b) of the Act is affirmative, CITA may provide tariff relief to a U.S. industry to the extent necessary to remedy or prevent serious damage or actual threat thereof and to facilitate adjustment by the domestic industry to import competition. The import tariff relief is effective beginning on the date that CITA's affirmative determination is published in the **Federal Register**.

Entities submitting requests, responses or rebuttals to CITA may submit both a public and confidential version of their submissions. If the request is accepted, the public version will be posted on the dedicated Korea Free Trade Agreement textile safeguards section of the Office of Textile and Apparel (OTEXA) Web site. The confidential version of the request, responses or rebuttals will not be shared with the public as it may contain business confidential information. Entities submitting responses or rebuttals may use the public version of the request as a basis for responses.

II. Method of Collection

When an interested party files a request for a textile and apparel safeguard action with CITA, ten copies of any such request must be provided in a paper format. If business confidential information is provided, two copies of a non-confidential version must also be provided. If CITA determines that the request provides the necessary information to be considered, it publishes a **Federal Register** notice seeking public comments on the request. To the extent business confidential information is provided, a non-confidential version must also be provided. Any interested party may submit information to rebut, clarify, or correct public comments submitted by any interested party.

III. Data

OMB Control Number: 0625–0269.
Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Individuals or households; Business or other for-profit organizations.

Estimated Number of Respondents: 14.

Estimated Time per Response: 4 hours for each Request; 4 hours for each Comment.

Estimated Total Annual Burden Hours: 56.

Estimated Total Annual Cost to Public: $2,800.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 29, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–21762 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–833]

Certain Polyester Staple Fiber From Taiwan: Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On June 1, 2012, the Department of Commerce published the preliminary results of the administrative review of the antidumping duty order on certain polyester staple fiber from Taiwan. The period of review is May 1, 2010, through April 30, 2011. We gave interested parties an opportunity to comment on the preliminary results, but we received no comments. The final weighted-average dumping margin for Far Eastern New Century Corporation is listed below in the ''Final Results of the Review'' section of this notice.

DATES: *Effective Date:* September 5, 2012.

FOR FURTHER INFORMATION CONTACT: Michael A. Romani, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–0198.

Background

On June 1, 2012, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on certain polyester staple fiber from Taiwan. *See Certain Polyester Staple Fiber From Taiwan: Preliminary Results of Antidumping Duty Administrative Review,* 77 FR 32503 (June 1, 2012) (*Preliminary Results*). We invited interested parties to comment on the *Preliminary Results.* We received no comments from interested parties.

The Department has conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The product covered by the order is polyester staple fiber. Polyester staple fiber is defined as synthetic staple fibers, not carded, combed or otherwise processed for spinning, of polyesters measuring 3.3 decitex (3 denier, inclusive) or more in diameter. This merchandise is cut to lengths varying from one inch (25 mm) to five inches (127 mm). The merchandise subject to the order may be coated, usually with a silicon or other finish, or not coated. Polyester staple fiber is generally used as stuffing in sleeping bags, mattresses, ski jackets, comforters, cushions, pillows, and furniture. Merchandise of less than 3.3 decitex (less than 3 denier) currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 5503.20.00.20 is specifically excluded from the order. Also specifically excluded from the order are polyester staple fibers of 10 to 18 denier that are cut to lengths of 6 to 8 inches (fibers used in the manufacture of carpeting). In addition, low-melt polyester staple fiber is excluded from the order. Low-melt polyester staple fiber is defined as a bi-component fiber with an outer sheath that melts at a significantly lower temperature than its inner core.

The merchandise subject to the order is currently classifiable in the HTSUS at subheadings 5503.20.00.45 and 5503.20.00.65. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.

Final Results of the Review

We made no changes to our calculations announced in the *Preliminary Results.* As a result of our review, we determine that a weighted-average dumping margin of 0.00 percent exists for Far Eastern New Century Corporation for the period May 1, 2010, through April 30, 2011.

Assessment Rates

In accordance with the *Final Modification,* we will instruct U.S. Customs and Border Protection (CBP) to liquidate the reviews entries without regard to antidumping duties. *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012) (*Final Modification*).

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the period of review produced by Far Eastern New Century Corporation for which it did not know its merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

The Department intends to issue assessment instructions directly to CBP 15 days after publication of these final results of review.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice of final results of administrative review for all shipments of polyester staple fiber from Taiwan entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for Far Eastern New Century Corporation will be 0.00 percent; (2) for merchandise exported by manufacturers

or exporters not covered in this review but covered in the original less-than-fair-value investigation or previous reviews, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; (4) the cash deposit rate for all other manufacturers or exporters will continue to be 7.31 percent, the all-others rate established in *Notice of Amended Final Determination of Sales at Less Than Fair Value: Certain Polyester Staple Fiber From the Republic of Korea and Antidumping Duty Orders: Certain Polyester Staple Fiber From the Republic of Korea and Taiwan,* 65 FR 33807 (May 25, 2000). These cash deposit requirements shall remain in effect until further notice.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these results and this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: August 28, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2012–21873 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–839]

Certain Polyester Staple Fiber From the Republic of Korea: Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from interested parties, the Department of Commerce (''the Department'') initiated an administrative review of the antidumping duty order on certain polyester staple fiber from the Republic of Korea (''the Order''). The period of review is May 1, 2011, through April 30, 2012. Based on the withdrawal of requests for review, we are now rescinding this administrative review.

DATES: *Effective Date:* September 5, 2012.

FOR FURTHER INFORMATION CONTACT: Mahnaz Khan or Yasmin Nair, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0914 or (202) 482–3183, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 1, 2012, the Department published in the **Federal Register** the notice of opportunity to request an administrative review of the Order for the period of review, May 1, 2011, through April 30, 2012.[1] On May 31, 2012, DAK Americas LLC, and Auriga Polymers, Inc. (the successor to Invista, S.a.r.L) (collectively, ''Petitioners'') timely requested that the Department conduct an administrative review of the following companies: (1) Huvis Corporation (''Huvis''); (2) Woongjin Chemical Company, Ltd. (''Woongjin''); and (3) Saehan Industries, Inc. (''Saehan'').[2] On May 31, 2012, Woongjin and Huvis requested that the Department conduct an administrative review of their respective companies.[3] Pursuant to these requests, and in accordance with 19 CFR 351.221(c)(1)(i), the Department published a notice initiating the administrative review of Huvis, Woongjin, and Saehan.[4] Petitioners withdrew their request for an administrative review of Huvis on July 20, 2012.[5] On July 25, 2012, Huvis withdrew its request for an administrative review.[6] On August 1, 2012, Petitioners withdrew their requests for an administrative review of Woongjin and Saehan, and Woongjin withdrew its request.[7]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation of the requested review. As noted above, Petitioners withdrew their requests for review of Huvis, Woongjin, and Saehan within 90 days of the date of publication of the notice of initiation. Moreover, Huvis and Woongjin timely withdrew their requests for an administrative review of their respective companies. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding this review in its entirety.

Assessment

The Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice of rescission of administrative review.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 77 FR 25679, 25680 (May 1, 2012).

[2] *See* Letter from Petitioners to the Department, dated May 31, 2012, at 2.

[3] *See* Letter from Woongjin to the Department, dated May 31, 2012, at 1–2; Letter from Huvis to the Department, dated May 31, 2012, at 1–2.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 77 FR 40565, 40567 (July 10, 2012).

[5] *See* Letter from Petitioners, dated July 20, 2012, at 2.

[6] *See* Letter from Huvis, dated July 25, 2012, at 1–2.

[7] *See* Letter from Petitioner, dated August 1, 2012, at 1–2; Letter from Woongjin, dated August 1, 2012, at 1–2.

presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice serves as a final reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: August 29, 2012.

Gary Taverman,

Senior Advisor for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–21877 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–806]

Silicon Metal from the People's Republic of China: Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On March 7, 2012, the Department of Commerce (''Department'') published the preliminary results of the administrative review of the antidumping duty order on silicon metal from the People's Republic of China (''PRC''). The period of review (''POR'') is June 1, 2010, through May 31, 2011.

Based on our analysis of the comments received, we have made changes to the margin calculations. Therefore, the final results differ from the preliminary results. The final weighted-average dumping margin for Shanghai Jinneng International Trade Co., Ltd. (''Shanghai Jinneng'') is listed below in the section entitled ''Final Results of the Review.''

FOR FURTHER INFORMATION CONTACT: Rebecca Pandolph or Howard Smith, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3627, and (202) 482–5193, respectively.

SUPPLEMENTARY INFORMATION: On March 7, 2012, the Department published *Silicon Metal from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review,* 77 FR 13534 (March 7, 2012) (''*Preliminary Results*'').

On March 27, 2012, Shanghai Jinneng submitted additional surrogate value information.[1] On March 30, 2012, the Department requested clarification of Shanghai Jinneng's surrogate value submission and on April 4, 2012, Shanghai Jinneng responded to the Department's request for clarification.[2] On April 16, 2012, Globe Metallurgical Inc. (''Petitioner'') submitted rebuttal surrogate value information.[3] On April 18, 2012, the Department requested clarification of Petitioner's rebuttal surrogate value submission and on April 19, 2012, Petitioner responded to the Department's request for clarification.[4]

On April 4, 2012, Petitioner requested additional time to submit case and rebuttal briefs.[5] On April 5, 2012 the Department extended the deadline for filing case briefs until April 13, 2012, and extended the deadline for filing rebuttal briefs until no later than five days after the time limit for filing the case briefs.[6] On April 6, 2012, Shanghai Jinneng requested additional time to submit case and rebuttal briefs.[7] On April 10, 2012, the Department extended the deadline for submitting case briefs until April 20, 2012 and extended the deadline for submitting rebuttal briefs until April 27, 2012.[8] On April 24, 2012, Petitioner requested additional time for filing rebuttal case briefs and on April 26, 2012, the Department granted an extension until May 4, 2012 to file rebuttal briefs.[9] On April 20, 2012, Petitioner and Shanghai Jinneng submitted case briefs and on May 4, 2012, both submitted rebuttal case briefs.

On April 5, 2012, Petitioner requested a public hearing and a closed session of the hearing.[10] On June 7, 2012, the Department held a hearing which was closed to the public, in part, pursuant to 19 CFR 351.310.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this review are addressed in the Memorandum from Gary Taverman, Senior Advisor for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, ''Issues and Decision Memorandum for the Final Results of the June 1, 2010 through May 31, 2011 Administrative Review of the Antidumping Duty Order on Silicon Metal from the People's Republic of China,'' dated August 29, 2012, which is hereby adopted by this

[1] *See* Letter from Shanghai Jinneng to the Honorable John Bryson, Secretary of Commerce, regarding, ''Silicon Metal from the People's Republic of China,'' dated March 27, 2012.

[2] *See* Letter from Howard Smith, Program Manager, AD/CVD Operations, Office 4 to All Interested Parties regarding, ''Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China: Surrogate Values Submission,'' dated March 30, 2012. *See also* Letter from Shanghai Jinneng to the Honorable John Bryson, Secretary of Commerce, regarding, ''Silicon Metal from the People's Republic of China: Shanghai Jinneng International Trade Co., Ltd. —Supplement to Surrogate Value Submission,'' dated April 4, 2012.

[3] *See* Letter from Petitioner to the Honorable John Bryson, Secretary of Commerce, regarding ''Silicon Metal From the People's Republic of China; 2010–11 Administrative Review; Submission of Factual Information to Rebut, Clarify, or Correct Surrogate Value Information Submitted by Shanghai Jinneng International Trade Co., Ltd.,'' dated April 16, 2012

[4] *See* Letter from Howard Smith, Program Manager, AD/CVD Operations, Office 4 to All Interested Parties regarding, ''Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China: Rebuttal Surrogate Values Submission,'' dated April 18, 2012. *See also* Letter from Petitioner to the Honorable John Bryson, Secretary of Commerce, regarding, ''Silicon Metal From the People's Republic of China; 2010–11 Administrative Review; Response to Department Request for Information Regarding Globe's Rebuttal Surrogate Value Submission,'' dated April 4, 2012.

[5] *See* Letter from Petitioner to the Honorable John Bryson, Secretary of Commerce, regarding ''Silicon Metal From the People's Republic of China; 2010–11 Administrative Review; Request for Extension of Time to Submit Case and Rebuttal Briefs,'' dated April 4, 2012.

[6] *See* Letter from Howard Smith, Program Manager, AD/CVD Operations, Office 4 to Interested Parties regarding, ''Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China for the period June 1, 2010 to May 31,2011,'' dated April 5, 2012.

[7] *See* Letter from Shanghai Jinneng to the Honorable John Bryson, Secretary of Commerce, regarding, ''Silicon Metal from the People's Republic of China,'' dated April 6, 2012.

[8] *See* Letter from Howard Smith, Program Manager, AD/CVD Operations, Office 4 to Interested Parties regarding, ''Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China for the period June 1, 2010 to May 31, 2011,'' dated April 10, 2012.

[9] *See* Letter from Petitioner to the Honorable John Bryson, Secretary of Commerce, regarding ''Silicon Metal From the People's Republic of China; 2010–11 Administrative Review; Request for Extension of Time to Submit Rebuttal Briefs,'' dated April 24, 2012 and Letter from Howard Smith, Program Manager, AD/CVD Operations, Office 4 to Interested Parties regarding, ''Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China for the period June 1, 2010 to May 31, 2011,'' dated April 26, 2012.

[10] *See* Letter from Petitioner to the Honorable John Bryson, Secretary of Commerce, regarding ''Silicon Metal From the People's Republic of China; 2010–11 Administrative Review; Request for Hearing and Closed Hearing Session,'' dated April 5, 2012.

notice (''Issues and Decision Memorandum''). A list of the issues which parties raised and to which we respond in the Issues and Decision Memorandum is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit, main Commerce building, Room 7046. In addition, a complete version of the Issues and Decision Memorandum is accessible on the Department's Web site at *http://www.trade.gov/ia.* The signed Issues and Decision Memorandum and electronic versions of the memorandum are identical in content.

Changes Since the Preliminary Results

Based on an analysis of the comments received, the Department has made the following changes:

- Calculated a new surrogate value for labor using data reported by Thailand to the International Labour Organization (''ILO'') in Chapter 6A of the ILO Yearbook for total manufacturing labor from 2005.[11]
- Recalculated the factors of production to exclude the quantity of container cliff and edge silicon sold from the total production quantity.[12]
- Weight-averaged the transportation costs for Shanghai Jinneng's quartz input.[13]

Period of Review

The POR is June 1, 2010, through May 31, 2011.

Scope of the Order

Imports covered by the order are shipments of silicon metal containing at least 96.00 but less than 99.99 percent of silicon by weight. Also covered by the order is silicon metal from the PRC containing between 89.00 and 96.00 percent silicon by weight but which contain a higher aluminum content than the silicon metal containing at least 96.00 percent but less than 99.99 percent silicon by weight. Silicon metal is currently provided for under subheadings 2804.69.10 and 2804.69.50 of the Harmonized Tariff Schedule of the United States (''HTSUS'') as a chemical product, but is commonly referred to as a metal. Semiconductor-grade silicon (silicon metal containing by weight not less than 99.99 percent of silicon and provided for in subheading 2804.61.00 of the HTSUS) is not subject to the order. Although the HTSUS subheadings are provided for convenience and for customs purposes, the written description of the merchandise is dispositive.

Separate Rates

In the *Preliminary Results,* we determined that Shanghai Jinneng demonstrated its eligibility for separate-rate status.[14] We have not received any information since the issuance of the *Preliminary Results* that provides a basis for reconsideration of this determination. Therefore, the Department continues to find that Shanghai Jinneng meets the criteria for a separate rate.

Final Results of the Review

We determine that the following weighted-average percentage margin exists for the POR:

Exporter	Margin (percentage)
Shanghai Jinneng International Trade Co., Ltd.	14.36

Disclosure

The Department intends to disclose calculations performed for these final results to the parties within five days of the date of the public announcement of the results of this review in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as amended (''the Act''), and 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. In accordance with 19 CFR 351.212(b)(1), we are calculating importer or customer-specific assessment rates for the merchandise subject to this review. Because we do not have entered values for all U.S. sales to a particular importer/customer, we are calculating a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to that importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).[15] Where a customer-specific *ad valorem* rate is zero or *de minimis* (*i.e.,* less than 0.50 percent), we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[16] To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer or customer-specific *ad valorem* ratios based on the estimated entered value. We intend to instruct CBP to liquidate entries containing subject merchandise exported by the PRC-wide entity at the PRC-wide rate.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporter listed above, the cash deposit rate will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* (*i.e.,* less than 0.5 percent), a zero cash deposit rate will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 139.49[17] percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant

[11] *See* Issues and Decision Memorandum at Issue 4.

[12] *See* Issues and Decision Memorandum at Issue 2.

[13] *See* Issues and Decision Memorandum at Issue 8.

[14] *See Preliminary Results,* 77 FR at 13535.

[15] *See, e.g., Certain Cased Pencils From the People's Republic of China: Final Results of the Antidumping Duty Administrative Review,* 76 FR 27988, 27989 (May 13, 2011).

[16] *See* 19 CFR 351.106(c)(2).

[17] *See Final Determination of Sales at Less Than Fair Value: Silicon Metal from the People's Republic of China,* 56 FR 18570, 18571–2 (April 23, 1991).

entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

The Department is issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: August 29, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix

Issue 1: Whether the Department should reduce the U.S. Price by export tax and/or value-added tax.
Issue 2: Whether to exclude container cliff and edge silicon from the reported production quantity.
Issue 3: By-product offsets.
Issue 4: Surrogate value for labor.
Issue 5: The appropriate weight over which to allocate brokerage and handling expenses.
Issue 6: Excluding certain expenses from brokerage and handling.
Issue 7: Surrogate value for rail freight.
Issue 8: Transportation cost for quartz.

[FR Doc. 2012–21879 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC192

Endangered and Threatened Species; Recovery Plans

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

ACTION: Notice of Availability and notice of public meetings.

SUMMARY: NMFS announces the adoption of a Final Endangered Species Act (ESA) recovery plan for the Central California Coast coho salmon (*Oncorhynchus kisutch*) Evolutionarily Significant Unit (ESU). The Final Recovery Plan for Central California Coast coho salmon (Final Recovery Plan) is now available. In addition, informative public meetings will be held (see below for dates and locations).

ADDRESSES: Electronic copies of the Final Recovery Plan are available online at: *http://www.nmfs.noaa.gov/pr/recovery/plans/htm, http://swr.nmfs.noaa.gov/recovery/index.htm.*

A CD–ROM of the Final Recovery Plan can be obtained by emailing a request to *Andrea.Berry@noaa.gov* with the subject line ''CD–ROM Request for CCC coho Salmon Recovery Plan'', by phone at 707–200–2788, or by writing to NMFS Protected Resources Division, 777 Sonoma Avenue, Room 325, Santa Rosa, CA 95404 ATTN: Recovery Coordinator.

FOR FURTHER INFORMATION CONTACT: Charlotte Ambrose, Central California Coast Recovery Coordinator by email to *Charlotte.A.Ambrose@noaa.gov* or by phone at 707–575–6068.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973 (ESA), as amended (16 U.S.C. 1531 *et seq.*) requires that we (NOAA) develop and implement recovery plans for the conservation and survival of threatened and endangered species under our jurisdiction, unless it is determined that such plans would not result in the conservation of the species. We designated Central California Coast coho salmon as threatened in the **Federal Register** on October 21, 1996 (61 FR 56138). Due to severe declines, we uplisted the species to endangered status on June 28, 2005 (70 FR 37160). We published a Notice of Availability of the Draft Recovery Plan in the **Federal Register** on March 18, 2010 (75 FR 13081) and held three public meetings to obtain comments on the Draft Plan. In response to multiple requests, we extended the public comment period for an additional 60 days on May 7, 2010 (75 FR 25204). We received extensive comments on the Draft Plan, summarized the comments and identified the comments that prompted revisions for the Final Recovery Plan. We revised the Draft Plan based on the comments received, and this final version now constitutes the Recovery Plan for the Evolutionarily Significant Unit of Central California Coast Coho Salmon.

The Final Plan

The ESA requires that recovery plans incorporate, to the extent practicable: (1) Objective, measurable criteria which, when met, would result in a determination that the species is no longer threatened or endangered; (2) site-specific management actions necessary to achieve the plan's goals; and (3) estimates of the time required and costs to implement recovery actions. Our goal is to restore endangered Central California Coast coho salmon to the point where they are again secure, self-sustaining members of their ecosystems and no longer need the protections of the ESA.

The Final Recovery Plan provides background on the natural history of Central California Coast coho salmon, population trends and the potential threats to their viability. The Final Recovery Plan lays out a recovery strategy to address the potential threats based on the best available science and includes goals that incorporate objective, measurable criteria which, when met, would result in a determination that the species be removed from the list. The Final Recovery Plan is not regulatory, but presents guidance for use by agencies and interested parties to assist in the recovery of Central California Coast coho salmon. The Final Recovery Plan identifies substantive actions needed to achieve recovery by addressing the threats to the species. The strategy for recovery includes a linkage between management actions and an active research and monitoring program intended to fill data gaps and assess effectiveness. The Final Recovery Plan incorporates an adaptive management framework by which management actions and other elements will evolve and adapt as we gain information through research and monitoring and it describes the agency guidance on time lines for reviews of the status of species and recovery plans. To address threats related to the species, the Final Recovery Plan references many of the significant efforts already underway to restore Central California Coast coho salmon access to high quality habitat and to improve habitat previously degraded.

We expect the Final Recovery Plan to help us and other Federal agencies take a consistent approach to section 7 consultations under the ESA and to other ESA decisions. For example, the Final Recovery Plan will provide information on the biological context for

the effects that a proposed action may have on the listed ESU. The best available information in the Final Recovery Plan on the natural history, threats, and potential limiting factors, and priorities for recovery can be used to help assess risks. Consistent with the adoption of this Final Recovery Plan for Central California Coast coho salmon, we will implement relevant actions for which we have authority, work cooperatively on implementation of other actions, and encourage other Federal and state agencies to implement recovery actions for which they have responsibility and authority.

Recovery of Central California Coast coho salmon will require a long-term effort in cooperation and coordination with Federal, state, tribal and local government agencies, and the community.

Conclusion

NMFS has reviewed the Plan for compliance with the requirements of ESA section 4(f), determined that it does incorporate the required elements and is therefore adopting it as the Final Recovery Plan for Central California Coast coho salmon.

Public Meetings

Public meetings are planned for Ukiah, Santa Cruz, and Santa Rosa, CA. Workshops will be held at the locations and dates listed below:

September 11, 2012, 10 a.m.–12 p.m.; Redwood Empire Fairgrounds, Fair Arts Building, 1055 State Street, Ukiah, CA, 95482.	September 5, 2012, 10 a.m.–12 p.m.; Hilton Santa Cruz/Scotts Valley, Pine/Oak Room, 6001 La Madrona Drive, Santa Cruz, CA 95060.	September 6, 2012, 10 a.m.–12 p.m.; Wells Fargo Center for the Arts, Carston Cabaret Room, 50 Mark West Springs Road Santa Rosa, CA 95403.

Information on exact locations, dates and times will also be posted on the above Web site.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: August 29, 2012.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–21850 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC215

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) Staff will hold the second meeting of the Visioning and Strategic Planning Working Group. During this meeting, the group will finalize draft vision and mission statements, perform an abridged analysis of the Council's strengths, weaknesses, opportunities, and threats, and develop a goal structure for the strategic plan.

DATES: The meeting will be held on Friday, September 21, 2012, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at O'Callaghan Hotel, 174 West Street, Annapolis, MD 21401; telephone: (866) 782–9624.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: This meeting of the Visioning and Strategic Planning Working Group is the second in a series of strategic planning meetings convened by MAFMC with facilitation services provided by RESOLVE. The purpose of the Working Group meetings is to develop a draft 10-year strategic plan and corresponding tactical plan through discussion of issues, opportunities, and objectives as they relate to the MAFMC's management responsibilities. In this meeting, the Working Group will finalize the Vision and Mission statements drafted at the first meeting held on August 13. The group will perform an abridged analysis of strengths, weaknesses, opportunities, and threats, and will develop a goal structure for the strategic plan. Time permitting, the Working Group may develop the goal, objective, strategy and tactical associations that support the development of a strategic goal on public engagement.

No formal actions will be taken by the Visioning and Strategic Planning Working Group at this meeting. Any documents produced by the Working Group will be reviewed by the full-Council following a period of public comment.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders at the Mid-Atlantic Council Office, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: August 30, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–21764 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA848

Endangered Species; File No. 16134

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

ACTION: Issuance of permit.

SUMMARY: Notice is hereby given that Virginia Aquarium and Marine Science Center Foundation [Responsible Party: Mark Swingle], 717 General Booth Blvd., Virginia Beach, VA 23451 has been issued a permit to take green (*Chelonia mydas*), Kemp's ridley (*Lepidochelys kempii*), hawksbill (*Eretmochelys imbricata*), leatherback (*Dermochelys coriacea*), and loggerhead (*Caretta caretta*) sea turtles for purposes of scientific research.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376;

Northeast Region, NMFS, 55 Great Republic Drive, Gloucester, MA 01930; phone (978) 281–9328; fax (978) 281–9394; and

Southeast Region, NMFS, 263 13th Ave. South, St. Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

FOR FURTHER INFORMATION CONTACT: Kristy Beard or Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On December 9, 2011, notice was published in the **Federal Register** (76 FR 76950) that a request for a scientific research permit to take the above-listed species had been submitted by the above-named organization. The requested permit has been issued under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The five-year permit authorizes research on leatherback, loggerhead, green, hawksbill, and Kemp's ridley sea turtles in mid-Atlantic waters from North Carolina to New Jersey. The purposes of the research are to: (1) Update current knowledge of loggerhead and Kemp's ridley sea turtle abundance, distribution, health, and nutrition in Chesapeake Bay and nearshore Virginia waters, (2) compare the relative abundance, size distribution, sex ratio, health parameters and genetic diversity of loggerhead and Kemp's ridley sea turtles in U.S. mid-Atlantic coastal waters, and (3) build baseline data on less common sea turtle species in the region. Turtles will be captured using tangle nets or hand/dip nets. Subject turtles may also be acquired from other legal sources: Virginia pound net fisheries and dredge mitigating trawls. The following procedures may be conducted on sea turtles prior to release: Epibiota removal, satellite tag, temporarily mark the carapace, attach flipper and passive integrated transponder tags, measure, photograph, oral swab, weigh, and sample blood, feces, keratin, and tissue.

Issuance of this permit, as required by the ESA, was based on a finding that such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of such endangered or threatened species, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: August 30, 2012.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–21852 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA963

Marine Mammals; File No. 15142

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

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that a permit has been issued to Colleen Reichmuth, Ph.D., University of California at Santa Cruz, Long Marine Laboratory, 100 Shaffer Road, Santa Cruz, CA, to take pinnipeds for scientific research purposes.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907) 586–7221; fax (907) 586–7249.

FOR FURTHER INFORMATION CONTACT: Amy Sloan or Tammy Adams, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On January 31, 2012, notice was published in the **Federal Register** (77 FR 4765) that a request for a permit to take pinnipeds for scientific research had been submitted by the above-named applicant. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The permit holder is authorized over a five-year period to collect from the wild up to two bearded seals (*Erignathus barbatus*) in the Northwest Arctic Borough of Alaska for a long-term behavioral study at Long Marine Laboratory in Santa Cruz, CA. Up to four bearded seals may be captured and temporarily held in order to evaluate their suitability for participation in research. Captured seals deemed unsuitable for the long-term study will be released at the capture site. Incidental harassment of up to one ringed seal (*Phoca hispida*) and one spotted seal (*Phoca larga*), and mortality of two bearded seals is authorized for the duration of the permit. After a quarantine period, the seals will be transferred to NMFS Permit No. 14535–01 (75 FR 58352) for research on the amphibious hearing capabilities of bearded seals to improve the understanding of the potential effects of expected increases in anthropogenic activities in polar habitats.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: August 28, 2012.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–21851 Filed 9–4–12; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2012–0038]

Submission for OMB Review; Comment Request: Requirements for Baby-Bouncers and Walker-Jumpers

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: In the **Federal Register** of June 20, 2012 (77 FR 3700), the Consumer Product Safety Commission (CPSC or Commission) published a notice in accordance with provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) to announce the CPSC's intention to seek extension of approval of the collection of information in the requirements for baby-bouncers and walker-jumpers in regulations codified at 16 CFR 1500.18(a)(6) and 1500.86(a)(4). No comments were received in response to that notice. Therefore, by publication of this notice, the Commission announces that it has submitted to the Office of Management and Budget (OMB) a request for extension of approval of this collection of information, without change.

ADDRESSES: To ensure that comments on the information collection are received, the OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, Fax: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified by Docket No. CPSC–2010–0038. In addition, written comments also should

be submitted at *http://www.regulations.gov,* under Docket No. CPSC–2010–0038, or by mail/hand delivery/courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mary K. James, Office of Information Technology, U.S. 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. Requirements for Baby-Bouncers and Walker-Jumpers

One CPSC regulation bans any product known as a baby-bouncer, walker-jumper, or similar article if it is designed in such a way that exposed parts present hazards of amputations, crushing, lacerations, fractures, hematomas, bruises or other injuries to children's fingers, toes, or other parts of the body. 16 CFR 1500.18(a)(6). A second CPSC regulation establishes criteria for exempting baby-bouncers and walker-jumpers from the banning rule under specified conditions. 16 CFR 1500.86(a)(4). The exemption regulation requires certain labeling on these products and their packaging to identify the name and address of the manufacturer or distributor and the model number of the product. Additionally, the exemption regulation requires that records must be established and maintained for three years relating to testing, inspection, sales, and distributions of these products. The regulation does not specify a particular form or format for the records. Manufacturers and importers may rely on records kept in the ordinary course of business to satisfy the recordkeeping requirements if those records contain the required information.

If a manufacturer or importer distributes products that violate the banning rule, the records required by section 1500.86(a)(4) can be used by the manufacturer or importer and the CPSC: (i) to identify specific models of products that fail to comply with applicable requirements; and (ii) to notify distributors and retailers if the products are subject to recall.

B. Estimated Burden

CPSC staff estimates that about 25 firms are subject to the testing and recordkeeping requirements of the regulations. Firms are expected to test on the average two new models per year per firm. CPSC staff estimates further that the burden imposed by the regulations on each of these firms is approximately 1 hour per year on the recordkeeping requirements and 30 minutes or less per model on the label requirements. Thus, the annual burden imposed by the regulations on all manufacturers and importers is approximately 50 hours on recordkeeping (25 firms × 2 hours) and 25 hours on labeling (25 firms × 1 hour) for a total annual burden of 75 hours per year.

CPSC staff estimates that the hourly wage for the time required to perform the required testing and recordkeeping is approximately $61.24 (Bureau of Labor Statistics: Total compensation rates for management, professional, and related occupations in private goods-producing industries, December, 2011) and that the hourly wage for the time required to maintain the required records is about $27.33 (Bureau of Labor Statistics: Total compensation rates for sales and office workers in private goods-producing industries, December 2011). The annualized total cost to the industry is estimated to be $3,745.

The Commission will expend approximately 2 days of professional staff time reviewing records required to be maintained by the regulations for baby-bouncers, and walker-jumpers. The annual cost to the federal government of the collection of information in these regulations is estimated to be about $165. This is based on an average hourly wage rate of $57.13 (the equivalent of a GS–14 Step 5 employee) with an additional 30.2 percent added for benefits (BLS, Percentage of total compensation comprised by benefits for all civilian management, professional, and related employees, December 2011), or $82.56 × 2 hours.

Dated: August 9, 2012.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2012–21730 Filed 9–4–12; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Defense Advisory Committee on Women in the Services (DACOWITS)

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a), Public Law 92–463, as amended, notice is hereby given of a forthcoming meeting of the Defense Advisory Committee on Women in the Services (DACOWITS). The purpose of the meeting is to receive briefings from the Services on their current retention programs, a briefing from the Army on their gender neutral standards, and a briefing on Australian Defence Force gender restrictions and development and implementation of physical standards for military positions. Additionally, the Committee will receive a briefing on Legislative Proposal for expanded health care coverage for military women. Finally, the Committee will develop and vote on their recommendations for the 2012 report. The meeting is open to the public, subject to the availability of space.

Interested persons may submit a written statement for consideration by the Defense Advisory Committee on Women in the Services. Individuals submitting a written statement must submit their statement to the Point of Contact and address listed in **FOR FURTHER INFORMATION CONTACT** no later than 5 p.m., Tuesday, September 25, 2012. If a written statement is not received by Tuesday, September 25, 2012, prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the Defense Advisory Committee on Women in the Services until its next open meeting. The Designated Federal Officer will review all timely submissions with the Defense Advisory Committee on Women in the Services Chairperson and ensure they are provided to the members of the Defense Advisory Committee on Women in the Services. If members of the public are interested in making an oral statement, a written statement should be submitted as above. After reviewing the written comments, the Chairperson and the Designated Federal Officer will determine who of the requesting persons will be able to make an oral presentation of their issue during an open portion of this meeting or at a future meeting. Determination of who will be making an oral presentation is at the sole discretion of the

Committee Chair and the Designated Federal Officer and will depend on time available and if the topics are relevant to the Committee's activities. Two minutes will be allotted to persons desiring to make an oral presentation. Oral presentations by members of the public will be permitted only on Thursday, September 27, 2012 from 3:40 p.m. to 4:30 p.m. in front of the full Committee. Number of oral presentations to be made will depend on the number of requests received from members of the public.

DATES: September 27, 2012, from 8:30 a.m. to 4:30 p.m.; September 28, 2012, from 1 p.m. to 4:30 p.m.

ADDRESSES: Sheraton Suites, 801 North Saint Asaph St., Alexandria, VA 22314.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Bowling or DACOWITS Staff at 4000 Defense Pentagon, Room 2C548A, Washington, DC 20301–4000. *Robert.bowling@osd.mil.* Telephone (703) 697–2122. Fax (703) 614–6233.

SUPPLEMENTARY INFORMATION:

Meeting agenda:

Thursday, September 27, 2012, 8:30 a.m.–4:30 p.m.

—Welcome, introductions, and announcements.
—Briefings—Services Retention Programs.
—Briefing—U.S. Army Gender Neutral Standards.
—Summary of Canada Visit.
—Briefing—Australian Defence Force Update.
—Briefing—Legislative Proposal on Military Women Health Care.
—Public Comment Period.

Friday, September 28, 2012, 1 p.m.–4:30 p.m.

—Welcome, introductions, and announcements.
—Committee Proposes and Votes on 2012 Recommendations.

Dated: August 29, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–21817 Filed 9–4–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Renewal of U.S. Naval Academy Board of Visitors

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 U.S. Naval Academy Board of Visitors (hereafter referred to as ''the Board'').

The Board is a non-discretionary federal advisory committee that shall provide independent advice and recommendations to the President of the United States on matters relating to but not limited to morale and discipline, curriculum, instruction, physical equipment, fiscal affairs, academic methods and other matters relating to the United States Naval Academy that the Board decides to consider.

The Board shall visit the Naval Academy annually, and any other official visits by the Board or its members to the Academy, other than the annual visit, shall be made in compliance with the requirements set forth in 10 U.S.C. 6968(d). The Board shall submit a written report to the President of the United States within 60 days after its annual visit to the Naval Academy, to include the Board's views and recommendations pertaining to the Academy, including its advice and recommendations on matters set forth in the paragraph above. Any report of a visit, other than an annual visit, must be made pursuant to 10 U.S.C. 6968(f).

The Board, pursuant to 10 U.S.C. 6968(a), shall be constituted annually and shall be composed of no more than 15 members. The Board membership shall include:

a. The Chairman of the Committee on Armed Services of the Senate, or his designee;

b. Three other members of the Senate designated by the Vice President or the President pro tempore of the Senate, two of whom are members of the Committee on Appropriations of the Senate;

c. The Chairman of the Committee on Armed Services of the House of Representatives, or his designee;

d. Four other members of the House of Representatives designated by the Speaker of the House of Representatives, two of whom are members of the Committee on Appropriations of the House of Representatives; and

e. Six persons designated by the President.

Board members designated by the President shall serve for three years each, except that any member whose term of office has expired shall continue to serve until his successor is appointed. In addition, the President shall designate two persons each year to succeed the members whose terms expire that year. If a Board member dies or resigns, a successor shall be designated for the unexpired portion of the term by the official who designated the member.

The Board members shall select the Board's Chairperson from the total membership. With the exception of travel and per diem for official travel, Board members shall serve without compensation.

The Board, pursuant to 10 U.S.C. § 6968(g) and (h), may upon approval by the Secretary of the Navy, call in advisers for consultation, and these advisers shall, with the exception of travel and per diem for official travel, serve without compensation.

With DoD approval, the Board is authorized to establish subcommittees, as necessary and consistent with its mission. Establishment of subcommittees will be based upon written determination, to include terms of reference, by the Secretary of Defense, the Deputy Secretary of Defense, or the Board's sponsor.

Such subcommittees or workgroups shall not work independently of the chartered Board, and shall report all their recommendations and advice to the Board for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered Board; nor can they report directly to the Department of Defense or any Federal officers or employees who are not Board members.

Subcommittee members shall be appointed by the Secretary of Defense even if the member in question is already a Board member. Subcommittee members, with the approval of the Secretary of Defense, may serve a term of service on the subcommittee of one-to-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 by the Secretary of Defense according to governing DoD policy and procedures. Such individuals shall be appointed to serve as experts and consultants under the authority of 5 U.S.C. 3109, and shall serve as special government employees, whose appointments must be renewed by the Secretary of Defense on an annual basis.

All subcommittees or working groups shall operate under the provisions of FACA, the Government in the Sunshine Act, governing Federal statutes and regulations, and governing DoD policies/procedures.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Board shall meet at the call of the Designated Federal Officer, in consultation with the Board's Chairperson. The estimated number of Board meetings is four per year.

In addition, the Designated Federal Officer is required to be in attendance at all Board and subcommittee meetings; however, in the absence of the Designated Federal Officer, a properly approved Alternate Designated Federal Officer shall attend the Board or subcommittee meeting.

The Designated Federal Officer, or the Alternate Designated Federal Officer, shall call all of the Board's and subcommittee's meetings; prepare and approve all meeting agendas; adjourn any meeting when the Designated Federal Officer, or the Alternate Federal Officer, determines adjournment to be in the public interest or required by governing regulations or DoD policies/procedures; and chair meetings when directed to do so by the official to whom the Board reports.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to U.S. Naval Academy Board of Visitors membership about the Board's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of U.S. Naval Academy Board of Visitors.

All written statements shall be submitted to the Designated Federal Officer for the U.S. Naval Academy Board of Visitors, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the U.S. Naval Academy Board of Visitors' 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 U.S. Naval Academy Board of Visitors. 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: August 29, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–21718 Filed 9–4–12; 8:45 am]

BILLING CODE 5001–06–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Senior Executive Service Performance Review Board

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Notice.

SUMMARY: This notice announces the membership of the Defense Nuclear Facilities Safety Board (DNFSB) Senior Executive Service (SES) Performance Review Board (PRB).

DATES: *Effective Date:* September 5, 2012.

ADDRESSES: Send comments concerning this notice to: Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 700, Washington, DC 20004–2001.

FOR FURTHER INFORMATION CONTACT: Deborah Biscieglia by telephone at (202) 694–7041 or by email at debbieb@dnfsb.gov.

SUPPLEMENTARY INFORMATION: 5 U.S.C. 4314(c)(1) through (5) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more PRBs. The PRB shall review and evaluate the initial summary rating of the senior executive's performance, the executive's response, and the higher level official's comments on the initial summary rating. In addition, the PRB will review and recommend executive performance bonuses and pay increases.

The DNFSB is a small, independent Federal agency; therefore, the members of the DNFSB SES Performance Review Board listed in this notice are drawn from the SES ranks of other agencies. The following persons comprise a standing roster to serve as members of the Defense Nuclear Facilities Safety Board SES Performance Review Board:

Christopher E. Aiello, Director of Human Resources, Federal Deposit Insurance Corporation; David M. Capozzi, Director of Technical and Information Services, United States Access Board; Barry S. Socks, Chief Operating Officer, National Capital Planning Commission; and Christopher W. Warner, General Counsel, U.S. Chemical Safety and Hazard Investigation Board.

Dated: August 29, 2012.

Peter S. Winokur,

Chairman.

[FR Doc. 2012–21726 Filed 9–4–12; 8:45 am]

BILLING CODE 3670–01–P

DEPARTMENT OF EDUCATION

Notice of Submission for OMB Review; Office of Planning, Evaluation and Policy Development; Evaluation of the Carol M. White Physical Education Program

SUMMARY: The Carol M. White Physical Education Program (PEP) is authorized by the Elementary and Secondary Education Act of 1965, as amended. In establishing PEP, Congress acknowledged the critical need to improve physical education programs for K–12 students, in order to help them make progress toward meeting state standards for physical education. The U.S. Department of Education (ED) is interested in gaining a thorough understanding of what PEP projects experience related to two new program competitive preference priorities: The establishment of official partnerships and the collection and use of Body Mass Index (BMI) measurements.

DATES: Interested persons are invited to submit comments on or before October 5, 2012.

ADDRESSES: Written comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 04878. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Privacy, Information and Records Management Services,

Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Evaluation of the Carol M. White Physical Education Program.

OMB Control Number: 1875–0258.

Type of Review: Revision.

Total Estimated Number of Annual Responses: 77.

Total Estimated Number of Annual Burden Hours: 77.

Abstract: To answer the evaluation questions put forth by U.S. Department of Education (ED) on how Carol M. White Physical Education Program (PEP) grantees formed and used partnerships and collected and used Body Mass Index (BMI) data, ED will conduct five case studies. Findings from the case studies will provide feedback to both ED and grantees and will inform future improvements to the program.

Dated: August 30, 2012.

Darrin A. King,

Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2012–21855 Filed 9–4–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Submission for OMB Review; Office of Postsecondary Education; Assessing Program Performance, National Resource Center, Business and International Education, and Undergraduate International Studies and Foreign Language Programs Phone Interviews

SUMMARY: The U.S. Department of Education is collecting data to conduct an assessment of the National Resource Center (NRC), Business and International Education (BIE), and Undergraduate and International Studies and Foreign Language (UISFL) programs. Institutions of Higher Education will be asked to provide quantitative data on their internationalization and capacity building efforts on each campus.

DATES: Interested persons are invited to submit comments on or before October 5, 2012.

ADDRESSES: Written comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 04868. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Assessing Program Performance, National Resource Center, Business and International Education, and Undergraduate International Studies and Foreign Language Programs Phone Interviews.

OMB Control Number: Pending.

Type of Review: New.

Total Estimated Number of Annual Responses: 45.

Total Estimated Number of Annual Burden Hours: 34.

Abstract: The data collected through phone interviews will be used to document the implementation of individual projects as well as of the programs collectively and to inform future studies looking at long-term impact. The results will be used to make a determination about what has been accomplished by the NRC, BIE, and UISFL programs and to inform program improvement in the future.

Dated: August 30, 2012.

Darrin A. King,

Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2012–21856 Filed 9–4–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

President's Board of Advisors on Historically Black Colleges and Universities

AGENCY: President's Board of Advisors on Historically Black Colleges and Universities (Board), U.S. Department of Education.

ACTION: Notice of an open meeting.

SUMMARY: This notice sets forth the schedule and agenda of the meeting of the President's Board of Advisors on Historically Black Colleges and Universities. The notice also describes the functions of the Board. Notice of the meeting is required by section 10(a)(2) of the Federal Advisory Committee Act and intended to notify the public of its opportunity to attend.

DATES: Thursday, September 27, 2012.

Time: 9:00 a.m.–2:00 p.m.

ADDRESSES: Grand Hyatt Washington, Lafayette Park and Farragut Square Rooms, 1000 H Street NW., Washington, DC 20001, 202–582–1234.

FOR FURTHER INFORMATION CONTACT: John Silvanus Wilson, Jr., Executive Director, White House Initiative on Historically Black Colleges and Universities, 400 Maryland Avenue SW., Washington, DC 20204; telephone: (202) 453–5634, fax: (202) 453–5632.

SUPPLEMENTARY INFORMATION: The President's Board of Advisors on Historically Black Colleges and Universities (the Board) is established by Executive Order 13532 (February 26, 2010). The Board is governed by the provisions of the Federal Advisory Committee Act (FACA), (Pub. L. 92–463; as amended, 5 U.S.C.A., Appendix 2) which sets forth standards for the formation and use of advisory committees. The purpose of the Board is to advise the President and the Secretary of Education (Secretary) on all matters pertaining to strengthening the educational capacity of Historically Black Colleges and Universities (HBCUs).

The Board shall advise the President and the Secretary in the following areas: (i) Improving the identity, visibility, and distinctive capabilities and overall competitiveness of HBCUs; (ii) engaging the philanthropic, business, government, military, homeland-security, and education communities in a national dialogue regarding new HBCU programs and initiatives; (iii) improving the ability of HBCUs to remain fiscally secure institutions that can assist the nation in reaching its goal of having the highest proportion of college graduates by 2020; (iv) elevating the public awareness of HBCUs; and (v) encouraging public-private investments in HBCUs.

Agenda

The Board will receive updates from the chairman of the President's Board of Advisors on HBCUs, the Board's subcommittees and the executive director of the White House Initiative on HBCUs on their respective activities, thus far, during Fiscal Year 2012 including activities that have occurred since the Board's last meeting, which was held on June 6, 2012. In addition, the Board will discuss possible strategies to meet its duties under its charter.

Individuals who will need accommodations for a disability in order to attend the meeting (e.g., interpreting services, assistive listening devices, or material in alternative format) should notify John P. Brown, Deputy Director, White House Initiative on HBCUs, at (202) 453–5645, no later than Friday, September 21, 2012. We will attempt to meet requests for such accommodations after this date, but cannot guarantee their availability. The meeting site is accessible to individuals with disabilities.

An opportunity for public comment is available on Thursday, September 27, 2012, from 1:30 p.m.–2:00 p.m. Individuals who wish to provide comments will be allowed three to five minutes to speak. Those members of the public interested in submitting written comments may do so by submitting them to the attention of John S. Wilson, Jr., White House Initiative on Historically Black Colleges and Universities, U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202, by Friday, September 21, 2012.

Records are kept of all Board proceedings and are available for public inspection at the office of the White House Initiative on Historically Black Colleges and Universities, U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC, 20202, Monday through Friday (excluding federal holidays) during the hours of 9:00 a.m. to 5:00 p.m.

Electronic Access to the Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *www.ed.gov/fedregister/index.html.* To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free at 1–866–512–1830; or in the Washington, DC, area at 202–512–0000.

Dated: August 29, 2012.

Martha J. Kanter,

Under Secretary, U.S. Department of Education.

[FR Doc. 2012–21853 Filed 9–4–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

President's Advisory Commission on Asian Americans and Pacific Islanders

AGENCY: President's Advisory Commission on Asian Americans and Pacific Islanders, U.S. Department of Education.

ACTION: Notice of an open meeting.

SUMMARY: This notice sets forth the schedule and agenda of the meeting of the President's Advisory Commission on Asian Americans and Pacific Islanders (Commission). The notice also describes the functions of the Commission. Notice of the meeting is required by section 10(a)(2) of the Federal Advisory Committee Act and intended to notify the public of its opportunity to attend.

DATES: September 28, 2012.

Time: 8:30 a.m.–5:00 p.m. EDT.

ADDRESSES: U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Shelly W. Coles, White House Initiative on Asian Americans and Pacific Islanders, 400 Maryland Avenue SW., Washington, DC 20202; telephone: (202) 453–7277, fax: 202–453–5632.

SUPPLEMENTARY INFORMATION: The President's Advisory Commission on Asian Americans and Pacific Islanders is established under Executive Order 13515, dated October 14, 2009 and subsequently continued and amended by Executive Order 13585. Per E.O. 13515, The Commission shall provide advice to the President, through the Secretary of Education and a senior official to be designated by the President, as Co-Chairs of the Initiative, on: (i) The development, monitoring, and coordination of executive branch efforts to improve the quality of life of AAPIs through increased participation in Federal programs in which such persons may be underserved; (ii) the compilation of research and data related to AAPI populations and subpopulations; (iii) the development, monitoring, and coordination of Federal efforts to improve the economic and community development of AAPI businesses; and (iv) strategies to increase public and private-sector collaboration, and community involvement in improving the health, education, environment, and well-being of AAPIs.

Agenda

The purpose of the meeting is to discuss strategic planning and establish sub-committees of the Commission to help facilitate and focus its work; review the work of the White House Initiative on Asian Americans and Pacific Islanders; and determine key strategies to help meet the Commission's charge as outlined in E.O. 13515.

Additional Information

Individuals of the public who would like to attend the meeting on September 28, 2012, please R.S.V.P. to Shelly Coles via email at *shelly.coles@ed.gov* no later than, September 24, 2012 at 3:00 p.m. EDT.

Individuals who will need accommodations for a disability in order to attend the meeting (e.g., interpreting services, assistive listening devices, or material in alternative format) should notify Shelly Coles at (202) 453–7277, no later than Wednesday, September 12, 2012. We will attempt to meet requests for accommodations after this date, but,

cannot guarantee their availability. The meeting site is accessible to individuals with disabilities.

Due to time constraints, there will not be a public comment period at this meeting. However, individuals wishing to provide comment(s) about the White House Initiative on Asian Americans and Pacific Islanders or the President's Advisory Commission on Asian Americans and Pacific Islanders may contact Shelly Coles via email at *shelly.coles@ed.gov.* Please include in the subject line, the wording, ''Public Comment''.

Records are kept of all Commission proceedings and are available for public inspection at the office of the White House Initiative on Asian Americans and Pacific Islanders, U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202, Monday–Friday during the hours of 8:30 a.m. to 5:00 p.m.

Electronic Access to this Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *www.ed.gov/news/fedregister/index.html.* To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free at 1–866–512–1800; or in the Washington, DC area at 202–512–0000.

Martha Kanter,

Under Secretary, U.S. Department of Education.

[FR Doc. 2012–21757 Filed 9–4–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection; Correction

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for comments; correction.

SUMMARY: The Department of Energy (DOE) published a document in the **Federal Register** of August 24, 2012, announcing the submission of an information request to the OMB for the Foreign Travel Management System (FTMS). This document corrects an error in that notice.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Umeki Thorne at *umeki.thorne@hq.doe.gov.*

Correction

In the **Federal Register** of August 24, 2012, in FR Doc No: 2012–20840 (77 FR 51530), on page 51530, under **SUPPLEMENTARY INFORMATION**, in the second column, correct the last paragraph beginning at ''(4)'' to read as follows:

(4) Estimated Annual number of 2,230.

(5) Estimated Annual number of Burden Hours of 5,389.

(6) Estimated Annual Cost Burden: $450,000.

Statutory Authority: DOE O 551.1D, ''Official Foreign Travel,'' dated April 2, 2012.

Issued in Washington, DC on August 27, 2012.

Julie Squires,

Staff Advisor, Office of Management, Office of International Travel and Exchange Visitor Programs.

[FR Doc. 2012–21802 Filed 9–4–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

State Energy Advisory Board (STEAB)

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of open teleconference.

SUMMARY: This notice announces a teleconference call of the State Energy Advisory Board (STEAB). The Federal Advisory Committee Act (Public Law 92–463; 86 Stat.770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, September 20, 2012, 3:30 p.m.–4 p.m. (EDT). To receive the call-in number and passcode, please contact the Board's Designated Federal Officer (DFO) at the address or phone number listed below.

FOR FURTHER INFORMATION CONTACT: Gil Sperling, STEAB Designated Federal Officer, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000 Independence Ave. SW., Washington, DC 20585. Phone number: (202) 287–1644.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: To provide advice and make recommendations to the Assistant Secretary for the Office of Energy Efficiency and Renewable Energy regarding goals and objectives, programmatic and administrative policies, and to otherwise carry out the Board's responsibilities as designated in the State Energy Efficiency Programs Improvement Act of 1990 (Pub. L. 101–440).

Tentative Agenda: Receive an update on the activities of the STEAB's Task Forces, review letters and resolutions transmitted to EERE on behalf of the STEAB, and provide an update to the Board on routine business matters and other topics of interest, and discuss the upcoming October 2012 meeting with the Brookhaven National Laboratory.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Gil Sperling at the address or telephone number listed above. Requests to make oral comments must be received five days prior to the meeting; reasonable provision will be made to include requested topic(s) on the agenda. The Chair of the Board is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes: The minutes of the meeting will be available for public review and copying within 60 days on the STEAB Web site at: *www.steab.org.*

Issued at Washington, DC, on August 29, 2012.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2012–21812 Filed 9–4–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC12–130–000.

Applicants: Viridity Energy Inc.

Description: Viridity Energy, Inc. submits additional information in support of the Application filed on 8/3/12.

Filed Date: 8/28/12.

Accession Number: 20120828–5117.

Comments Due: 5 p.m. ET 9/4/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–1102–000; *AC12–38–000.*

Applicants: Entergy Services, Inc.

Description: Supplemental Information of Entergy Services, Inc.

Filed Date: 8/28/12.

Accession Number: 20120828–5135.
Comments Due: 5 p.m. ET 9/18/12.

Docket Numbers: ER12–1823–001.
Applicants: Southern California Edison Company.
Description: 2010 CWIP Compliance Filing to be effective 6/1/2010.
Filed Date: 8/28/12.
Accession Number: 20120828–5105.
Comments Due: 5 p.m. ET 9/18/12.

Docket Numbers: ER12–2535–000.
Applicants: PJM Interconnection, L.L.C.
Description: 2nd Quarter 2012 Updates to PJM Operating Agreement and RAA Membership List to be effective 6/30/2012.
Filed Date: 8/28/12.
Accession Number: 20120828–5102.
Comments Due: 5 p.m. ET 9/18/12.

Docket Numbers: ER12–2536–000.
Applicants: Frontier El Dorado Refining LLC.
Description: Application for Market Based Rate Authority to be effective 11/1/2012.
Filed Date: 8/28/12.
Accession Number: 20120828–5109.
Comments Due: 5 p.m. ET 9/18/12.

Docket Numbers: ER12–2537–000.
Applicants: Limon Wind, LLC.
Description: Limon Wind, LLC SFA and Assignment and Assumption Agreement to be effective 9/1/2012.
Filed Date: 8/28/12.
Accession Number: 20120828–5110.
Comments Due: 5 p.m. ET 9/18/12.

Docket Numbers: ER12–2538–000.
Applicants: Wolverine Power Supply Cooperative, Inc.
Description: Cancellation record no 1000 from filing 21 to be effective 8/28/2012.
Filed Date: 8/28/12.
Accession Number: 20120828–5111.
Comments Due: 5 p.m. ET 9/18/12.

Docket Numbers: ER12–2539–000.
Applicants: California Independent System Operator Corporation.
Description: 2012–08–28 Exceptional Dispatch & Residual Imbalance Energy Mitigation Amdt to be effective 8/29/2012.
Filed Date: 8/28/12.
Accession Number: 20120828–5112.
Comments Due: 5 p.m. ET 9/18/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 29, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21775 Filed 9–4–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–1021–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Request of Midwest Independent Transmission System Operator, Inc.
Filed Date: 8/23/12.
Accession Number: 20120823–5149.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–1161–002.
Applicants: Fibrominn LLC.
Description: FIBRO Compliance Filing of Revised Tariff and Request for Category 1 to be effective 8/29/2012.
Filed Date: 8/29/12.
Accession Number: 20120829–5073.
Comments Due: 5 p.m. ET 9/19/12.

Docket Numbers: ER12–2240–001.
Applicants: ALLETE, Inc.
Description: Revised MBR Tariff Filing to be effective 7/14/2012.
Filed Date: 8/29/12.
Accession Number: 20120829–5078.
Comments Due: 5 p.m. ET 9/19/12.

Docket Numbers: ER12–2374–000.
Applicants: Tall Bear Group, LLC.
Description: Supplemental Information of Tall Bear Group, LLC.
Filed Date: 8/21/12.
Accession Number: 20120821–5032.
Comments Due: 5 p.m. ET 9/7/12.

Docket Numbers: ER12–2540–000.
Applicants: Arizona Public Service Company.
Description: OMR Agreement between Electrical District 3 and Arizona Public Service Company to be effective 11/1/2012.
Filed Date: 8/29/12.
Accession Number: 20120829–5063.
Comments Due: 5 p.m. ET 9/19/12.

Docket Numbers: ER12–2541–000.
Applicants: Wolverine Power Supply Cooperative, Inc.
Description: Refile to be effective 8/29/2012.
Filed Date: 8/29/12.
Accession Number: 20120829–5072.
Comments Due: 5 p.m. ET 9/19/12.

Docket Numbers: ER12–2542–000.
Applicants: Prairie Rose Wind, LLC.
Description: Prairie Rose Wind, LLC submits tariff filing per 35.12: Prairie Rose Wind, LLC MBR Tariff to be effective 10/1/2012.
Filed Date: 8/29/12.
Accession Number: 20120829–5144.
Comments Due: 5 p.m. ET 9/19/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 29, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21776 Filed 9–4–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–2529–000]

KODE Novus II, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of KODE Novus II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal

Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 18, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 29, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21777 Filed 9–4–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–2536–000]

Frontier El Dorado Refining LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Frontier El Dorado Refining LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 18, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 29, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21774 Filed 9–4–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Pacific Northwest-Pacific Southwest Intertie Project—Rate Order No. WAPA–159

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of Order Temporarily Extending Transmission Service Rates.

SUMMARY: This action is to extend the existing Pacific Northwest-Pacific Southwest Intertie Project (Intertie) transmission services rates through September 30, 2013. The existing rates under Rate Schedules INT–FT4 and INT–NFT3 are set to expire September 30, 2012.

FOR FURTHER INFORMATION CONTACT: Mr. Jack Murray, Rates Manager, Desert Southwest Customer Service Regional Office, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005–6457, email *jmurray@wapa.gov.*

SUPPLEMENTARY INFORMATION: Rate Schedules INT–FT4 and INT–NFT3 for Rate Order No. WAPA–130 were approved by the Federal Energy Regulatory Commission (FERC) for a 5-year period through September 30, 2012.[1] Western Area Power Administration (Western) is proposing to extend the existing rates under Rate Schedules INT–FT4 and INT–NFT3 pursuant to 10 CFR 903.23(b). Extending these rate schedules through September 30, 2013, will provide time for Western to complete an on-going rate adjustment process. Western initiated a public process to adjust the Intertie transmission service rates via publication of a **Federal Register** notice on June 11, 2012 (77 FR 34381). Western is extending the existing transmission service rates to allow sufficient time to evaluate comments and determine if modifications to the proposed rates are warranted.

By Delegation Order No. 00–037.00, effective December 6, 2001, the

[1] WAPA–130 was approved by FERC on a final basis on March 18, 2008, in Docket No. EF08–5191–000 (122 FERC ¶ 62,236).

Secretary of Energy delegated: (1) The authority to develop power and transmission rates to Western's Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to FERC.

Western did not have a consultation and comment period and did not hold public information and comment forums for this extension, in accordance with 10 CFR 903.23(b). Following review of Western's proposal with DOE, I hereby approve Rate Order No. WAPA–159, which temporarily extends Rate Schedules INT–FT4 and INT–NFT3 for Intertie transmission service through September 30, 2013.

Dated: August 27, 2012.

Daniel B. Poneman,

Deputy Secretary.

Department of Energy

Deputy Secretary

In the Matter of: Western Area Power Administration, Rate Extension for the Pacific Northwest-Pacific Southwest Intertie Project, Transmission Services Rates; Rate Order No. WAPA–159; Order Confirming and Approving a Temporary Extension of the Pacific Northwest-Pacific Southwest Intertie Project Transmission Service Rates

Section 302(a) of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152) transferred to and vested in the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)), and other acts that specifically apply to the project involved.

By Delegation Order No. 00–037.00, effective December 6, 2001, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Administrator of the Western Area Power Administration (Western); (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to the Federal Energy Regulatory Commission (FERC). This rate extension is issued pursuant to the Delegation Order and DOE rate extension procedures at 10 CFR part 903.23(b).

Background

Rate Schedules INT–FT4 and INT–NFT3 for Rate Order No. WAPA–130 were approved for a 5-year period through September 30, 2012. FERC confirmed Rate Order No. WAPA–130 on a final basis on March 18, 2008, in Docket No. EF08–5191–000 (122 FERC ¶ 62,236).

Discussion

Western proposes to extend the existing rates under Rate Schedules INT–FT4 and INT–NFT3 pursuant to 10 CFR 903.23(b). The existing rates under Rate Schedules INT–FT4 and INT–NFT3 expire September 30, 2012. This temporary extension ensures these rates will remain effective until September 30, 2013, or until the rate schedules are superseded.

Western has initiated a formal process to adjust the transmission service rates via publication of a **Federal Register** notice on June 11, 2012 (77 FR 34381). The consultation and comment period will end September 10, 2012. Since the existing transmission service rates will expire on September 30, 2012, Western is extending the existing rates to allow sufficient time to evaluate comments and decide whether to revise the proposed rates.

Western did not have a consultation and comment period and did not hold public information and comment forums for this extension, in accordance with 10 CFR 903.23(b).

[FR Doc. 2012–21806 Filed 9–4–12; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9724–5]

Proposed RCRA Prospective Purchaser Agreement, Order on Consent and Covenant Not To Sue for a Portion of the Delphi Flint West Site, a/k/a Chevy in the Hole in Flint, Genesee County, MI

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with the RCRA Prospective Purchaser Agreement, notice is hereby given of a proposed administrative settlement concerning a portion of the Delphi Flint West Site, a/k/a Chevy in the Hole in Flint, Michigan with the following settling party: The City of Flint. The settlement requires the Settling Party to conduct various actions at the Property including: Conducting a Phase 1 and Baseline Assessment of the Property; capping and enhancement of the existing cover over contaminated soils; planting of trees and other native vegetation; installing walkways; installing new groundwater monitoring wells and the performance of groundwater monitoring at new and existing wells; executing and recording a Declaration of Restrictive Covenant and providing access to the Property.

The settlement includes a covenant not to sue the Settling Party pursuant to Sections 3008, 7003, or 9006 of RCRA, with respect to the Existing Contamination. Existing Contamination is defined as any Waste Material present or existing on or under the Property as of the Effective Date of the Settlement Agreement; any Waste Material that migrated from the Property prior to the Effective Date; and any Waste Material presently at the Site that migrates onto, on, under, or from the Property after the Effective Date.

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at the EPA, Region 5, Records Center, 77 W. Jackson Blvd., 7th Fl., Chicago, Illinois 60604.

DATES: Comments must be submitted on or before 30 days from date of publication.

ADDRESSES: The proposed settlement is available for public inspection at the EPA, Region 5, Records Center, 77 W. Jackson Blvd., 7th Fl., Chicago, Illinois 60604. A copy of the proposed settlement may be obtained from Peter Felitti, Assoc. Regional Counsel, EPA, Office of Regional Counsel, Region 5, 77 W. Jackson Blvd., mail code: C–14J, Chicago, Illinois 60604. Comments should reference the Delphi Flint West Site, Flint, Michigan and EPA Docket No. and should be addressed to Peter Felitti, Assoc. Regional Counsel, EPA, Office of Regional Counsel, Region 5, 77 W. Jackson Blvd., mail code: C–14J, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Peter Felitti, Assoc. Regional Counsel, EPA, Office of Regional Counsel, Region

5, 77 W. Jackson Blvd., mail code: C–14J, Chicago, Illinois 60604.

SUPPLEMENTARY INFORMATION: The Respondent proposes to acquire ownership of specified parcels of the former RCRA hazardous waste treatment, storage, or disposal facility known as the Delphi Flint West Site, located at 300 N. Chevrolet Avenue, Flint, Michigan (Site). The EPA identification number for the Site is MID 005 356 654.

Dated: June 29, 2012.

Margaret M. Guerriero,

Director, Land and Chemicals Division.

[FR Doc. 2012–21841 Filed 9–4–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 92–237; DA 12–1412]

Next Meeting of the North American Numbering Council

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission released a public notice announcing the meeting and agenda of the North American Numbering Council (NANC). The intended effect of this action is to make the public aware of the NANC's next meeting and agenda.

DATES: Thursday, September 20, 2012, 10 a.m.

ADDRESSES: Requests to make an oral statement or provide written comments to the NANC should be sent to Deborah Blue, Competition Policy Division, Wireline Competition Bureau, Federal Communications Commission, Portals II, 445 12th Street SW., Room 5–C162, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Deborah Blue, Special Assistant to the Designated Federal Officer (DFO) at (202) 418–1466 or *Deborah.Blue@fcc.gov.* The fax number is: (202) 418–1413. The TTY number is: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document in CC Docket No. 92–237, DA 12–1412 released August 29, 2012. The complete text in this document is available for public inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The document my also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone (800) 378–3160 or (202) 863–2893, facsimile (202) 863–2898, or via the Internet at *http://www.bcpiweb.com.* It is available on the Commission's Web site at *http://www.fcc.gov.*

The North American Numbering Council (NANC) has scheduled a meeting to be held Thursday, September 20, 2012, from 10 a.m. until 2 p.m. The meeting will be held at the Federal Communications Commission, Portals II, 445 12th Street SW., Room TW–C305, Washington, DC. This meeting is open to members of the general public. The FCC will attempt to accommodate as many participants as possible. The public may submit written statements to the NANC, which must be received two business days before the meeting. In addition, oral statements at the meeting by parties or entities not represented on the NANC will be permitted to the extent time permits. Such statements will be limited to five minutes in length by any one party or entity, and requests to make an oral statement must be received two business days before the meeting.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty). Reasonable accommodations for people with disabilities are available upon request. Include a description of the accommodation you will need, including as much detail as you can. Also include a way we can contact you if we need more information. Please allow at least five days advance notice; last minute requests will be accepted, but may be impossible to fill.

Proposed Agenda: Thursday, September 20, 2012, 10 a.m. *

1. Announcements and Recent News
2. Approval of Transcript
   —Meeting of June 7, 2012
3. Report of the North American Numbering Plan Administrator (NANPA)
4. Report of the National Thousands Block Pooling Administrator (PA)
5. Report of the Numbering Oversight Working Group (NOWG)
6. Report of the North American Numbering Plan Billing and Collection (NANP B&C) Agent
7. Report of the Billing and Collection Working Group (B&C WG)
8. Report of the North American Portability Management LLC (NAPM LLC)
9. Report of the LNPA Selection Working Group (SWG)
10. Report of the Local Number Portability Administration (LNPA) Working Group
11. Status of the Industry Numbering Committee (INC) activities
12. Report of the Future of Numbering Working Group (FoN WG)
13. Summary of Action Items
14. Public Comments and Participation (5 minutes per speaker)
15. Other Business

Adjourn no later than 2 p.m.

* The Agenda may be modified at the discretion of the NANC Chairman with the approval of the DFO.

Federal Communications Commission.

Marilyn Jones,

Attorney, Wireline Competition Bureau.

[FR Doc. 2012–21848 Filed 9–4–12; 8:45 am]

BILLING CODE 6712–01–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 September 18, 2012.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President), 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Rebecca Watson Vizard, St. Joseph Louisiana; Michael Rene Vizard, St. Joseph, Louisiana; Sarah Scott Vizard, New Orleans, Louisiana; Michael Ross Vizard, Nashville, Tennessee; and William Wade Watson, St. Joseph, Louisiana, (collectively known as the ''Vizard Family Group'') to retain of the shares of, and thereby control of, BSJ Bancshares, Inc., St. Joseph, Louisiana, and indirectly control Cross Keys Bank, St. Joseph, Louisiana.

Dated: Board of Governors of the Federal Reserve System, August 30, 2012.

Margaret Shanks,

Associate Secretary and Ombudsman.

[FR Doc. 2012–21808 Filed 9–4–12; 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 September 28, 2012.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) P.O. Box 55882, Boston, Massachusetts 02106–2204:

1. Eastern Bank Corporation, Boston, Massachusetts, to acquire Campello Bancorp, and its subsidiary bank, The Community Bank, A Massachusetts Co-operative Bank, both of Brockton, Massachusetts.

Dated: Board of Governors of the Federal Reserve System, August 30, 2012.

Margaret Shanks,

Associate Secretary and Ombudsman.

[FR Doc. 2012–21810 Filed 9–4–12; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2012–02; Docket No. 2012–0004; Sequence 5]

Maximum Per Diem Rates for the Continental United States (CONUS)

AGENCY: Office of Governmentwide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of GSA Per Diem Bulletin FTR 13–01, Fiscal Year (FY) 2013 Continental United States (CONUS) per diem rates.

SUMMARY: The General Services Administration's (GSA) Fiscal Year (FY) 2013 per diem review has resulted in lodging and meal allowance changes for certain locations within the continental United States (CONUS) to provide for reimbursement of Federal employees' expenses covered by per diem. All current non-standard area (NSA) lodging per diem rates will remain at FY 2012 levels for FY 2013. The standard lodging per diem rate of $77 will also continue to remain the same for FY 2013. The meals and incidental expense tiers remain unchanged for FY 2013 and range from $46–$71. GSA identified 10 new NSAs: Bakersfield/Ridgecrest, California (Kern County); Stockton, California (San Joaquin County); Hancock and Pearl River Counties in Mississippi; Sidney/Glendive, Montana (Richland and Dawson Counties); Dickinson/Beulah, North Dakota (Stark, Mercer, and Billings Counties); Minot, North Dakota (Ward County); Williston, North Dakota (Williams, Mountrail, and McKenzie Counties); Carlsbad, New Mexico (Eddy County); Watertown, New York (Jefferson County); and Pasco, Washington (Franklin County). The CONUS per diem rates prescribed in Bulletin 13–01 may be found at *www.gsa.gov/perdiem*. GSA bases the lodging rates on the average daily rate that the lodging industry reports to an independent organization. If a lodging rate or a per diem rate is insufficient to meet necessary expenses in any given location, Federal executive agencies can request that GSA review that location. Please review numbers five and six of GSA's per diem Frequently Asked Questions at (*www.gsa.gov/perdiemfaqs*) for more information on the special review process.

In addition, the Federal Travel Regulation allows for actual expense reimbursement as provided in §§ 301–11.300 through 301–11.306.

DATES: This notice is effective on September 5, 2012 and applies for travel performed on or after October 1, 2012.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Jill Denning, Office of Governmentwide Policy, Office of Asset and Transportation Management, at 202–208–7642, or by email at *travelpolicy@gsa.gov*. Please cite Notice of GSA Per Diem Bulletin FTR 13–01.

SUPPLEMENTARY INFORMATION:

Background

GSA issues and publishes the CONUS per diem rates, formerly published in Appendix A to 41 CFR Chapter 301, solely on the Internet at *www.gsa.gov/perdiem*. This process, implemented in 2003, ensures more timely changes in per diem rates established by GSA for Federal employees on official travel within CONUS. Notices published periodically in the **Federal Register**, such as this one, now constitute the only notification of revisions in CONUS per diem rates to agencies.

Dated: August 27, 2012.

Janet Dobbs,

Deputy Associate Administrator, Office of Asset and Transportation Management.

[FR Doc. 2012–21854 Filed 9–4–12; 8:45 am]

BILLING CODE 6820–14–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.

Enhanced Nanoparticle Cell-Entry for Cancer Therapy

Description of Technology: Nanoparticles are being used as a method of drug delivery for the treatment of several diseases, cancer in particular. While the use and versatility of these particles have increased over the years, the speed with which these particles can enter the cells and deliver the drugs remains challenging.

This technology describes a method of modifying nanoparticles to markedly enhance their entry into cancer cells and their delivery of therapeutic drugs. The nanoparticles use a multi-shell calcium phosphate nanocore designed with target-specific siRNA and an endocytosis-enhancing agent. The inventors have shown that the intravenous systemic administration of the enhanced nanoparticles noticeably increases nanoparticle cell-entry along with concomitant delivery of siRNA to cancer cells in vivo. They further demonstrate that the composite calcium phosphate nanoparticle delivery of anti-cancer therapy can preferentially target in vivo tumors and cause tumor growth arrest. Consequently, these modified nanoparticles can exert a greater effect on cancer cells.

Potential Commercial Applications:

- Nanoparticle delivery of therapeutic treatments to cancers cells.
- Nanoparticle delivery of imaging agents for the identification and monitoring of tumor cells.

Competitive Advantages:

- Preferentially taken up by cancer cells and not normal cells
- Faster uptake into cells than other nanoparticles
- Tissue and/or cell specific
- Can be customized for targeted therapy
- Extremely versatile—can transport a variety of therapeutic agents and the constructs can incorporate siRNA, chemotherapy agents, targeted drugs, pro-drugs, tracers, and radioactive molecules.

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventors: King F. Kwong and Lisa A. Tobin (NCI)

Intellectual Property: HHS Reference No. E–164–2012/0 — U.S. Patent Application No. 61/648,735 filed 18 May 2012

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov*

Collaborative Research Opportunity: The Kwong Laboratory, Surgery Branch, NCI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize nanoparticles in anti-cancer therapy. For collaboration opportunities, please contact King F. Kwong, M.D. at *kwongk2@mail.nih.gov.*

Therapy for Cancer and Other Diseases Associated With Angiogenesis Driven by Vascular Endothelial Growth Factor-A

Description of Technology: Vascular Endothelial Growth Factor-A (VEGF–A) is an angiogenic agent that drives blood vessel formation in solid tumors and other diseases, such as macular degeneration and diabetic retinopathy. Several therapies that target the ability of VEGF to stimulate angiogenesis have been approved. These therapies regulate VEGF–A activity by binding VEGF–A, thereby blocking VEGF–A from binding to its receptor on target cells. This technology utilizes a different approach to regulating VEGF–A activity by providing a VEGF–A protein antagonist that is produced by engineering native VEGF–A protein. The engineered VEGF–A protein disrupts heparan sulfate proteoglycan binding to the VEGF–A/VEGF receptor complex, an activity that is essential for the angiogenic properties of native VEGF–A. The antagonist has a binding affinity for both FLT–1 (VEGFR–1) and KDR/FLK–1 (VEGFR–2) that is equivalent to that of native VEGF–A and specifically antagonizes all VEGF–A-stimulated signaling events.

Potential Commercial Applications: Therapy for solid tumors or other diseases associated with angiogenic activity modulated by Vascular Endothelial Growth Factor-A expression.

Competitive Advantages:

- Specificity/Selectivity
- Cost-effectiveness in production

Development Stage:

- Early-stage
- In vitro data available
- In vivo data available (animal)

Inventors: Donald P. Bottaro and Fabiola Cecchi (NCI)

Intellectual Property: HHS Reference No. E–230–2011/0 — U.S. Patent Application No. 61/639,230 filed 27 Apr 2012

Licensing Contact: Susan S. Rucker, CLP; 301–435–4478; *ruckersu@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute's Urologic Oncology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize antagonists to VEGF–A and hepatocyte growth factor (HGF) that block signal transduction and associated cellular responses by competitive displacement of native growth factors and concomitant disruption of heparan sulfate proteoglycan binding to the growth factor-receptor complex. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Methods for Identifying and Isolating Pancreatic Precursor Cells

Description of Technology: Diabetes results when beta cell performance is compromised through loss of cells or reduced cell function. Anti-diabetic drugs that stimulate insulin production, such as sulfonylureas and meglitinides, have limited efficacy when beta cell responsiveness is deficient. There exists a critical need for methods to increase beta cell responsiveness by enhancing cell function or by increasing beta cell numbers.

Notch has been shown to play an important role in pancreas development and diabetes and NIA investigators discovered that pancreatic precursor cells can be identified and isolated using Notch and its ligands. This technology describes methods for identifying pancreatic precursor cells using a Notch ligand, as well as methods for isolating pancreatic precursor cells from a pancreatic cell sample, such as pancreatic islet cells or pancreatic extra-islet cells from a diabetic patient.

Potential Commercial Applications:

- Isolation and expansion of pancreatic progenitor cells for diabetes therapy
- Development of a diagnostic test to monitor beta cell function

Competitive Advantages:

- New diagnostic strategies for diabetes
- Potential use in regenerative medicine (pancreatic precursor cells recently have been shown to have the potential to develop into other cell types)

Development Stage:

- Early-stage
- In vitro data available

Inventors: Josephine M. Egan and Maire Doyle (NIA)

Publication: Kim W, *et al.* Notch signaling in pancreatic endocrine cell and diabetes. Biochem Biophys Res Commun. 2010 Feb 12;392(3):247–51. [PMID 20035712]

Intellectual Property: HHS Reference No. E–262–2003/0 —

- U.S. Provisional Application No. 60/590,281 filed 22 Jul 2004
- PCT Application No. PCT/US2005/026207 filed 22 Jul 2005, which published as WO 2006/023209 on 02 Mar 2006

• U.S. Patent No. 7,888,116 issued 15 Feb 2012

Licensing Contact: Tara L. Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov*

Dated: August 28, 2012.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2012–21749 Filed 9–4–12; 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: Healthcare Delivery and Methodologies Integrated Review Group, Health Disparities and Equity Promotion Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Delia Olufokunbi Sam, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, 301–435–0684, *olufokunbisamd@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group, Biomedical Imaging Technology B Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Lee Rosen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435–1171. *rosenl@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Hypersensitivity, Autoimmune, and Immune-mediated Diseases Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington Dupont Circle, 1143 New Hampshire Avenue, Washington, DC 20037.

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: Cell Biology Integrated Review Group, Membrane Biology and Protein Processing Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person: Janet M Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301–806–2765, *larkinja@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Biochemistry and Biophysics of Membranes Study Section.

Date: October 4, 2012.

Time: 8 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Macromolecular Structure and Function C Study Section.

Date: October 4, 2012.

Time: 8 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Washington, 1515 Rhode Island Ave. NW., Washington, DC 20005.

Contact Person: William A. Greenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435–1726, *greenbergwa@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Transplantation, Tolerance, and Tumor Immunology Study Section.

Date: October 4–5, 2012.

Time: 8a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Jin Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4199, MSC 7812, Bethesda, MD 20892, 301–435–1230, *jh377p@nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Skeletal Biology Structure and Regeneration Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Daniel F McDonald, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, MSC 7814, Bethesda, MD 20892, (301) 435–1215, *mcdonald@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group, Biomedical Imaging Technology A Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Behrouz Shabestari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5126, MSC 7854, Bethesda, MD 20892, (301) 435–2409, *shabestb@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group, Kidney, Nutrition, Obesity and Diabetes Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Churchill Hotel, 1914 Connecticut Avenue NW., Washington, DC 20009.

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: Risk, Prevention and Health Behavior Integrated Review Group, Risk, Prevention and Intervention for Addictions Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Mark Center, 5000 Seminary Road, Alexandria, VA 22311.

Contact Person: Gabriel B Fosu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435–3562, *fosug@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group, Kidney Molecular Biology and Genitourinary Organ Development.

Date: October 4, 2012.

Time: 8 a.m. to 6 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: Ryan G Morris, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301–435–1501, *morrisr@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Synthetic and Biological Chemistry B Study Section.

Date: October 4–5, 2012.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Kathryn M Koeller, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301–435–2681, *koellerk@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Immunity and Host Defense Study Section.

Date: October 4–5, 2012.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Patrick K Lai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2215, MSC 7812, Bethesda, MD 20892, 301–435–1052, *laip@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group,Cellular and Molecular Immunology—A Study Section.

Date: October 4–5, 2012.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Baltimore Marriott Inner Harbor at Camden Yards, 110 South Eutaw Street, Baltimore, MD 21201.

Contact Person: David B Winter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, 301–435–1152, *dwinter@mail.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Skeletal Muscle and Exercise Physiology Study Section.

Date: October 4–5, 2012.

Time: 8:30 a.m. to 6 p.m.

*Agenda:*To review and evaluate grant applications

*Place:*Virginian Suites, 1500 Arlington Boulevard, Arlington, VA 22209.

Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, *ingrahamrh@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, AREA (R15) Applications in Language, Speech, and Voice.

Date: October 4, 2012.

Time: 2 p.m. to 3:30 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: Weijia Ni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 237–9918, *niw@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: August 29, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–21748 Filed 9–4–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, BTRC P41 Review.

Date: October 10–12, 2012.

Time: 6 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Marriott Milwaukee Brookfield, 16865 West Bluemound Road, Brookfield, WI 53008.

Contact Person: Manana Sukhareva, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301–451–3397, *sukharem@mail.nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, 2013–01 K Award Application Review.

Date: October 22, 2012.

Time: 10 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, 301–496–4773, *zhour@mail.nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, P41 Review 2013–01.

Date: October 24–26, 2012.

Time: 6 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Minneapolis Metrodome, 1500 Washington Avenue South, Minneapolis, MN 55454.

Contact Person: Ruth Grossman, DDS, Scientific Review Officer, National Institute

of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 960, Bethesda, MD 20892, 301–496–8775, *grossmanrs@mail.nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, BTRC P41 Review.

Date: November 7–9, 2012.

Time: 6 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Atrium Hotel, 18700 MacArthur Blvd., Irvine, CA 92612.

Contact Person: Manana Sukhareva, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301–451–3397, *sukharem@mail.nih.gov.*

Dated: August 29, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–21750 Filed 9–4–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Multi-Center Clinical Trial Review.

Date: September 14, 2012.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Neutrophil Dysfunction in Early Onset Crohn's Disease.

Date: September 27, 2012.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *ls38z@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 29, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–21752 Filed 9–4–12; 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: Biobehavioral and Behavioral Processes Integrated Review Group, Cognition and Perception Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 10 a.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Dana Jeffrey Plude, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, (301) 435–2309, *pluded@csr.nih.gov.*

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group, Neuroscience and Ophthalmic Imaging Technologies Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Yvonne Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, *bennetty@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group, Biobehavioral Mechanisms of Emotion, Stress and Health Study Section.

Date: October 4–5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Maribeth Champoux, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, MSC 7848, Bethesda, MD 20892, (301) 594–3163, *champoum@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group, Clinical Molecular Imaging and Probe Development.

Date: October 5, 2012.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Eileen W Bradley, DSC, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5100, MSC 7854, Bethesda, MD 20892, (301) 435–1179, *bradleye@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group, Health Services Organization and Delivery Study Section.

Date: October 5, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Kathy Salaita, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7770, Bethesda, MD 20892, 301–451–8504, *salaitak@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group,

Behavioral Genetics and Epidemiology Study Section.

Date: October 5, 2012.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street, NW., Washington, DC 20037.

Contact Person: George Vogler, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, Bethesda, MD 20892, 301–435–0694.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Academic Research Enhancement Award (Parent R15) AREA Review.

Date: October 5, 2012.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Maribeth Champoux, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, MSC 7848, Bethesda, MD 20892, 301–594–3163, *champoum@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: October 5, 2012.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Dana Jeffrey Plude, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, *pluded@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PA11–260: Research Project Grant (Parent R01).

Date: October 5, 2012.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Riverwalk, 420 W. Market Street, San Antonio, TX 78205.

Contact Person: Lee S Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301–435–0677, *mannl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–11–216: Early Phase Clinical Trials in Imaging and Image-Guided Interventions.

Date: October 5, 2012.

Time: 2:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: David L Williams, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7854, Bethesda, MD 20892, (301) 435–1174, *williamsdl2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Shared Instrumentation: Grant Program.

Date: October 5, 2012.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Yvonne Bennett, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, *bennetty@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Collaborative: R01s For Clinical And Services Studies of Mental Disorders.

Date: October 5, 2012.

Time: 4 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Yvonne Bennett, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, *bennetty@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: August 29, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–21754 Filed 9–4–12; 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: Biobehavioral and Behavioral Processes Integrated Review Group, Motor Function, Speech and Rehabilitation Study Section.

Date: October 1, 2012.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW., Washington, DC 20008.

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, 301–402–4411, *tianbi@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Aging Systems and Geriatrics Study Section.

Date: October 8, 2012.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: James P Harwood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5168, MSC 7840, Bethesda, MD 20892, 301–435–1256, *harwoodj@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Virology—B Study Section.

Date: October 8–9, 2012.

Time: 8:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 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.*

Name of Committee: Vascular and Hematology Integrated Review Group, Molecular and Cellular Hematology Study Section.

Date: October 9–10, 2012.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn by Marriott—Seattle Downtown, 800 Fairview Avenue North, Seattle, WA 98109.

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: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Macromolecular Structure and Function D Study Section.

Date: October 9, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: James W Mack, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154,

MSC 7806, Bethesda, MD 20892, (301) 435–2037, *mackj2@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences, Integrated Review Group, Molecular and Cellular Endocrinology Study Section.

Date: October 9, 2012.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: John Bleasdale, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170 MSC 7892, Bethesda, MD 20892, 301–435–4514, *bleasdaleje@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Auditory System Study Section.

Date: October 9, 2012.

Time: 8 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: Lynn E Luethke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 806–3323, *luethkel@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group, Pathobiology of Kidney Disease Study Section.

Date: October 9–10, 2012.

Time: 8 a.m. to 6 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: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301–435–1198, *sahaia@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Cell Biology.

Date: October 9, 2012.

Time: 11 a.m. to 1 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: Wallace Ip, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, 301–435–1191, *ipws@mail.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: August 29, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–21753 Filed 9–4–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, ZEB1 OSR–D(J2) P Tissue Engineering Resource Center (P41).

Date: November 7–9, 2012.

Time: 6 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Best Western Hotel III Tria, 220 Alewife Brook Parkway, Cambridge, MA 02138.

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Room 959, Bethesda, MD 20892, 301–451–3398, *hayesj@mail.nih.gov.*

Dated: August 29, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–21751 Filed 9–4–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Final Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

SUMMARY: On March 4, 2009, the National Institutes of Health (NIH) Office of Biotechnology Activities, Office of Science Policy (NIH/OBA) published a proposal in the **Federal Register** (74 FR 9411) to revise the *NIH Guidelines* in two regards. The first was to address biosafety considerations for research with synthetic nucleic acids. The proposal modified the scope of the *NIH Guidelines* specifically to cover certain basic and clinical research with nucleic acid molecules created solely by synthetic means. The second proposed revision was to modify the criteria for determining whether an experiment to introduce drug resistance into a microorganism must be reviewed by the Recombinant DNA Advisory Committee (RAC) and approved by the NIH Director (as a Major Action under Section III–A–1–a of the *NIH Guidelines*). Comments submitted were discussed at the ''NIH Public Consultation on Proposed Changes to the *NIH Guidelines* for Synthetic Nucleic Acids'' on June 23, 2009 (*http://oba.od.nih.gov/rdna_rac/rac_pub_con.html''.*

This notice sets forth final changes to the *NIH Guidelines* regarding those two proposals. The scope of the *NIH Guidelines* is being modified to cover certain classes of basic and clinical research with synthetic nucleic acids while exempting others. As discussed herein, the majority of research with synthetic nucleic acids that are not designed to replicate does not raise significant biosafety concerns that warrant oversight under the *NIH Guidelines*. Because of the modification of the scope of the *NIH Guidelines*, the title of the *NIH Guidelines* will be revised from *NIH Guidelines for Research Involving Recombinant DNA Molecules* to *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules.*

These changes also clarify the criteria for determining whether an experiment to introduce drug resistance into a microorganism raises sufficient public health issues to warrant the experiment being reviewed by the RAC and approved by the NIH Director under Section III–A–1–a of the *NIH Guidelines*. While the current criteria for determining whether an experiment requires review under Section III–A–1–a are being retained, additional language is being added regarding the assessment of whether a drug is therapeutically useful. In addition, NIH/OBA has clarified that Institutional Biosafety Committees (IBCs) can consult with NIH/OBA regarding a specific experiment that does not meet the criteria for review under Section III–A–1–a but nonetheless raises important public health issues. Finally, a section is added to give NIH/OBA the authority

to approve new experiments utilizing the same drug resistance trait and organism used in an experiment previously reviewed by the RAC and approved by the NIH Director.

In March 2009, NIH/OBA also proposed changes to Section III-E–1 of the *NIH Guidelines*, which sets containment for recombinant experiments involving two-thirds or less of the genome of certain viruses in tissue culture. In response to the comments on the proposed changes to Section III–E–1, NIH/OBA revised the proposal and published a notice for comment on April 22, 2010 (75 FR 21008). Comments received in response to this notice were discussed at the June 16, 2010, public meeting of the RAC and additional discussions of subsequent revisions to the proposed changes took place at the June 7, 2011, meeting of the RAC. As these changes are not yet finalized, NIH/OBA will move forward with the other changes outlined below pending finalization of changes to Section III–E–1.

DATES: These changes are effective March 5, 2013. All ongoing and proposed experiments that will be newly subject to these amended *NIH Guidelines* will need to be registered by the Principal Investigator with the IBC by the effective date listed above. The six-month time frame was deemed sufficient to allow institutions to develop new procedures, as well as outreach and training for investigators whose research will now be subject to the *NIH Guidelines*. While NIH/OBA does not anticipate a significant increase in experiments subject to the *NIH Guidelines,* it is important that institutions be afforded ample time to implement effectively these changes.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional information about these proposed changes, please contact NIH/OBA by e-mail at *oba@od.nih.gov,* by telephone at 301–496–9838, by fax to 301–496–9839, or by mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892.

SUPPLEMENTARY INFORMATION: As discussed in more detail in the March 2009 **Federal Register** notice, nucleic acid (NA) synthesis technology, in combination with other rapidly evolving capabilities in the life sciences, such as directed molecular evolution and viral reverse genetics, has the potential to accelerate scientific discovery, yield new therapeutics for disease, and facilitate the modification of existing organisms or the creation of new organisms, including pathogens.

The impetus for these changes to the *NIH Guidelines* is two-fold: (1) Recognition that appropriate biosafety containment of an agent is critical regardless of the technology used to generate that agent (i.e., recombinant DNA or synthetic biology), and (2) a recommendation from the National Science Advisory Board for Biosecurity (NSABB). The NSABB was formed to advise the U.S. Government on strategies for minimizing the potential for misuse of information, products, and technologies from life sciences research, taking into consideration both national security concerns and the needs of the research community. In 2006, the NSABB published a report titled ''Addressing Biosecurity Concerns Related to the Synthesis of Select Agents'' (available at *http://oba.od.nih.gov/biosecurity/pdf/Final_NSABB_Report_on_Synthetic_Genomics.pdf).*

In that report, the NSABB noted that practitioners of synthetic genomics or researchers using synthetic nucleic acids in the emerging field of synthetic biology are not necessarily biologists and, therefore, may not have been trained in biosafety. These researchers may be uncertain about how to conduct a risk assessment, as required for research currently subject to the *NIH Guidelines*, and when to have their work undergo review by an IBC. The NSABB report recommended that the U.S. Government ''examine the language and implementation of current biosafety guidance to ensure that such guidelines and regulations provide adequate guidance for working with synthetically derived DNA and are understood by all those working in areas addressed by the guidelines.''

The recommendation on the need for examination of existing biosafety guidance was accepted by the U.S. Government with the understanding that implementation would be through examination and modification of the *NIH Guidelines*, as appropriate. The changes to the *NIH Guidelines* would then be cross-referenced in the joint publication by the U.S. Centers for Disease Control and Prevention and NIH titled: *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) (available at *http://www.cdc.gov/biosafety/publications/bmbl5/index.htm*).

As stated in the March 2009 **Federal Register** notice, these changes were developed in consultation with the RAC. A total of 50 comments were received in response to the March 2009 **Federal Register** notice from individuals, academic and government researchers, private pharmaceutical companies and trade organizations that represent the biosafety community, researchers in gene and cell therapy, and microbiologists. In addition, a day-long public discussion of the proposed changes was held on June 23, 2009, in Arlington, Virginia. The agenda and webcast of that meeting are available at the following URL: *http://oba.od.nih.gov/rdna_rac/rac_pub_con.html.*

The *NIH Guidelines* currently apply to all recombinant DNA research that is conducted at or sponsored by institutions that receive NIH funding for any research involving recombinant DNA. In addition, some federal agencies, including the U.S. Departments of Energy, Veterans Affairs, and Agriculture, currently have policies in place stating that all recombinant DNA research conducted by or funded by these agencies must comply with the *NIH Guidelines*. While the *NIH Guidelines* may not apply to all Government-funded and privately funded research, it may be used as a tool for the entire research community to understand the potential biosafety implications of this type of research.

Summary of Comments

All of the comments submitted in response to the **Federal Register** notice are available for review on the NIH/OBA Web site at: *http://oba.od.nih.gov/rdna_rac/rac_pub_con.html.* The public comments generally fell into two groups: (1) Comments on the proposed changes regarding research with synthetic nucleic acids and (2) comments on the proposed changes to Section III-A–1-a (experiments involving the deliberate transfer of a drug resistance trait into microorganisms). Overall, the comments favored modifying the scope of the *NIH Guidelines* to include research with synthetic nucleic acids. As one commenter noted, ''With the ability to chemically synthesize entire genes or substantial portions of viral genomes, such synthetic entities would have the potential to (1) Express proteins, (2) replicate in cells, and (3) integrate into the host genome. As such, these entities warrant the same scrutiny as traditional recombinant DNA with respect to studies being conducted in [a] research laboratory and when being considered for use in human subjects, and thus should be subject to NIH/OBA registration and RAC review.'' However, there were concerns that the proposed amendments would lead to oversight of the synthesis of small nucleic acid primers used in basic research. This was a misinterpretation of the proposed

changes; research with nucleic acids that are not in cells or organisms is not subject to the *NIH Guidelines* and the proposed exemption for non-replicating synthetic nucleic acids, discussed herein, would also preclude these constructs from being subject to the *NIH Guidelines*.

Most of the comments regarding synthetic nucleic acids and the *NIH Guidelines* focused on whether certain synthetic nucleic acids used in human clinical trials should also be exempt from the *NIH Guidelines* and in particular from the requirements for submission and review of human gene transfer trials (as outlined in Appendix M of the *NIH Guidelines*). These comments directly addressed a question posed in the March 2009 **Federal Register**: ''For human gene transfer research, are there classes of non-replicating, synthetic molecules that should be exempt due to lower potential risk (*e.g.* antisense RNA, RNAi)? If so, what criteria should be applied to determine such classes?''

Many of the respondents to this question were involved in developing such products to be used as therapeutics or represent companies and investigators involved in such research. As discussed in more detail herein, the respondents argued that small non-replicating synthetic nucleic acids used as therapeutics are more akin to small molecule drugs than traditional gene transfer agents. A session at the June 23, 2009, public consultation focused on whether certain non-replicating synthetic nucleic acids used in human clinical trials should be exempted from the *NIH Guidelines* due to characteristics that are distinct from recombinant molecules as currently defined in the *NIH Guidelines.*

The second set of comments focused on the proposed changes to Section III–A–1–a, which addresses certain experiments that involve the introduction of drug resistance into microorganisms. The comments uniformly disagreed with the proposed changes stating that the new proposed criteria were too broad and would lead to federal review of experiments that did not raise public health issues warranting heightened scrutiny. Moreover, they stated that there is no evidence that the current language had failed to serve the public health and therefore the changes were not warranted given the potential problems raised by expanding such review. As discussed herein, the III–A–1–a language in the current *NIH Guidelines* (October 2011 version) will be retained.

The following paragraphs review (1) The specific comments received on each section of the *NIH Guidelines,* both the written comments and those received at public meeting; (2) NIH/OBA's response to those comments; and (3) the final changes to the *NIH Guidelines.*

Amendments to the NIH Guidelines

In order to ensure that biosafety considerations of synthetic biology research are addressed appropriately, changes are being made to the following sections of the *NIH Guidelines:*
the NIH Guidelines

Section I. Scope of the NIH Guidelines
Section I–B. Definition of Recombinant DNA
Section I–C. General Applicability
Section III–C. Experiments Involving the Deliberate Transfer of Recombinant DNA,or DNA or RNA Derived from Recombinant DNA, into One or More Human Research Participants
Section III–F. Exempt Experiments
Section IV–A. Policy
Section II–A–3. Comprehensive Risk Assessment

As discussed herein, the *NIH Guidelines* will no longer be limited to oversight of research with recombinant nucleic acid molecules but will also address research with certain synthetic nucleic acids. Throughout the *NIH Guidelines,* the term ''recombinant DNA molecules'' will be replaced with ''recombinant or synthetic nucleic acids,'' which will encompass research with either recombinant or synthetic or both types of nucleic acids. This change will not be made to the name of the Recombinant DNA Advisory Committee, although the Committee will provide advice on both recombinant and synthetic nucleic acid research.

In addition to the changes being made specifically to address research with synthetic nucleic acids, the following sections are also being revised:

Section III–A–1. Major Actions under the NIH Guidelines
Section III–B. Experiments that Require NIH/OBA and Institutional Biosafety Committee Approval before Initiation

Title of the NIH Guidelines

The title of the document will be changed from the *NIH Guidelines for Research Involving Recombinant DNA Molecules* to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.* NIH received no comments regarding the proposed change to the title of the *NIH Guidelines.*

Section I. Scope of the NIH Guidelines

To clarify the applicability of the *NIH Guidelines* to research involving synthetic nucleic acids, modifications were proposed to Section I, Scope of the *NIH Guidelines.* Section I–A (Purpose) of the *NIH Guidelines* previously stated:

> The purpose of the *NIH Guidelines* is to specify practices for constructing and handling: (i) recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules.

Section I–A was proposed to be changed to:

> The purpose of the *NIH Guidelines* is to specify the practices for constructing and handling: (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those wholly or partially containing functional equivalents of nucleotides, and (iii) organisms and viruses containing such molecules.

NIH/OBA received one comment regarding the use of the term ''constructing'' in reference to synthetic nucleic acids. The concern was that the *NIH Guidelines* would govern the chemical synthesis of nucleic acids. However, this language was not a revision to the original scope of the *NIH Guidelines.* While the scope of the *NIH Guidelines* has always referred to ''constructing'' or construction of recombinant nucleic acids, the *NIH Guidelines* then exempts research with nucleic acids that are not contained in cells, organisms, or viruses. Therefore, the chemical synthesis of nucleic acids not placed in cells, organisms, or viruses would likewise be exempt; the *NIH Guidelines* will only apply once synthetic nucleic acids are placed in a biological system.

NIH/OBA also received comments requesting a definition of the term ''functional equivalents of nucleotides.'' This term was intended to capture synthetic nucleic acids that contain nucleotides that have been chemically modified and do not have the same chemical structure as the nucleotides in naturally occurring nucleic acids (see, for example, S. Benner, Redesigning Genetics. *Science.* 306, 625–626 (2004)). For clarity, the term ''functional equivalents'' has been changed to ''nucleotides that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules.''

Thus, the amended Section 1–A Purpose will state:

> Section 1–A. Purpose
> The purpose of the *NIH Guidelines* is to specify the practices for constructing and handling: (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules.

As a result of these modifications, the *NIH Guidelines* will apply (unless otherwise exempted by other sections of the *NIH Guidelines, e.g.* III–F) to both recombinant and synthetically derived nucleic acids, including those that are chemically or otherwise modified analogs of nucleotides (*e.g.* , morpholinos).

Section I–B. Definition of Recombinant Nucleic Acids

The current definition of a recombinant DNA molecule in the *NIH Guidelines* (Section I–B) only explicitly refers to DNA and requires that segments be joined, which may not need to occur in research with synthetic nucleic acids. The revision to this section largely retains the definition of recombinant DNA but also adds a definition for synthetic nucleic acids that are created without joining segments of nucleic acids.

Section I–B also contains a paragraph that states:

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (*e.g.* , a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the *NIH Guidelines.*

A second paragraph in the definition states:

Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the *NIH Guidelines* unless the transposon itself contains recombinant DNA.

The final changes eliminate the first paragraph above, referring to synthetic DNA segments, because the *NIH Guidelines* now specifically includes an exemption for certain low-risk synthetic constructs (see III–F–1). For consistency, the second paragraph on transposons was moved to the portion of the *NIH Guidelines* that covers exemptions (Section III–F). The NIH received no comments on eliminating the first paragraph and moving the second paragraph; therefore these changes are being implemented.

With respect to the definition of recombinant and synthetic nucleic acids, NIH/OBA received several comments with suggestions to use a single definition for recombinant and synthetic nucleic acids. NIH/OBA considered these proposals carefully but decided instead to largely retain the original definition of recombinant DNA, with clarification that it applies to both DNA and RNA and to add a new definition of synthetic nucleic acids. This was done because the definition of recombinant DNA will not change with this revision to the *NIH Guidelines.* As in the Scope section, the modification to the language ''functional equivalent'' will be included in the definition as well.

Section I–B is changed as follows:

Section I–B. Definition of Recombinant and Synthetic Nucleic Acid Molecules:

In the context of the *NIH Guidelines,* recombinant and synthetic nucleic acids are defined as:

(i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, *i.e.* , recombinant nucleic acids;

(ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, *i.e.* , synthetic nucleic acids; or

(iii) molecules that result from the replication of those described in (i) or (ii) above.

Section I–C. General Applicability

In the March 2009 **Federal Register** notice, NIH/OBA stated that it would change, throughout the *NIH Guidelines,* as appropriate, the term ''recombinant DNA molecules'' to ''recombinant and synthetic nucleic acid molecules.'' NIH/OBA received a comment that this substitution would imply that the *NIH Guidelines* only apply to research that uses synthetic and recombinant nucleic acids together, not just recombinant nucleic acid molecules or synthetic nucleic acid molecules alone. NIH/OBA agrees with the comment on the original proposed language and instead will replace, where appropriate recombinant DNA with ''recombinant or synthetic nucleic acid molecules'' to specify that the section applies to research with recombinant or synthetic nucleic acids or both. Section 1–C–1 currently states:

Section I–C. General Applicability

Section I–C–1. The *NIH Guidelines* are applicable to:

Section I–C–1–a. All recombinant DNA research within the United States (U.S.) or its territories that is within the category of research described in either Section I–C–1–a–(1) or Section I–C–1–a–(2).

Section I–C–1–a–(1). Research that is conducted at or sponsored by an institution that receives any support for recombinant DNA research from NIH, including research performed directly by NIH. An individual who receives support for research involving recombinant DNA must be associated with or sponsored by an institution that assumes the responsibilities assigned in the *NIH Guidelines.*

Section I–C–1–a–(2). Research that involves testing in humans of materials containing recombinant DNA developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials.

Section I–C–1–b. All recombinant DNA research performed abroad that is within the category of research described in either Section I–C–1–b–(1) or Section I–C–1–b–(2).

Section I–C–1–b–(1). Research supported by NIH funds.

Section I–C–1–b–(2). Research that involves testing in humans of materials containing recombinant DNA developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials.

Section I–C will now read:

Section I–C. General Applicability

Section I–C–1. The *NIH Guidelines* are applicable to:

Section I–C–1–a. All recombinant or synthetic nucleic acid research within the United States (U.S.) or its territories that is within the category of research described in either Section I–C–1–a–(1) or Section I–C–1–a–(2).

Section I–C–1–a–(1). Research that is conducted at or sponsored by an institution that receives any support for recombinant or synthetic nucleic acid research from NIH, including research performed directly by NIH. An individual who receives support for research involving recombinant or synthetic nucleic acids must be associated with or sponsored by an institution that assumes the responsibilities assigned in the *NIH Guidelines.*

Section I–C–1–a–(2). Research that involves testing in humans of materials containing recombinant or synthetic nucleic acids developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials.

Section I–C–1–b. All recombinant or synthetic nucleic acid research performed abroad that is within the category of research described in either Section I–C–1–b–(1) or Section I–C–1–b–(2).

Section I–C–1–b–(1). Research supported by NIH funds.

Section I–C–1–b–(2). Research that involves testing in humans of materials containing recombinant or synthetic nucleic acids developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials.

Section III–C–1. Experiments Involving the Deliberate Transfer of Recombinant DNA, or DNA or RNA Derived From Recombinant DNA, Into One or More Human Research Participants

In March 2009, NIH/OBA proposed the following change to the definition of human gene transfer:

For an experiment involving the deliberate transfer of recombinant and/or synthetic nucleic acids into one or more human research participants (human gene transfer), no research participant shall be enrolled (see definition of enrollment in Section I–E–7) until the RAC review process has been completed (see Appendix M–I–B, RAC Review Requirements).

NIH/OBA had proposed exempting from the *NIH Guidelines* non-clinical research with certain synthetic nucleic acids but did not propose to extend that exemption to the use of these constructs in a clinical setting. NIH/OBA noted that many gene transfer trials that are currently subject to the *NIH Guidelines* use non-replicating recombinant molecules because they are derived through recombinant technology which involves replication. NIH/OBA proposed that there are shared safety issues raised by clinical protocols that use synthetic non-replicating nucleic acids and those that use non-replicating recombinant vectors.

The proposal to exempt basic research with non-replicating synthetic nucleic acids but not to extend that exemption to human gene transfer research was based on the differences in the potential health risk from inadvertent exposure during basic or preclinical work versus intentional exposure in a clinical setting. The doses and routes of administration used in human gene transfer generally increase the safety risks as compared to exposures that may occur in a basic research setting. Moreover, the clinical safety risks to be considered for human gene transfer are not limited to the replicative nature of the vector but include transgene effects, risks of insertional mutagenesis, immunological responses, and potential epigenetic changes. Human gene transfer also raises scientific, medical, social, and ethical considerations that warrant special attention and public discussion.

NIH/OBA received a number of comments from industry, including several comments from the Oligonucleotide Safety Working Group (OSWG), which represents 70 pharmaceutical and regulatory professionals involved in the clinical development of oligonucleotide-based therapies. The OSWG stated that synthetic nucleic acid oligonucleotides that are less than 100 nucleotides and are not delivered in a bacterial or viral vector are more analogous to small molecule drugs than to the agents currently used in human gene transfer. They noted that these constructs can be distinguished from the recombinant agents currently used in human gene transfer by their inability to integrate into the genome or replicate in cells, their lack of a transgene that can be transcribed into RNA or translated into a protein, and their transient nature, i.e., they are degraded within days. They recognized that the review of gene transfer protocols by the RAC is useful to address such risks in gene transfer, but they did not believe that review should be extended to these constructs merely because they are synthetic nucleic acids. They noted that no significant safety issues have arisen in the ongoing Phase I and Phase II clinical trials using short-interfering RNA oligonucleotides (siRNAs). In addition to these trials, there is significant interest in developing clinical applications directed at microRNAs (miRNAs). For recent reviews of the field see K. Tiemann, J. Rossi, RNAi-based therapeutics-current status, challenges and prospects. *EMBO Mol. Med.* 1,142–151 (2009), and D. Grimm, M. A. Kay, Therapeutic application of RNAi: is mRNA targeting finally ready for prime time. *The Journal of Clinical Investigation.* 117(12), 3633–3641 (2007).

While this clinical data is reassuring, several preclinical investigations raised important questions regarding the current understanding about the mechanisms underlying the clinical action of these constructs. For example, clinical trials using a siRNA against vascular endothelial growth factor-A (VEGFA) or its receptor (VEGFR1) in patients with blinding choroidal neovascularization (CNV) from age-related macular degeneration have demonstrated promising results. The hypothesis is that the siRNAs that are specific for VEGFA or its receptor are responsible for the clinical responses seen. In 2008, M.E. Kleinman, *et al.* found that a siRNA that did not specifically target VEGFA or VEGFR1 could also suppress CNV in mice through an immune response generated through toll-like receptors and induction of interferon-gamma and interleukin-12 (see M.E., Kleinman, *et al.*, Sequence- and target-independent angiogenesis suppression by siRNA via TLR3. *Nature.* 452, 591–598 (2008)). In another study, investigators developed anti-macrophage inhibitory factor (MIF) siRNAs designed to block MIF expression in mammary adenocarcinoma cells (MCF–7). MIF is a ''pleiotropic cytokine with well described roles in cell proliferation, tumorigenesis and angiogenesis'' (M.E. Armstrong, *et al.* , Small Interfering RNAs Induce Macrophage Migration Inhibitory Factor Production and Proliferation in Breast Cancer Cells via a Double Stranded RNA-Dependent Protein Kinase-Dependent Mechanism. *J. Imm.*180, 7125–7133 (2008)). MIF has been shown to exert its actions through activation of CD44 and enhanced CD44 activation has been shown to promote breast cancer cell invasion. Unexpectedly, when these anti-MIF siRNAs were delivered to MCF–7 cells, the result was increased MIF production and an increase in proliferation of these cells.

In addition to questions regarding the mechanisms of action and potential off target effects raised by these publications, the RAC discussed whether administration of these synthetic RNAs could potentially lead to long-term gene silencing and phenotypic changes. As stated by the OSWG in their comments, one of the reasons for the RAC oversight of recombinant research is to assess the potential for alteration of a research participant's DNA, which could have unknown and unintended consequences. Recent research indicates that siRNA and miRNAs may be involved in long-term gene silencing (A. Verdel, *et al.*, Common themes in siRNA-mediated epigenetic silencing pathways. *Int. J. Dev. Biol.* 53, 245–257 (2009); D. H. Kim, *et al.* , MicroRNA-directed transcriptional gene silencing in mammalian cells. *PNAS.* 105(42), 16230–16235 (2008)). The implications of these preliminary findings and whether such effects on genes are fundamentally different than those exerted by certain small molecules, for example histone deacetylation inhibitors, remains an open question: It has been shown that histone deacetylation can silence genes through chromatin modification and deacetylation of the chromatin histone protein. Histone deacetylase inhibitors are in development as potential cancer therapeutics (see *e.g.* , A.A Lane, B.A. Chabner, Histone deacetylase inhibitors in cancer therapy. *J. Clin. Oncol.* 27(32), 5459–68 (2009)).

After considering the comments by the OSWG and other interested stakeholders, as well as the available literature, the RAC initially recommended that NIH/OBA consider an exemption for certain well characterized synthetic oligonucleotides, such as synthetic DNA

oligonucleotides that have been in clinical development for a number of years and whose mechanism of action is well understood. The RAC had reservations regarding extending that exemption to all synthetic RNA oligonucleotides because of the emerging literature that raised questions regarding our understanding of the potentially complex biological pathways being targeted. Indeed certain pathways are highly conserved across species and individual miRNAs have been shown to suppress the production of hundreds of proteins (D. Baek, *et al.* The impact of microRNAs on protein output. *Nature.* 455, 64–71(2008)). Additionally, the RAC considered that review of clinical protocols that administered RNA oligonucleotides without a vector would inform and enhance the review of similar protocols that use vectors (*e.g.* , short hairpin RNA (shRNA) expressed from a plasmid) and also inform the field and promote the exchange of data that could enhance its development. The RAC noted that this review might only be for several years until more data were developed.

The RAC, however, continued to reflect upon the data and considered additional stakeholder input. Further discussions were held with leading experts on RNAi, including Noble Prize laureates Dr. Phillip Sharp and Dr. Craig Mello. The RAC carefully considered the differences between synthetic nucleic acids that are not delivered in vectors and those delivered in bacterial or viral vectors, taking into account their inability to replicate, integrate, or be transcribed or translated. Finally, given the uncertain significance of preclinical data in the absence of adverse effects in the ongoing clinical trials, the RAC concluded that oversight is not warranted at this time. NIH/OBA concurs with this assessment, and the *NIH Guidelines* will only apply to recombinant constructs that are currently covered by the *NIH Guidelines* and those synthetic constructs that are equivalent to their recombinant counterparts, i.e. synthetic investigational agents that share the same characteristics as recombinant gene transfer constructs. However, in light of some unresolved outstanding questions regarding the mechanisms of actions of synthetic nucleic acids used clinically, including the potential for epigenetic changes, the RAC recommended NIH/OBA convene a meeting to further explore these questions. NIH/OBA hosted this meeting on December 15–16, 2011. (The agenda and slide presentations are available at: *http://oba.od.nih.gov/rdna/rdna_symposia.html.*)

Therefore, Section III–C–1 will be revised as follows:

Section III–C–1. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants

Human gene transfer is the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or

2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:

a. Contain more than 100 nucleotides; or

b. Possess biological properties that enable integration into the genome (e.g., *cis* elements involved in integration); or

c. Have the potential to replicate in a cell; or

d. Can be translated or transcribed.

No research participant shall be enrolled (see definition of enrollment in Section 1–E–7) until the RAC review process has been completed (see Appendix M–1–B, *RAC Review Requirements*).

Section III–F. Exempt Experiments

Modifications were proposed to augment or clarify experiments that are exempt from the *NIH Guidelines* (III–F). Certain nucleic acid molecules are exempt from the *NIH Guidelines* under Section III–F because (1) their introduction into a biological system is not expected to present a biosafety risk that requires review by an IBC, or (2) the introduction of these nucleic acid molecules into biological systems would be akin to processes of nucleic acid transfer that already occur in nature, so that the appropriate biosafety practices would be the same as those used for the natural organism and/or would be covered by other guidances.

As stated in the March 2009 **Federal Register** notice, with the exception of the new proposed Section III–F–1 discussed below, the exemptions from the current *NIH Guidelines* (October 2011) have been preserved with minor modifications. The addition of research with synthetic nucleic acids to the *NIH Guidelines* does not warrant modification of most of these exemptions except to extend them to synthetic constructs.

To emphasize that research exempt from the *NIH Guidelines* may still have biosafety considerations and that other standards of biosafety may apply, a modification is being made to the introductory language for this section. Section III–F currently states:

The following recombinant DNA molecules are exempt from the *NIH Guidelines* and registration with the Institutional Biosafety Committee is not required.

This portion is amended to read:

The following recombinant or synthetic nucleic acid molecules are exempt from the *NIH Guidelines* and registration with the Institutional Biosafety Committee is not required; however, other federal and state standards of biosafety may still apply to such research (for example, the Centers for Disease Control and Prevention (CDC)/NIH publication Biosafety in Microbiological and Biomedical Laboratories).

Section III–F–1. Exempt Experiments

A new entry under Section III–F was proposed to exempt from the *NIH Guidelines* synthetic nucleic acids that cannot replicate unless they are administered to one or more human research participant(s) (see Section III–C–1). This exemption was proposed so that the *NIH Guidelines* apply to synthetic nucleic acid research in a manner consistent with the current oversight of basic and preclinical recombinant DNA research. Currently oversight is limited to recombinant molecules that replicate or are derived from such molecules. The added section exempts basic, non-clinical research with synthetic nucleic acids that cannot replicate or are not derived from molecules that can replicate. The biosafety risks of using such constructs in basic and preclinical research are likely low. If a nucleic acid is incapable of replicating in a cell, any toxicity associated with that nucleic acid should be confined to that particular cell or organism, and spread to neighboring cells or organisms should not occur to any appreciable degree. This type of risk is analogous to that observed with chemical exposures, although nucleic acids are generally far less toxic than most chemicals.

NIH/OBA received a number of comments on this proposed exemption. Most of the comments questioned whether this exemption should be extended to certain non-replicating nucleic acids used in human gene transfer because such constructs are likely to pose quantitatively different risks than vector-based gene transfer. The response to these comments is articulated in the prior section of this notice that focuses on Section III–C–1.

With respect to basic research, NIH/OBA received comments questioning whether all non-replicating synthetic nucleic acids used in basic research pose sufficiently low biosafety risks to be exempt from the *NIH Guidelines*. Concerns were also raised about the use of synthetic non-replicating, integrating

viral vectors, such as lentiviral vectors, which could result in persistent transgene expression and have the potential to induce insertional oncogenesis. Non-replicating synthetic cassettes for toxins were also identified as raising potential biosafety risks as were oncogenes. In addition, clarification was sought regarding what was meant by the term ''replication.'' For example, would the following be considered replicating nucleic acids: (1) Plasmids lacking sequences to replicate in eukaryotic cells or (2) complementary DNAs (cDNAs) of positive strand RNA viruses, in which cDNA is not replicated but is transcribed into viral RNAs? In addition, another commenter asked why the exemption was limited to synthetic nucleic acids rather than all nucleic acids.

NIH/OBA carefully considered all of these comments. With respect to making this exemption apply generally to all nucleic acid constructs, recombinant and synthetic, NIH/OBA notes that the definition of recombinant DNA molecules, which remains unchanged, only includes molecules that can replicate in a living cell or molecules that result from the replication of those described above. Therefore, to include them in the exemption under III–F–1 would be redundant, as this exemption only applies to nucleic acids that cannot replicate and are not derived from those that can replicate. NIH/OBA acknowledges that research with an integrating vector could raise biosafety considerations even if the vector does not replicate. With respect to toxins, a non-replicating expression cassette can only express the toxin in a single cell and the toxin cannot spread from cell to cell, thereby limiting its toxic effect. Nonetheless, NIH/OBA agrees that constructs expressing toxins that are currently reviewed under Section III–B–1, Experiments Involving the Cloning of Toxin Molecules with LD50 of Less Than 100 Nanograms per Kilogram Body Weight, should remain subject to the NIH Guidelines. Indeed, under the current NIH Guidelines, even if an experiment falls under a Section III–F exemption, it may still be subject to review under Section III–B–1. For clarity, NIH/OBA therefore decided to specify that toxin-producing expression cassettes that would fall under Section III–B–1 will not be exempt under III–F.

Synthetic constructs that have the potential to integrate will not likewise be exempted because they could inadvertently activate an oncogene, or an integrating sequence containing an oncogene could inadvertently be integrated into a cell and persist and transform that cell and its progeny.

In the March 2009 **Federal Register** notice, Section III–F–1 was written so as to exempt from the NIH Guidelines ''Synthetic nucleic acids that cannot replicate, and that are not deliberately transferred into one or more human research participants (Section III–C and Appendix M).'' To clarify the interpretation of ''replicating,'' the language has been changed to match more closely that of the definition of recombinant DNA, ''cannot replicate in a living cell.'' This change is to make it clear that it is the ability to replicate in any cell type that determines whether the research is subject to the NIH Guidelines (*i.e.* , plasmids that can replicate in bacteria would be subject to the NIH Guidelines even if in eukaryotic cells). To address the cDNA of positive strand RNA viruses, the language has been changed to ''cannot replicate or generate nucleic acids that can replicate in a living cell.'' In addition, to make it clear that a synthetic replication incompetent virus is not exempt under this section of the NIH Guidelines, a parenthetical has been added to clarify that this section is meant to exempt only research with small synthetic oligonucleotides and expression cassettes, not synthetic viruses or bacteria that cannot replicate because of omission of one or more genes.

Section III–F–1 is changed to exempt the following experiments:

Section III–F–1. Those synthetic nucleic acids that: (1) Can neither replicate nor generate nucleic acids that can replicate in any living cell (*e.g.* , oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III–C, it is not exempt under this Section.

Section III–F–2. Exempt Experiments

Section III–F–1 will now be renumbered to III–F–2 and is amended to clarify that replicating nucleic acids that are not in cells, organisms, or viruses are exempt. The current NIH Guidelines only mentions organisms and viruses, and for clarity the term ''cells'' has been added. In addition, if a molecule is modified to facilitate entry into a cell, this will also not be exempt. Nucleic acids that are not in a biological system that will permit replication and that have not been modified to enable improved penetration of cell membranes are unlikely to have associated biosafety risks. NIH/OBA received no comments on this change.

The current Section III–F–1 states: ''Those that are not in organisms or viruses.''

Section III–F–1 is re-numbered to III–F–2 and will exempt the following experiments:

Section III–F–2. Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (*e.g.*, encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.

Sections III–F–3 through III–F–7

Revised Sections III–F–3 through III–F–7 retain exemptions that were in the current version of NIH Guidelines (October 2011) with minor revisions. There were no comments to the minor changes made in Sections III–F–3 through III–F–7. The following changes will be made for these Section III–F exemptions.

Section III–F–3. Exempt Experiments

Section III–F–2 exempts nucleic acid sequences that are essentially copies of those found in nature. The language has been modified as discussed in the March 2009 **Federal Register** notice by limiting this exemption to those nucleic acid sequences that exist contemporaneously in nature. Research in the lab with nucleic acid sequences for organisms that do not currently exist in nature, for example, an identical copy of the 1918 H1N1 influenza virus would not be exempt.

Section III–F–2 will be re-numbered to III–F–3 and will exempt the following experiments:

Section III–F–3. Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.

Section III–F–4. Exempt Experiments

The current Section III–F–3 exempts nucleic acids that are being propagated only in a prokaryotic host that is either the natural host or a closely related strain of the natural host. Again such constructs may already exist outside of a laboratory. It is renumbered to Section III–F–4 and no amendment to the language is made. It exempts the following experiments:

Section III–F–4. Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.

Section III–F–5: Exempt Experiments

The current Section III–F–4 exempts nucleic acids that are being propagated

in a eukaryotic host that is either the natural host or closely related strain of the natural host. Section III–F–4 is renumbered to Section III–F–5 and no amendment to the language is made. The following experiments are exempt per this section.

Section III–F–5. Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

Section III–F–6. Exempt Experiments

Research that falls under Section III–F–6 (formerly Section III–F–5) is exempt because the manipulation of these nucleic acids in a laboratory setting would be equivalent to processes that occur in nature when certain organisms exchange genetic material via physiological processes (*e.g.* , bacterial conjugation). It is limited to those organisms, as specified in Appendices A–I through A–VI, that are already known to exchange DNA in nature. The current Section III–F–5 is renumbered to Section III–F–6 and no amendment to the language is made. The following experiments are exempt per this section.

Section III–F–6. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C–1–b–(1)–(c), Major Actions). See Appendices A–I through A–VI, Exemptions under Section III–F–6—Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the *NIH Guidelines*.

Additionally, Appendix A will be amended to reference Section III–F–6 rather than III–F–5.

Section III–F–7. Exempt Experiments

Research that falls under the proposed Section III–F–7 exemption also involves a natural physiological process, *i.e.* transposition. Transposons are nucleic acid molecules that exist in a wide variety of organisms from bacteria to humans. These molecules have the ability to move from one portion of an organism's genome to another. This new Section of III–F captures what was previously an exemption to the definition of a recombinant DNA molecule in the *NIH Guidelines* (Section I–B). Unless a transposon has been modified to be a recombinant molecule, genomic DNA that has acquired a transposon is not subject to the *NIH Guidelines*. Transposons that have not been modified by the insertion of recombinant or synthetic DNA are equivalent to what exists in nature and the process occurs naturally outside of a laboratory setting. The language from the definition of recombinant DNA (Section I–B) is being moved to this Section so that the definition of recombinant and synthetic nucleic acids found in Section I–B is solely a definition and does not include exemptions. The exemption described in Section I–B previously stated, ''Genomic DNA molecules of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA.'' The exemption language has been simplified to make it clear that unmodified transposons used in research are not subject to the NIH Guidelines even if derived from a recombinant or synthetic system. In addition, the reference to only plants and bacteria has been removed since it is now known that transposons are also found in animals. Section III–F–7 will exempt the following experiments:

Section III–F–7. Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.

Section III–F–8. Exempt Experiments

The current Section III–F–6 provides a mechanism by which other experiments that do not raise significant biosafety risks can be exempted from the NIH Guidelines after review by the RAC and approval by the NIH Director. The language has not been amended but, due to the insertion of two additional exemptions, it is being renumbered to Section III–F–8 and will exempt the following experiments:

Section III–F–8. Those that do not present a significant risk to health or the environment (see Section IV–C–1–b–(1)–(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, Exemptions under Section III–F–8 for other classes of experiments which are exempt from the *NIH Guidelines*.

Additionally, Appendix C will be amended to reference Section III–F–8 rather than III–F–6.

Section IV–A. Policy

Section IV–A addresses the roles and responsibilities of local institutions and investigators in implementing the *NIH Guidelines*. It contains a general policy statement that acknowledges the inability of the *NIH Guidelines* to address specifically all conceivable research or emerging techniques and therefore states that researchers and institutions should adhere to ''the intent of the *NIH Guidelines* as well as to their specifics.'' NIH/OBA received no comments on the proposed changes, which emphasize that the *NIH Guidelines* are expected to be modified to address new developments in research or scientific techniques. In addition, in rewriting this section of the *NIH Guidelines,* NIH/OBA has removed the sentence ''[G]eneral recognition of institutional authority and responsibility properly establishes accountability for safe conduct of the research at the local level,'' since the previous sentences adequately explains that the institution is accountable for implementation of the *NIH Guidelines*. Section IV–A currently states:

The safe conduct of experiments involving recombinant DNA depends on the individual conducting such activities. The *NIH Guidelines* cannot anticipate every possible situation. Motivation and good judgment are the key essentials to protection of health and the environment. The *NIH Guidelines* are intended to assist the institution, Institutional Biosafety Committee, Biological Safety Officer, and the Principal Investigator in determining safeguards that should be implemented. The *NIH Guidelines* will never be complete or final since all conceivable experiments involving recombinant DNA cannot be foreseen. Therefore, it is the responsibility of the institution and those associated with it to adhere to the intent of the *NIH Guidelines* as well as to their specifics. Each institution (and the Institutional Biosafety Committee acting on its behalf) is responsible for ensuring that all recombinant DNA research conducted at or sponsored by that institution is conducted in compliance with the *NIH Guidelines*. General recognition of institutional authority and responsibility properly establishes accountability for safe conduct of the research at the local level. The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of research involving recombinant DNA molecules. Further clarifications and interpretations of roles and responsibilities will be issued by NIH as necessary.

Section IV–A is amended to read:

The safe conduct of experiments involving recombinant or synthetic nucleic acid molecules depends on the individual conducting such activities. The *NIH Guidelines* cannot anticipate every possible situation. Motivation and good judgment are the key essentials to protection of health and the environment. The *NIH Guidelines* are intended to assist the institution, Institutional Biosafety Committee, Biological Safety Officer, and the Principal Investigator in determining safeguards that should be implemented. The *NIH Guidelines* will never be complete or final since all experiments

involving recombinant or synthetic nucleic acid molecules cannot be foreseen. The utilization of new genetic manipulation techniques may enable work previously conducted using recombinant means to be accomplished faster, more efficiently, or at larger scale. These techniques have not yet yielded organisms that present safety concerns that fall outside the current risk assessment framework used for recombinant nucleic acid research. Nonetheless, an appropriate risk assessment of experiments involving these techniques must be conducted taking into account the way these approaches may alter the risk assessment. As new techniques develop, the *NIH Guidelines* should be periodically reviewed to determine whether and how such research should be explicitly addressed.

It is the responsibility of the institution and those associated with it to adhere to the intent of the *NIH Guidelines* as well as to its specifics. Therefore, each institution (and the Institutional Biosafety Committee acting on its behalf) is responsible for ensuring that all research with recombinant or synthetic nucleic acid molecules conducted at or sponsored by that institution is conducted in compliance with the *NIH Guidelines*. The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of research involving recombinant or synthetic nucleic acid molecules. Further clarifications and interpretations of roles and responsibilities will be issued by NIH as necessary.

Section II–A–3. Comprehensive Risk Assessment

Currently, the risk assessment framework of the NIH Guidelines uses the Risk Group (RG) of the parent organism as a starting point for determining the necessary containment level. For example, genetic modifications of a Risk Group 3 organism (defined as agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available) would generally be carried out at Biosafety Level 3 (BL3) containment, but the containment level might be raised or lowered depending on the specific construct and the experimental manipulations. The RAC concluded that the current risk assessment framework under the *NIH Guidelines* can be effectively applied to assess the biosafety risks of experiments with synthetic nucleic acids. However, additional language was proposed to provide further guidance for evaluating synthetic biology research, which has the potential to create complex, novel organisms for which identification of a parent organism may be more difficult or may not be as relevant to the risk assessment as it is with more traditional recombinant organisms. The risk assessment may also be complicated by the limitations in predicting function from sequence(s), as recently addressed in a report by the Committee on Scientific Milestones for the Development of Gene-Sequence-Based Classification System for the Oversight of Select Agents, National Research Council, *Sequence-Based Classification of Select Agents: A Brighter Line,* ISBN–10: 0–309–15904–0. Further complications may also result from synergistic effects caused by combining sequences from different sources in a novel context.

NIH/OBA received one comment on its proposed revisions to Section II–A–3. The comment asked for clarification of the meaning of the term ''chimera'' because it is not currently used in the *NIH Guidelines*. The term was meant to capture the concept that with the advent of more sophisticated synthetic techniques, a complex organism may be created using nucleic acid sequences from multiple sources. For clarity, this wording will be used in lieu of the term ''chimera.''

Section II–A–3 Comprehensive Risk Assessment currently states:

In deciding on the appropriate containment for an experiment, the initial risk assessment from Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard,* should be followed by a thorough consideration of the agent itself and how it is to be manipulated. Factors to be considered in determining the level of containment include agent factors such as: Virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity. Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher containment level. Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain (see Section V–B, *Footnotes and References of Sections I–IV*). A final assessment of risk based on these considerations is then used to set the appropriate containment conditions for the experiment (see Section II–B, *Containment*). The containment level required may be equivalent to the Risk Group classification of the agent or it may be raised or lowered as a result of the above considerations. The Institutional Biosafety Committee must approve the risk assessment and the biosafety containment level for recombinant DNA experiments described in Sections III–A, *Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation; III–B, Experiments that Require NIH/OBA and Institutional Biosafety Committee Approval Before Initiation; III–C, Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and NIH/OBA Registration Before Initiation; III–D, Experiments that Require Institutional Biosafety Committee Approval Before Initiation.*

Careful consideration should be given to the types of manipulation planned for some higher Risk Group agents. For example, the RG2 dengue viruses may be cultured under the Biosafety Level 2 (BL2) containment (see Section II–B); however, when such agents are used for animal inoculation or transmission studies, a higher containment level is recommended. Similarly, RG3 agents such as Venezuelan equine encephalomyelitis and yellow fever viruses should be handled at a higher containment level for animal inoculation and transmission experiments.

Individuals working with human immunodeficiency virus (HIV), hepatitis B virus (HBV) or other bloodborne pathogens should consult the applicable Occupational Safety and Health Administration (OSHA) regulation, 29 CFR 1910.1030, and OSHA publications, e.g., OSHA 3186–06R (2003 revised). BL2 containment is recommended for activities involving all blood-contaminated clinical specimens, body fluids, and tissues from all humans, or from HIV-or HBV-infected or inoculated laboratory animals. Activities such as the production of research-laboratory scale quantities of HIV or other bloodborne pathogens, manipulating concentrated virus preparations, or conducting procedures that may produce droplets or aerosols, are performed in a BL2 facility using the additional practices and containment equipment recommended for BL3. Activities involving industrial scale volumes or preparations of concentrated HIV are conducted in a BL3 facility, or BL3 Large Scale if appropriate, using BL3 practices and containment equipment.

Exotic plant pathogens and animal pathogens of domestic livestock and poultry are restricted and may require special laboratory design, operation and containment features not addressed in *Biosafety in Microbiological and Biomedical Laboratories* (see Section V–C, *Footnotes and References of Sections I through IV*). For information regarding the importation, possession, or use of these agents see Section V–G and V–H, *Footnotes and References of Sections I through IV.*

The first paragraph is being revised to clarify that the assignment of an organism to a Risk Group in Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard,* is based on a risk assessment and identification of the Risk Group of the parent organism. The first paragraph is amended as follows:

In deciding on the appropriate containment for an experiment, the first step is to assess the risk of the agent itself. Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard,* classifies agents into Risk Groups based on an assessment of their ability to cause disease in humans and the available treatments for such disease. Once the Risk Group of the agent is identified, this should be followed

by a thorough consideration of how the agent is to be manipulated. Factors to be considered in determining the level of containment include agent factors such as: Virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity. Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher containment level. Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain (see Section V–B, *Footnotes and References of Sections I–IV*).

The following new paragraphs will then be inserted:

While the starting point for the risk assessment is based on the identification of the Risk Group of the parent agent, as technology moves forward, it may be possible to develop an organism containing genetic sequences from multiple sources such that the parent agent may not be obvious. In such cases, the risk assessment should include at least two levels of analysis. The first involves a consideration of the Risk Groups of the source(s) of the sequences and the second involves an assessment of the functions that may be encoded by these sequences (e.g., virulence or transmissibility). It may be prudent to first consider the highest Risk Group classification of all agents that are the source of sequences included in the construct. Other factors to be considered include the percentage of the genome contributed by each parent agent and the predicted function or intended purpose of each contributing sequence. The initial assumption should be that all sequences will function as they did in the original host context.

The Principal Investigator and Institutional Biosafety Committee must also be cognizant that the combination of certain sequences in a new biological context may result in an organism whose risk profile could be higher than that of the contributing organisms or sequences. The synergistic function of these sequences may be one of the key attributes to consider in deciding whether a higher containment level is warranted, at least until further assessments can be carried out. A new biosafety risk may occur with an organism formed through combination of sequences from a number of organisms or due to the synergistic effect of combining transgenes that results in a new phenotype.

A final assessment of risk based on these considerations is then used to set the appropriate containment conditions for the experiment (see Section II–B, *Containment*). The appropriate containment level may be equivalent to the Risk Group classification of the agent or it may be raised or lowered as a result of the above considerations. The Institutional Biosafety Committee must approve the risk assessment and the biosafety containment level for recombinant or synthetic nucleic acid experiments described in Sections III–A, *Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation;* III–B, *Experiments that Require NIH/OBA and Institutional Biosafety Committee Approval Before Initiation;* III–C, *Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and NIH/OBA Registration Before Initiation;* and III–D, *Experiments that Require Institutional Biosafety Committee Approval Before Initiation.*

Section III–A–1. Major Actions under the *NIH Guidelines*

In reviewing the *NIH Guidelines* and the different levels of review required for each category of experiment, the RAC determined that it is important also to evaluate the class of experiments that require the highest level of review: Both RAC review and NIH Director approval. In doing so, it was determined that the language for Section III–A–1–a of the *NIH Guidelines* (research involving the introduction of drug resistance into a microorganism) may not capture all of the experiments that warrant this heightened review. Moreover, given the change in the use of antibiotics and the public health problems raised by the emergence of multidrug resistant bacterial strains, clearly defining those experiments that require heightened review is a public health priority.

Section III–A–1–a currently states:

The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V–B, *Footnotes and References of Sections I–IV*), if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by RAC.

In March 2009, NIH/OBA proposed to remove the phrase *not known to acquire the trait naturally* in order to allow some flexibility in review of experiments that may raise public health concern but for which there may be low levels of antibiotic resistance in the community. For example, only a small number of vancomycin-resistant *Staphylococcus* aureus strains have been isolated (B.P. Howden, *et al.* , Reduced Vancomycin Susceptibility in Staphylococcus aureus, including Vancomycin-Intermediate and Heterogeneous Vancomycin-Intermediate Strains: Resistance Mechanisms, Laboratory Detection and Clinical Implications. *Clinical Microbiology Reviews.* 32(1), 99–139 (2010)). However, as there are only a limited number of antibiotics with which to treat these multidrug resistant *S. aureus* strains, the use of vancomycin resistance as a marker could raise public health concerns. Another example would be the use of ciprofloxacin resistance as a marker for *Neisseria meningitidis.* Again, there are a small number of documented cases of resistance, but ciprofloxacin remains the primary drug for post-exposure prophylaxis (H.M. Wu, *et al.,* Emergence of Ciprofloxacin-resistant *Neisseria meningitides* in North America. *N. Engl. J. Med.* 360(9), 886–92 (2009)).

In the March 2009 **Federal Register** notice, Section III–A–1–a was proposed to be amended as follows:

The deliberate transfer of a drug resistance trait to microorganisms, if such acquisition could compromise the ability to treat or manage disease agents in human and veterinary medicine, or agriculture will be reviewed by RAC. Even if an alternative drug or drugs exist for the control or management of disease, it is important to consider how the research might affect the ability to control infection in certain groups or subgroups by putting them at risk of developing an infection by such microorganism for which alternative treatments may not be available. Affected groups or subgroups may include, but are not limited to: children, pregnant women, and people who are allergic to effective alternative treatments, immunocompromised or living in countries where the alternative effective treatment is not readily available.

In response to this proposed change in the language to Section III–A–1, NIH/OBA received a total of 36 written comments. Most either specifically noted their concurrence with comments from the American Society for Microbiology (ASM) or substantively concurred with ASM's comment. ASM commented that based on their interpretation of the proposed language the net effect would be to broaden substantially the scope of research that would be subject to the requirements of Section III–A–1–a and ''have a chilling impact on microbiological research where antibiotic resistance is routinely used in molecular and genetic studies.'' The ASM did agree that whether an organism is ''known to acquire the trait naturally'' is not always the critical factor in evaluating the safety of the experiment. ASM further stated that broadening the range of concern to include consideration of possible rare uses of an antibiotic that is not the ''drug of choice'' will only confound the work of the IBCs.

Other commenters noted that it was the overuse and likely misuse use of antibiotics throughout the world that pose a much greater and better documented public health threat through the development of highly resistant organisms that are capable of surviving outside of a laboratory. They noted that this threat is distinct from the laboratory setting as many laboratory-generated strains may not have a

selective advantage outside the laboratory and, even if there were inadvertent release, may not become a public health risk. Some comments suggested adding qualifiers to narrow the scope of the proposed section. For example, one commenter suggested the addition of the word ''reasonably'' to the concept of whether the transfer of drug resistance could compromise the ability to treat disease. Another commenter suggested that a list of criteria be developed that could be considered when a determination is made as to whether the transfer of a drug resistance trait could compromise public health. An additional commenter suggested that a list of ''acceptable'' transfers of drug resistance be incorporated into the *NIH Guidelines*.

Other comments revealed some potential misinterpretation of what constitutes research that falls under Section III–A–1–a. For clarification, NIH/OBA notes that transfer of a drug resistance trait to any non-pathogenic organism is not subject to the requirements of Section III–A–1–a of the *NIH Guidelines*, and transfer of resistance to a drug that is not currently used to treat disease caused by a pathogenic organism is not subject to review under Section III–A–1–a. These experiments, however, may be subject to other portions of the *NIH Guidelines*.

The changes proposed in the March 2009 **Federal Register** notice were further discussed at the public consultation on June 23, 2009. The panel of experts generally agreed that public health concerns may be raised by the use of certain antibiotic markers in pathogens that have resistance to a number of antibiotics, for example the use of vancomycin resistance as a marker in *S. aureus.* However, they concluded that these concerns could be adequately addressed by the IBC by requiring appropriate containment. The experts at the June 23, 2009, meeting agreed with ASM's observation that the safety of an experiment is not dictated solely by whether the organism can naturally acquire the resistance trait, i.e., an organism resistant to that drug has been found outside of a laboratory setting. Nonetheless, the consensus was that the original language should be maintained. They noted that there was no evidence that this section had failed to protect the public health. They also noted that once resistance has occurred in the microbial community outside of a laboratory setting, the use of such strains in a contained laboratory environment poses no additional risk to public health. Therefore, only those experiments that propose to introduce resistance to a therapeutic drug, when such resistance does not yet exist in the community, should require both RAC review and NIH Director approval. As to whether a single documented case of drug resistance is sufficient to allow this work to proceed without the necessity of RAC review and NIH Director approval, at least one expert noted that when there is a single case report, it is naïve to believe that there is only a single clinical isolate with that resistance trait. There are probably dozens or hundreds of isolates that were never reported and more that are undetected. The point is that once resistance occurs naturally, as opposed to in a laboratory setting, it is likely to occur again if acquisition of the antibiotic resistance confers a survival advantage upon the organism.

The introduction of a drug resistance trait into organisms in a laboratory setting when there are organisms outside the laboratory with this same drug resistance trait is fundamentally different than creating a novel drug resistant strain that does not exist outside of the lab. While one expert commented initially that the focus should be on resistance patterns in the U.S., others did not agree that such a limited perspective was warranted. There was consensus that there should be good documentation that this resistance exists outside of a laboratory setting and a single case report may need to be confirmed. Reports of clinical or environmental isolates should be the source of documentation of resistance.

In sum, this section of the current *NIH Guidelines* appears to protect public health adequately. There may indeed be some experiments that raise important public health considerations but would not qualify as Major Actions because there is a low level of documented resistance to the drug that will be used for selection. However, it was not possible to develop clear and easily interpretable criteria for identifying such experiments. The solution proposed was to encourage IBCs to consult with NIH/OBA and for NIH/OBA to consult with the RAC as needed when there is an experiment that does not meet the criteria for Section III–A–1–a but nonetheless raises important public health questions.

There were very few comments on the proposed language regarding analyzing subpopulations in determining the therapeutic usefulness of any antibiotic. However, there was some concern that this language might capture all antibiotics that could possibly be used rather than being limited to those antibiotics that were used clinically. Additional concern was raised about focusing on antibiotics that are not commonly used in the U.S. and therefore whether the definition of therapeutically useful should be limited to U.S. practice.

The intent of the proposed clarification regarding what is a therapeutically useful drug was not meant to expand the requirement for RAC review and NIH Director approval to all antimicrobials that might exhibit *in vitro* activity against a microorganism, but rather to focus on those that are used clinically as first or second line therapies in certain populations. The additional language was intended to raise awareness that the analysis of whether a drug is therapeutically useful needs to include consideration of certain subpopulations, in particular children and pregnant women, as many antibiotics may not be appropriate for these specific populations. With respect to antibiotics not used in the U.S., to the extent that certain pathogens have extensive impact on international populations, it is prudent to consider the antibiotic of choice in countries in which this pathogen causes disease. For example, as background to the discussion of whether the transfer of chloramphenicol resistance to *Rickettsia typhi* should be reviewed under Section III–A–1–a, the investigators noted that chloramphenicol is rarely used in the U.S. to treat disease caused by this organism. However, as this disease has considerable impact worldwide, and in particular in many developing countries in which chloramphenicol is used, this antibiotic was considered to be a therapeutically useful drug.

NIH/OBA agrees with the comments stating that the phrase ''not known to acquire the trait naturally'' serves to identify the majority of experiments that potentially pose higher risk to public health, and therefore this language will be retained. One clarification to the language was suggested by the RAC. Section III–A–1–a currently states that the ''deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by the RAC.'' As the introduction of a drug resistance trait would normally eliminate *that drug* as a therapeutic option, the analysis of whether this section applies has focused on whether the acquisition of the resistance trait by that microorganism will compromise the ability to control disease using alternative drugs. Therefore, the wording has been clarified as follows:

The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see *Section V–B, Footnotes and References of Sections I–IV*), if such acquisition could compromise the ability to control that disease agent in humans, veterinary medicine, or agriculture, will be reviewed by the RAC.

While there was consensus that this language adequately protected public health for many years and served the scientific community, there was acknowledgement that the mere fact that resistance to a drug has been documented does not necessarily mean that there are no potential public health concerns raised by use of that drug resistance trait in that microorganism. These concerns may be handled by imposing appropriate containment and other occupational health measures. In some cases, an IBC may have adequate expertise from members with training in infectious diseases to assess these risks and adopt appropriate measures, but because other IBCs may not have that same expertise, providing a mechanism for consultation with NIH/OBA or the RAC would be helpful. In order to emphasize the fact that part of NIH/OBA's role is to assist IBCs and other interested parties in evaluating containment for recombinant and synthetic nucleic acid research, the following will be added to Section III–A–1–a. This statement is a slight modification to that found currently in Section IV–C–3 (Roles and Responsibilities of the Office of Biotechnology Activities) of the *NIH Guidelines*.

At the request of an IBC, NIH/OBA will make a determination regarding whether a specific experiment involving the deliberate transfer of a drug resistance trait falls under Section III–A–1–a and therefore requires RAC review and NIH Director approval. IBCs may also consult with NIH/OBA regarding experiments that do not meet the requirements of Section III–A–1–a but nonetheless raise important public health issues. NIH/OBA will consult, as needed, with one or more experts, which may include the RAC.

With respect to the comments about providing a list of drugs that are clinically useful for a particular disease or to generate a list of allowable transfers, inclusion of such information in the *NIH Guidelines* is not appropriate. The drugs of choice for diseases are often updated, and NIH/OBA follows the recommendation of the leading medical textbooks and medical literature. Information on where to obtain such guidance is already included in a Frequently Asked Questions document on NIH/OBA's website under IBC Information *http://oba.od.nih.gov/rdna_ibc/ibc.html.* Experiments involving the deliberate transfer of antibiotic resistance that present little or no risk to the environment, agriculture, or public health, should be addressed in informational guidances that are easily updated. Listing all acceptable transfers of antibiotic resistance is not feasible.

Section III–A–1–a will now state:

The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see *Section V-B, Footnotes and References of Sections I–IV*), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by the RAC.

Consideration should be given as to whether the drug resistance trait to be used in the experiment would render that microorganism resistant to the primary drug available to and/or indicated for certain populations, for example children or pregnant women.

At the request of an Institutional Biosafety Committee, NIH/OBA will make a determination regarding whether a specific experiment involving the deliberate transfer of a drug resistance trait falls under Section III–A–1–a and therefore requires RAC review and NIH Director approval. An Institutional Biosafety Committee may also consult with NIH/OBA regarding experiments that do not meet the requirements of Section III–A–1–a but nonetheless raise important public health issues. NIH/OBA will consult, as needed, with one or more experts, which may include the RAC.

Section III–B. Experiments That Require NIH/OBA and Institutional Biosafety Committee Approval

Once a Section III–A–I–a experiment is reviewed by the RAC and approved by the NIH Director, equivalent experiments may not need to follow the same approval process to determine the appropriate biosafety containment level for the work. A new section under Section III–B (Experiments that Require NIH/OBA and IBC Approval before Initiation) was proposed to allow NIH/OBA (rather than the NIH Director) to review and approve certain experiments deemed equivalent to those already approved by the NIH Director, providing there is no new information that would raise new biosafety or public health issues.

The following section is proposed to be added to the *NIH Guidelines*:

Section III–B–2. Experiments that have been Approved (under Section III–A–1–a) as Major Actions under the *NIH Guidelines*

Upon receipt and review of an application from the investigator, NIH/OBA may determine that a proposed experiment is equivalent to an experiment that has previously been approved by the NIH Director as a Major Action, including experiments approved prior to implementation of these changes. An experiment will only be considered equivalent if, as determined by NIH/OBA, there are no substantive differences and pertinent information has not emerged since submission of the initial III–A–1 experiment that would change the biosafety and public health considerations for the proposed experiments. If such a determination is made by NIH/OBA, these experiments will not require review and approval under Section III–A.

Summary of Revised Language

The following provides the new language for the amended sections discussed above.

Title of the NIH Guidelines

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

Section I. Scope of the NIH Guidelines

Section I–A. Purpose

The purpose of the NIH Guidelines is to specify the practices for constructing and handling: (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules.

Section I–B. Definition of Recombinant and Synthetic Nucleic AcidsIn the context of the *NIH Guidelines,* recombinant and synthetic nucleic acids are defined as:

(i) Molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, *i.e.* , recombinant nucleic acids;

(ii) Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or

(iii) Molecules that result from the replication of those described in (i) or (ii) above.

Section I–C. General Applicability

Section I–C–1. The *NIH Guidelines* are applicable to:

Section I–C–1–a. All recombinant or synthetic nucleic acid research within the United States (U.S.) or its territories that is within the category of research described in either Section I–C–1–a–(1) or Section I–C–1–a–(2).

Section I–C–1–a–(1). Research that is conducted at, or sponsored by, an institution that receives any support for recombinant or synthetic nucleic acid research from NIH, including research performed directly by NIH.

An individual who receives support for research involving recombinant or synthetic nucleic acids must be associated with or sponsored by an institution that assumes the responsibilities assigned in the *NIH Guidelines.*

Section I–C–1–a–(2). Research that involves testing in humans of materials containing recombinant or synthetic nucleic acids developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials.

Section I–C–1–b. All recombinant or synthetic nucleic acid research performed abroad that is within the category of research described in either Section I–C–1–b–(1) or Section I–C–1–b–(2).

Section I–C–1–b–(1). Research supported by NIH funds.

Section I–C–1–b–(2). Research that involves testing in humans of materials containing recombinant or synthetic nucleic acids developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials.

Section II–A–3. Comprehensive Risk Assessment

In deciding on the appropriate containment for an experiment, the first step is to assess the risk of the agent itself. Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard,* classifies agents into Risk Groups based on an assessment of their ability to cause disease in humans and the available treatments for such disease. Once the Risk Group of the agent is identified, this should be followed by a thorough consideration of how the agent is to be manipulated. Factors to be considered in determining the level of containment include agent factors such as: virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity. Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher containment level. Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain (see Section V–B, *Footnotes and References of Sections I–IV*).

While the starting point for the risk assessment is based on the identification of the Risk Group of the parent agent, as technology moves forward, it may be possible to develop an organism containing genetic sequences from multiple sources such that the parent agent may not be obvious. In such cases, the risk assessment should include at least two levels of analysis. The first involves a consideration of the Risk Groups of the source(s) of the sequences and the second involves an assessment of the functions that may be encoded by these sequences (e.g., virulence or transmissibility). It may be prudent to first consider the highest Risk Group classification of all agents that are the source of sequences included in the construct. Other factors to be considered include the percentage of the genome contributed by each parent agent and the predicted function or intended purpose of each contributing sequence. The initial assumption should be that all sequences will function as they did in the original host context.

The Principal Investigator and Institutional Biosafety Committee must also be cognizant that the combination of certain sequences in a new biological context may result in an organism whose risk profile could be higher than that of the contributing organisms or sequences. The synergistic function of these sequences may be one of the key attributes to consider in deciding whether a higher containment level is warranted, at least until further assessments can be carried out. A new biosafety risk may occur with an organism formed through combination of sequences from a number of organisms or due to the synergistic effect of combining transgenes that results in a new phenotype.

A final assessment of risk based on these considerations is then used to set the appropriate containment conditions for the experiment (see Section II–B, *Containment*). The appropriate containment level may be equivalent to the Risk Group classification of the agent or it may be raised or lowered as a result of the above considerations. The Institutional Biosafety Committee must approve the risk assessment and the biosafety containment level for recombinant or synthetic nucleic acid experiments described in Sections III–A, *Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation; III–B, Experiments that Require NIH/OBA and Institutional Biosafety Committee Approval Before Initiation; III–C, Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and NIH/OBA Registration Before Initiation; and III–D, Experiments that Require Institutional Biosafety Committee Approval Before Initiation.*

Section III–A–1. Major Actions under the NIH Guidelines

The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see *Section V–B Footnotes and References of Sections I–IV*), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by the RAC.

Consideration should be given as to whether the drug resistance trait to be used in the experiment would render that microorganism resistant to the primary drug available to and/or indicated for certain populations, for example children or pregnant women.

At the request of an Institutional Biosafety Committee, NIH/OBA will make a determination regarding whether a specific experiment involving the deliberate transfer of a drug resistance trait falls under Section III–A–1–a and therefore requires RAC review and NIH Director approval. An Institutional Biosafety Committee may also consult with NIH/OBA regarding experiments that do not meet the requirements of Section III–A–1–a but nonetheless raise important public health issues. NIH/OBA will consult, as needed, with one or more experts, which may include the RAC.

Section III–B–2. Experiments that have been Approved (under Section III–A–1–a) as Major Actions under the NIH Guidelines

Upon receipt and review of an application from the investigator, NIH/OBA may determine that a proposed experiment is equivalent to an experiment that has previously been approved by the NIH Director as a Major Action, including experiments approved prior to implementation of these changes. An experiment will only be considered equivalent if, as determined by NIH/OBA, there are no substantive differences and pertinent information has not emerged since submission of the initial III–A–1 experiment that would change the biosafety and public health considerations for the proposed experiments. If such a determination is made by NIH/OBA, these experiments will not require review and approval under Section III–A.

Section III–C–1.

Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants

Human gene transfer is the deliberate transfer into human research participants of either:

Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or

Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:

a. Contain more than 100 nucleotides; or

b. Possess biological properties that enable integration into the genome (e.g., *cis* elements involved in integration); or

c. Have the potential to replicate in a cell; or

d. Can be translated or transcribed.

No research participant shall be enrolled (see definition of enrollment in Section 1–E–7) until the RAC review process has been completed (see Appendix M–I–B, *RAC Review Requirements*).

Section III–F. Exempt Experiments

The following recombinant or synthetic nucleic acid molecules are exempt from the

and registration with the Institutional Biosafety Committee is not required; however, other federal and state standards of biosafety may still apply to such research (for example, the Centers for Disease Control and Prevention (CDC)/NIH publication Biosafety in Microbiological and Biomedical Laboratories).

Section III–F–1. Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (*e.g.* , oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an

LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III–C it is not exempt under this Section.

Section III–F–2. Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.

Section III–F–3. Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.

Section III–F–4. Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.

Section III–F–5. Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

Section III–F–6. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV–C–1–b–(1)–(c), Major Actions). See Appendices A–I through A–VI, Exemptions under Section III–F–6–Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the *NIH Guidelines.*

Section III–F–7. Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.

Section III–F–8. Those that do not present a significant risk to health or the environment (see Section IV–C–1–b–(1)–(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, Exemptions under Section III–F–8 for other classes of experiments which are exempt from the *NIH Guidelines.*

Section IV–A. Policy

The safe conduct of experiments involving recombinant or synthetic nucleic acids depends on the individual conducting such activities. The *NIH Guidelines* cannot anticipate every possible situation. Motivation and good judgment are the key essentials to protection of health and the environment. The *NIH Guidelines* are intended to assist the institution, Institutional Biosafety Committee, Biological Safety Officer, and the Principal Investigator in determining safeguards that should be implemented. The *NIH Guidelines* will never be complete or final since all experiments involving recombinant or synthetic nucleic acid molecules cannot be foreseen. The utilization of new genetic manipulation techniques may enable work previously conducted using recombinant means to be accomplished faster, more efficiently, or at larger scale. These techniques have not yet yielded organisms that present safety concerns that fall outside the current risk assessment framework used for recombinant nucleic acid research. Nonetheless, an appropriate risk assessment of experiments involving these techniques must be conducted taking into account the way these approaches may alter the risk assessment. As new techniques develop, the *NIH Guidelines* should be periodically reviewed to determine whether and how such research should be explicitly addressed.

It is the responsibility of the institution and those associated with it to adhere to the intent of the *NIH Guidelines* as well as to their specifics. Therefore, each institution (and the Institutional Biosafety Committee acting on its behalf) is responsible for ensuring that all research with recombinant or synthetic nucleic acid molecules conducted at or sponsored by that institution is conducted in compliance with the *NIH Guidelines.* The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of research involving recombinant or synthetic nucleic acid molecules. Further clarifications and interpretations of roles and responsibilities will be issued by NIH as necessary.

Dated: August 29, 2012.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2012–21849 Filed 9–4–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the Laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently certified Laboratories and Instrumented Initial Testing Facilities (IITF) is published in the **Federal Register** during the first week of each month. If any Laboratory/IITF's certification is suspended or revoked, the Laboratory/IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any Laboratory/IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1042, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs'', as amended in the revisions listed above, requires strict standards that Laboratories and Instrumented Initial Testing Facilities (IITF) must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies.

To become certified, an applicant Laboratory/IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a Laboratory/IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and Instrumented Initial Testing Facilities (IITF) in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A Laboratory/IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following Laboratories and Instrumented Initial Testing Facilities (IITF) meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Instrumented Initial Testing Facilities (IITF)

None.

Laboratories

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016 (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150.

Aegis Analytical Laboratories, 345 Hill Ave., Nashville, TN 37210, 615–255–2400 (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc.).

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.).

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130 (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917.

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229–671–2281.

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215–674–9310.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609.

Gamma-Dynacare Medical Laboratories*, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630.

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.,).

Maxxam Analytics*, 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905–817–5700 (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.).

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244.

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515.

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory).

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7.

Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858–643–5555.

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370 (Formerly: SmithKline Beecham Clinical Laboratories).

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176 x1276.

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027.

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438.

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273.

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St.,Fort George G. Meade, MD 20755–5235, 301–677–7085.

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Janine Denis Cook,

Chemist, Division of Workplace Programs, Center for Substance Abuse Prevention, SAMHSA.

[FR Doc. 2012–21763 Filed 9–4–12; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3347–EM; Docket ID FEMA–2011–0001]

Louisiana; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Louisiana (FEMA–3347–EM), dated August 27, 2012, and related determinations.

DATES: Effective August 27, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 27, 2012, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Louisiana resulting from Tropical Storm Isaac beginning on August 26, 2012, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of Louisiana.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Gerard M. Stolar, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of Louisiana have been designated as adversely affected by this declared emergency:

The parishes of Ascension, Assumption, Jefferson, Lafourche, Livingston, Orleans, Plaquemines, St. Bernard, St. Charles, St. James, St. John, St. Tammany, Tangipahoa, Terrebonne, and Washington for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–21756 Filed 9–4–12; 8:45 am]

BILLING CODE 9110–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3347–EM; Docket ID FEMA–2012–0002]

Louisiana; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Louisiana (FEMA–3347–EM), dated August 27, 2012, and related determinations.

DATES: *Effective Date:* August 28, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared an emergency by the President in his declaration of August 27, 2012.

The parishes of Acadia, Allen, Avoyelles, Cameron, East Baton Rouge, East Feliciana, Franklin, Iberia, Iberville, Jefferson Davis, Morehouse, Natchitoches, Ouachita, Pointe Coupee, Rapides, St. Helena, St. Martin, St. Mary, and West Baton Rouge for emergency protective measures (Category B),limited to direct federal assistance, under the Public Assistance program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–21787 Filed 9–4–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3348–EM; Docket ID FEMA–2012–0002]

Mississippi; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Mississippi (FEMA–3348–EM), dated August 28, 2012, and related determinations.

DATES: *Effective Date:* August 28, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the

State of Mississippi is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared an emergency by the President in his declaration of August 28, 2012.

Attala, Carroll, Grenada, Holmes, and Montgomery Counties for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–21785 Filed 9–4–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3348–EM; Docket ID FEMA–2011–0001]

Mississippi; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Mississippi (FEMA–3348–EM), dated August 28, 2012, and related determinations.

DATES: *Effective Date:* August 28, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 28, 2012, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Mississippi resulting from Tropical Storm Isaac beginning on August 26, 2012, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of Mississippi.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Terry L. Quarles, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of Mississippi have been designated as adversely affected by this declared emergency:

Amite, Clarke, Copiah, Covington, Forrest, George, Greene, Hancock, Harrison, Hinds, Jackson, Jasper, Jefferson Davis, Jones, Lamar, Lauderdale, Lawrence, Lincoln, Madison, Marion, Pearl River, Perry, Pike, Rankin, Stone, Walthall, Wayne, Wilkinson, and Yazoo Counties for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–21782 Filed 9–4–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4077–DR; Docket ID FEMA–2012–0002]

Ohio; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Ohio (FEMA–4077–DR), dated August 20, 2012, and related determinations.

DATES: Effective August 20, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 20, 2012, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Ohio resulting from severe storms and straight-line winds during the period of June 29 to July 2, 2012, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Ohio.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for

Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, W. Michael Moore, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Ohio have been designated as adversely affected by this major disaster:

Adams, Allen, Athens, Auglaize, Belmont, Champaign, Clark, Coshocton, Fairfield, Franklin, Gallia, Guernsey, Hancock, Hardin, Harrison, Highland, Hocking, Jackson, Knox, Lawrence, Licking, Logan, Meigs, Miami, Monroe, Morgan, Morrow, Muskingum, Noble, Paulding, Perry, Pickaway, Pike, Putnam, Shelby, Van Wert, and Washington Counties for Public Assistance.

All counties within the State of Ohio are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–21746 Filed 9–4–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4078–DR; Docket ID FEMA–2012–0002]

Oklahoma; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–4078–DR), dated August 22, 2012, and related determinations.

DATES: *Effective Date:* August 22, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 22, 2012, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Oklahoma resulting from the Freedom Wildfire during the period of August 3–14, 2012, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Oklahoma.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated area and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William J. Doran III, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Oklahoma have been designated as adversely affected by this major disaster:

Creek County for Individual Assistance.

All counties within the State of Oklahoma are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–21747 Filed 9–4–12; 8:45 am]

BILLING CODE 9110–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4079–DR; Docket ID FEMA–2012–0002]

New Mexico; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of New Mexico (FEMA–4079–DR), dated August 24, 2012, and related determinations.

DATES: Effective August 24, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 24, 2012, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of New Mexico resulting from flooding during the period of June 22 to July 12, 2012, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of New Mexico.

In order to provide Federal assistance, you are hereby authorized to allocate from funds

available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Nancy M. Casper, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of New Mexico have been designated as adversely affected by this major disaster:

Lincoln and Sandoval Counties and the Santa Clara Pueblo for Public Assistance.

All counties and Indian Tribes in the State of New Mexico are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–21755 Filed 9–4–12; 8:45 am]

BILLING CODE 9110–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5617–N–01]

RIN 2502–ZA13

Notice of Intent To Conduct Affirmatively Furthering Fair Housing Demonstration in Baltimore, MD, Standard Metropolitan Statistical Area (SMSA)

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of Intent To Conduct Affirmatively Furthering Fair Housing Demonstration in Baltimore, Maryland, SMSA.

SUMMARY: Through this proposed demonstration, HUD seeks to encourage developers and owners of multifamily housing properties in ''communities of opportunity''—as defined by *Thompson* v. *HUD*—in the Baltimore, Maryland, SMSA to make units in these properties affordable to low-income persons. HUD seeks to determine if, as proposed in this notice, providing developers with financial incentives, to create such housing can help reduce segregation in the Baltimore SMSA.

DATES: *Comments Due Date:* November 5, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding HUD's Affirmatively Furthering Fair Housing demonstration, as announced in this notice, to the Office of General Counsel, Rules Docket Clerk, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0001. Communications should refer to the above docket number and title and should contain the information specified in the ''Request for Comments'' of this notice.

Submission of Hard Copy Comments. To ensure that the information is fully considered by all of the reviewers, each commenter submitting hard copy comments, by mail or hand delivery, should submit comments or requests to the address above. Due to security measures at all federal agencies, submission of comments or requests by mail often result in delayed delivery. To ensure timely receipt of comments, HUD recommends that any comments submitted by mail be submitted at least 2 weeks in advance of the public comment deadline.

Electronic Submission of Comments. Interested persons may submit comments 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 interested members of the public. Commenters should follow instructions provided on that site to submit comments electronically.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Comments. All comments submitted to HUD regarding this notice will be available, without charge, 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 documents must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Copies of all documents submitted are available for inspection and downloading at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mary Ann Henderson, Office of Housing, U.S. Department of Housing and Urban Development, City Crescent Building, 10 South Howard Street, Fifth Floor, Baltimore, Maryland 21201–2505, telephone number 410–209–6545 (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 800–877–8339.

SUPPLEMENTARY INFORMATION

I. Background

Section 808(e) of the Fair Housing Act (42 U.S.C. 3608(e)) requires HUD to administer its programs relating to housing and urban development in a manner to affirmatively further fair housing (AFFH). HUD carries out this obligation by requiring its program participants to affirmatively further fair housing. AFFH means undertaking affirmative efforts to overcome barriers to fair housing choice and reduce segregation of persons on the basis of race, national origin, and other protected classifications. HUD has funded a number of voucher mobility programs, for example, which pair Housing Choice Vouchers with mobility counseling to facilitate greater housing choice and overcome the effects of historic patterns of segregation. One such regional voucher mobility program

was established in the Baltimore SMSA in 1996.

Multifamily housing assisted by or with financing insured by HUD is subject to the Fair Housing Act's AFFH requirement. Through this proposed demonstration, HUD seeks to encourage investment in multifamily housing and promote the availability of affordable housing units in a manner that reduces racial segregation and increases geographic and economic mobility in the Baltimore SMSA. For its multifamily housing programs that insure financing for multifamily housing development, HUD will offer incentives to make more affordable housing available in mixed-income, integrated communities. In addition, HUD will require that this new affordable housing is made available to Housing Choice Voucher holders, expanding housing options for these families.

II. Proposed Demonstration

HUD proposes to make available incentives for Federal Housing Administration (FHA) insured financing to developers in order to encourage the production and availability of more affordable housing units in areas identified as communities of opportunity in the Baltimore SMSA. Eligible areas are those in which the regional mobility program, established under the *Thompson* v. *HUD* settlement, operates, and which are identified as ''communities of opportunities'' in the *Thompson* v. *HUD* settlement. HUD believes that the proposed incentives will contribute to reducing racial segregation and increasing opportunities for low-income families to live in areas identified as communities of opportunity throughout the Baltimore SMSA.

This demonstration would be open to multifamily owners and developers pursuing FHA mortgage insurance under the section 221(d)(4) program or other FHA multifamily finance programs for properties to be developed in eligible areas in the Baltimore SMSA. For such owners and developers who agree to set aside a percentage of newly constructed or rehabilitated two- or three-bedroom units for nonelderly families holding Housing Choice Vouchers, either under a project-based voucher contract or offered at rents less than or equal to the Fair Market Rent (FMR) for the Baltimore SMSA, and in order to encourage the construction of more affordable housing for these voucher holders, HUD proposes to offer one or a combination of the following incentives:

- Lowering the mortgage insurance premium (MIP);
- Lowering the occupancy/vacancy rate when establishing the project's anticipated budget; or
- Establishing a procedure that results in greater or more frequent surplus cash distributions for projects containing a specified number of affordable units. The incentives offered would be subject to any constraints of current and future program and budget authorities and would be commensurate with the number of affordable units set aside in the property, which in no case would be less than 10 percent of the newly constructed or rehabilitated units in that property. HUD will provide, in the notice soliciting applications, which incentives will be available based on the percentage of affordable units that are set aside.

Owners, developers, and lenders seeking to participate in the demonstration described in this notice must: [1]

- Certify that they meet all other requirements for FHA-insured financing, comply with the terms of the demonstration, and comply with HUD's nondiscrimination and equal opportunity requirements;
- Submit an affirmative fair housing marketing plan satisfactory to HUD for both the market-rate units and the units that will be affordable to Housing Choice Voucher holders in Baltimore City and throughout the Baltimore SMSA (a satisfactory affirmative fair housing marketing plan must include marketing of affordable units to Housing Choice Voucher holders in Baltimore City through the *Thompson* regional mobility program);
- Agree to not establish local residency preferences for properties that receive incentives pursuant to this demonstration; and
- Maintain statistics on the race and ethnicity of applicants and occupants for both the affordable and market rate units

HUD has estimated that a total of 1,200 to 1,500 units in multifamily housing properties may be made available per year in the Baltimore SMSA. If 10 percent of those units were set aside as affordable and available for vouchers holders under HUD's Housing Choice Voucher program, the demonstration would yield approximately 120 to 150 affordable units per year. HUD will offer the above incentives for not more than 300 affordable units per year, and will carefully monitor the demonstration to determine whether it is succeeding in increasing available affordable housing units in *Thompson* v. *HUD* settlement communities of opportunity in the Baltimore SMSA. If, in any year during this demonstration fewer than 300 affordable units are created through the demonstration, the unused allocation of units would roll over and be available in subsequent years, not to exceed 500 units created through these incentives in any given year. To enable it to evaluate the success of the demonstration, HUD proposes to operate the program for a minimum of 7 years, as long as continued operation of the demonstration is consistent with prudent fiscal management of the FHA insurance fund. If the demonstration indicates that it is succeeding in increasing the number of affordable housing units in areas identified as communities of opportunity in the Baltimore SMSA, HUD will consider if the demonstration should be expanded to other SMSAs.

III. Evaluating the Demonstration

One of the principal purposes of the demonstration is to determine whether the incentives that HUD is proposing to provide developers and owners of multifamily housing properties results in the availability of more affordable housing to low-income persons in a manner that reduces racial segregation and increases geographic and economic mobility. HUD will, therefore, undertake an evaluation of the demonstration to determine whether the demonstration could serve as a model that could be successful nationwide or, alternatively, whether modifications to the demonstration are needed.

IV. Solicitation of Public Comment

In accordance with section 470 of the Housing and Urban-Rural Recovery Act of 1983 (42 U.S.C. 3542), HUD is seeking comment on the demonstration for a period of 60 days, before commencing the demonstration. After the close of the public comment period, and following full consideration of comments submitted, HUD will publish another notice that will advise of the commencement of the demonstration, the specific incentives that HUD would offer multifamily housing owners and developers for properties to be developed in communities of opportunity in the Baltimore SMSA, as identified for the *Thompson* regional mobility program, and other features or requirements of the demonstration that HUD may prescribe.

During the comment period, HUD invites comment on all aspects of the demonstration, but specifically solicits

[1] Published elsewhere in today's **Federal Register** is HUD's 60-day notice soliciting comment on the burden hours of the proposed information collection requirements as set forth in this section.

comment on the incentives, and the criteria for receiving them, that are proposed to be offered to multifamily owners and developers under the demonstration, and seeks suggestions on specific parameters for these incentives and additional incentives that may be helpful to HUD in achieving the goals of the demonstration.

Dated: August 28, 2012.

Carol J. Galante,

Acting Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2012–21840 Filed 9–4–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2012–N216; FXIA16710900000P5–123–FF09A30000]

Endangered Species; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before October 5, 2012.

ADDRESSES: Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358–2280; or email *DMAFR@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2280 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone 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.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken.

III. Permit Applications

A. Endangered Species

Applicant: Big Game Studio, Bronte, TX; PRT–82880A

The applicant requests a permit to export sport hunted trophies of one male addax (*Addax nasomaculatus*), one male Dama gazelle (*Nanger dama*), one male Eld's deer (*Rucervus eldii*), two male scimitar-horned oryx (*Oryx dammah*), and one male lechwe (*Kobus leche*) culled from captive herds in the United States for the purpose of enhancement to the survival of the species.

Applicant: Corinne Zawacki, Tulane University, New Orleans, LA; PRT–80058A

The applicant requests a permit to import biological samples of Panamanian golden frogs (*Atelopus zeteki*) from Panama for the purpose of enhancement of the species through scientific research. This notification covers activities conducted by the applicant over a 5-year period.

Applicant: Cedars-Sinai Medical Center Research Institute, Los Angeles, CA; PRT–68962A

The applicant requests a permit to import biological samples of Western gorilla (*Gorilla gorilla*) from Canada for the purpose of enhancement of the species through scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Jim Beck, Shavano Park, TX; PRT 81901A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Jim Beck, Shavano Park, TX; PRT 81902A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Whitetail Junction Ranch, Junction, TX; 82527A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the barasingha (*Rucervus duvaucelii*), Eld's deer (*Rucervus eldii*), scimitar-horned oryx (*Oryx dammah*), Arabian oryx (*Oryx leucoryx*), addax (*Addax nasomaculatus*), dama gazelle (*Nanger dama*), and red lechwe (*Kobus leche*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Whitetail Junction Ranch, Junction, TX; 82897A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*), addax (*Addax nasomaculatus*), and dama gazelle (*Nanger dama*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Elizabeth Lyons Trust, San Antonio, TX; PRT–83159A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Elizabeth Lyons Trust, San Antonio, TX; PRT–83160A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Lawrence Lerner, Staten Island, NY; PRT–220871

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the red siskin (*Carduelis cucullata*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Star S Ranch Inc., Mason, TX; PRT–77537A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*), dama gazelle (*Nanger dama*) and Grevy's zebra (*Equus grevyi*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Star S Ranch Inc., Mason, TX; PRT–77536A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*) and dama gazelle (*Nanger dama*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: John Fry, Carson City, NV; PRT–82592A

The applicant requests a permit to import a sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2012–21793 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2010–N214; 1112–0000–81440–F2; FXES11120800000F2–123–FF08EVEN00]

Longworth Low-Effect Habitat Conservation Plan for the Morro Shoulderband Snail, Community of Los Osos, San Luis Obispo County, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application from Scott and Rita Longworth for a 10-year incidental take permit under the Endangered Species Act of 1973, as amended (Act). The application addresses the potential for ''take'' of the federally endangered Morro shoulderband snail that is likely to occur incidental to the construction, maintenance, and occupation of a single-family residence on a legally created single-family zoned parcel in the unincorporated community of Los Osos, San Luis Obispo County, California. The applicants would implement a conservation program to minimize and mitigate project activities that are likely to result in take of the Morro shoulderband snail as described in their plan. We invite comments from the public on the application, which includes the Longworth Low-Effect Habitat Conservation Plan for the Morro Shoulderband Snail. This proposed action has been determined to be eligible for a Categorical Exclusion under the National Environmental Policy Act of 1969, as amended (NEPA).

DATES: To ensure consideration, please send your written comments by October 5, 2012.

ADDRESSES: You may download a copy of the habitat conservation plan, draft environmental action statement and low-effect screening form, and related documents on the Internet at *http://www.fws.gov/ventura/,* or you may request copies of the documents by U.S. mail or phone (see below). Please address written comments to Diane K. Noda, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003. You may alternatively send comments by facsimile to (805) 644–3958.

FOR FURTHER INFORMATION CONTACT: Julie M. Vanderwier, Fish and Wildlife Biologist, at the above address or by calling (805) 644–1766.

SUPPLEMENTARY INFORMATION:

Background

The Morro shoulderband snail (= banded dune snail; *Helminthoglypta walkeriana*) was listed by the Service as endangered on December 15, 1994 (59 FR 64613). Section 9 of the Act and its implementing regulations (16 U.S.C. 1531 *et seq.*) prohibit the take of fish or wildlife species listed as endangered or threatened. ''Take'' is defined under the Act to include the following activities: ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532); however, under section 10(a)(1)(B) of the Act, we may issue permits to authorize incidental take of listed species. ''Incidental take'' is defined by the Act as take that is not the purpose of carrying out of an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species are provided in the Code of Federal Regulations at 50 CFR 17.32 and 17.22. Issuance of an

incidental take permit must not jeopardize the existence of federally listed fish, wildlife, or plant species.

Take of listed plants is not prohibited under the Act unless such take would violate State law. As such, take of plants cannot be authorized under an incidental take permit. Plant species may be included on a permit in recognition of the conservation benefits provided them under a habitat conservation plan. All species, including plants, covered by the incidental take permit receive assurances under our ''No Surprises'' regulations (50 CFR 17.22(b)(55) and 17.32(b)(5)). In addition to meeting other specific criteria, actions undertaken through implementation of the HCP must not jeopardize the continued existent of federally listed animal or plant species.The applicants have submitted a low-effect habitat conservation plan (HCP) in support of their application for an incidental take permit (ITP) that would address take of Morro shoulderband snail that is likely to occur as the result of direct impacts to up to 0.46 acre (20,038 square feet) of disturbed and intact coastal dune scrub occupied by the species. Take would be associated with the construction, maintenance, and occupation of a single-family residence on an existing parcel legally described as Assessor Parcel Number 074–483–036 and located at the eastern terminus of Madera Street Road in western portion of Los Osos, an unincorporated community of San Luis Obispo County, California. The applicants are requesting a permit for take of Morro shoulderband snail that would result from ''covered activities'' in the HCP that include the construction, maintenance, and occupation of a single-family residence and associated landscaping/infrastructure.

The applicants propose to minimize and mitigate take of Morro shoulderband snail associated with the covered activities by fully implementing the HCP. The following measures would be implemented to minimize the effects of the taking: (1) Pre-construction and concurrent construction monitoring surveys for Morro shoulderband snail would be conducted; (2) all identified individuals of any life stage of Morro shoulderband snail would be captured and moved out of harm's way to a Service-approved receptor site by an individual in possession of a current valid recovery permit for the species; and (3) a contractor and employee training program for Morro shoulderband snail would be developed and presented. To mitigate for unavoidable take, the applicants would contribute $10,200 to an impact-directed environmental account held and administered by the National Fish and Wildlife Foundation. These funds would be used to implement recovery tasks identified in the *Recovery Plan for the Morro Shoulderband Snail and Four Plants from Western San Luis Obispo County, California* (USFWS 1998). The applicants would fund up to $16,710, as needed, to ensure implementation of all of the minimization measures identified in the HCP.

In the proposed HCP, the applicants consider two alternatives to the proposed action: ''No Action'' and ''Project Design.'' Under the ''No Action'' alternative, an ITP for the Longworth single-family residence would not be issued. The Longworth single-family residence would not be built, and a contribution of in-lieu fees would not be provided to effect recovery actions for Morro shoulderband snail. Since the property is privately owned, there are ongoing economic considerations associated with continued ownership without use, which include payment of associated taxes. The sale of the properties for purposes other than the identified activity is not economically feasible. Because of economic considerations and because the proposed action results in a net benefit for the covered species, the Morro shoulderband snail, the No Action Alternative has been rejected.

Under the ''Project Redesign'' alternative, the project would be redesigned to avoid or further reduce take of Morro shoulderband snail. Because the coastal dune scrub occupied by Morro shoulderband snail is in the center of the property, and 6,252 square feet (31 percent) of the parcel along the eastern boundary is constrained by an easement where no structures may be placed, it is not feasible to implement a project such that take could be avoided. Further reducing the footprint of the house would not meet the applicants' needs and would not significantly reduce impacts to Morro shoulderband snail such that there would be a greater benefit to the species. For these reasons, the alternate design alternative has also been rejected.

We are requesting comments on our preliminary determination that the applicants' proposal will have a minor or negligible effect on the Morro shoulderband snail and that the plan qualifies as a low-effect HCP as defined by our Habitat Conservation Planning Handbook (November 1996). We base our determinations on three criteria: (1) Implementation of the proposed project as described in the HCP would result in minor or negligible effects on federally listed, proposed, and/or candidate species and their habitats; (2) implementation of the HCP would result in minor negligible effects on other environmental values or resources; and (3) HCP impacts, considered together with those of other past, present, and reasonably foreseeable future projects, would not result in cumulatively significant effects. In our analysis of these criteria, we have made a preliminary determination that the approval of the HCP and issuance of an ITP qualify for categorical exclusion under the NEPA (42 U.S.C. 4321 *et seq.*), as provided by the Department of Interior Manual (516 DM 2 Appendix 2 and 516 DM 8); however, based upon our review of public comments that we receive in response to this notice, this preliminary determination may be revised.

Next Steps

We will evaluate the permit application, including the plan and comments we receive, to determine whether the application meets the requirements of section 10(a)(1)(B) of the Act. We will also evaluate whether issuance of the ITP would comply with section 7(a)(2) of the Act by conducting an intra-Service Section 7 consultation for the plan.

Public Review

We provide this notice under section 10(c) of the Act and the NEPA public involvement regulations (40 CFR 1500.1(b), 1500.2(d), and 1506.6). We are requesting comments on our determination that the applicants' proposal will have a minor or neglible effect on the Morro shoulderband snail and that the plan qualifies as a low-effect HCP. We will evaluate the permit application, including the plan and comments we receive, to determine whether the application meets the requirements of section 10(a)(1)(B) of the Act. We will use the results of our internal Service consultation, in combination with the above findings, in our final analysis to determine whether or not to issue the permits. If the requirements are met, we will issue an ITP to the applicants for the incidental take of Morro shoulderband snail. We will make the final permit decision no sooner than 30 days after the date of this notice.

Public Comments

If you wish to comment on the permit applications, plans, and associated documents, you may submit comments by any one of the methods in **ADDRESSES**.

Public Availability of Comments

Before including your address, phone 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 view, we cannot guarantee that we will be able to do so.

Authority: We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: August 29, 2012.

Diane K. Noda,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2012–21823 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proclaiming Certain Lands, Dafter Parcel, as an Addition to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Reservation Proclamation.

SUMMARY: This notice informs the public that the Assistant Secretary—Indian Affairs proclaimed approximately 110.06 acres, more or less, to be added to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan.

FOR FURTHER INFORMATION CONTACT: Ben Burshia, Bureau of Indian Affairs, Division of Real Estate Services, Mail Stop 4639–MIB, 1849 C Street NW., Washington, DC 20240, telephone (202) 208–7737.

SUPPLEMENTARY INFORMATION: This Notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according with Section 7 of the Act of June 18, 1934 (48 Stat. 986; 25 U.S.C. 467), for the land described below. The land was proclaimed to be an addition to the Bay Mills Indian Reservation and part of the Bay Mills Indian Community of Michigan for the exclusive use of Indians on that Reservation who are entitled to reside at the Reservation by enrollment or tribal membership.

Bay Mills Indian Community Reservation

Township of Dafter, Chippewa County, Michigan

A parcel of land located in the South ½ of Section 15, Township 46 North, Range 1 West, Dafter Township, Chippewa County, Michigan, more particularly described as commencing at the Southwest corner of said Section 15; thence North 89°20′34″ E along the South line of said Section 15 a distance of 1139.96 feet; thence North 00°39′26″ W a distance of 75.00 feet to a point on the Northerly right of way line of M–28, said point is the POINT OF BEGINNING: Thence S 89°20′34″ W along said Northerly right of way line a distance of 98.76 feet; Thence N 00°00′36″ E a distance of 200.00 feet; thence N 8°20′34″ E a distance of 273.00 feet to a point on the West line of the East ½ of the Southwest ¼ of said Section 15; Thence N 00°00′36″ E along said West line a distance of 2461.49 feet to the Northwest corner of said East ½, said point is on the East-West ¼ line of said Section 15; Thence N 83°41′56″ E along said East-West ¼ line a distance of 2340.11 feet to a point the Westerly Limited Access Right of Way line of Highway I–75; Thence the following six courses and distances along said Westerly right of way line; Thence Southwesterly 1271.34 feet along the arc of a non-tangent curve, concave to the Southeast, said curve has a delta angle of 06°16′28″, a radius of 11,609.16 feet and is subtended by a chord that bears S 14°12′52″ W a distance of 1270.70 feet; Thence S 11°04′38″ W a distance of 286.72 feet; Thence S 34°58′27″ W a distance of 713.99 feet; Thence S 53°09′38″ W a distance of 1070.00 feet; Thence S 68°06′45″ W a distance of 353.64 feet; Thence S 84°50′34″ W a distance of 542.00 feet, to the POINT OF BEGINNING.

The above-described lands contain a total of 110.06 acres, more or less, which are subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the land described above, nor does it affect any valid existing easements for public roads and highways, public utilities and for railroads and pipelines and any other rights-of-way or reservations of record.

Dated: August 23, 2012.

Donald E. Laverdure,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2012–21825 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proclaiming Certain Lands, Sugar Parcel Lands, as an Addition to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Reservation Proclamation.

SUMMARY: This notice informs the public that the Assistant Secretary—Indian Affairs proclaimed approximately 80.00 acres, more or less, to be added to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan.

FOR FURTHER INFORMATION CONTACT: Ben Burshia, Bureau of Indian Affairs, Division of Real Estate Services, Mail Stop 4639–MIB, 1849 C Street NW., Washington, DC 20240, telephone (202) 208–7737.

SUPPLEMENTARY INFORMATION: This Notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according with Section 7 of the Act of June 18, 1934 (48 Stat. 986; 25 U.S.C. 467), for the land described below. The land was proclaimed to be an addition to the Bay Mills Indian Reservation and part of the Bay Mills Indian Community of Michigan for the exclusive use of Indians on that Reservation who are entitled to reside at the Reservation by enrollment or tribal membership.

Bay Mills Indian Community Reservation

Township of Bay Mills, Chippewa County, Michigan

East One Half (E½) of Northeast One Quarter (NE ¼), Section 36, Township 47 North, Range 3 West (80 acres).

The above-described lands contain a total of 80.00 acres, more or less, which are subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the land described above, nor does it affect any valid existing easements for public roads and highways, public utilities and for railroads and pipelines and any other rights-of-way or reservations of record.

Dated: August 23, 2012.

Donald E. Laverdure,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2012–21822 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORB00000.L10200000.PH0000.LX.SS.036H0000; HAG 12–0282]

Southeast Oregon Resource Advisory Council (RAC); Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management, the Southeast Oregon Resource Advisory Council (RAC) will meet as indicated below:

DATES: The Southeast Oregon RAC will hold a public meeting Monday, September 10, 2012, from 8:30 a.m. to 4:30 p.m. and Tuesday, September 11, 2012, from 8:30 a.m. to 12 p.m. Public comment is scheduled at 11 a.m. each day. Unless otherwise approved by the Southeast Oregon RAC Chair, the public comment period will last no longer than 30 minutes, and each speaker may address the RAC for a maximum of 5 minutes. Meeting times and the duration scheduled for public comment periods may be extended or altered when the authorized representative considers it necessary to accommodate necessary business and all who seek to be heard regarding matters before the RAC.

ADDRESSES: The meetings will be held at the BLM Burns District Office, 28910 Hwy 20 West, in Hines, Oregon 97738.

FOR FURTHER INFORMATION CONTACT: Tara Martinak, Public Affairs Specialist, Bureau of Land Management Burns District Office, 28910 Highway 20 West, Hines, Oregon 97738, (541) 573–4519 or email *tmartina@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Southeast Oregon RAC consists of 15 members chartered and appointed by the Secretary of the Interior. Their diverse perspectives are represented in commodity, conservation, and general interests. They provide advice to BLM and Forest Service resource managers regarding management plans and proposed resource actions on public land in southeast Oregon.

Tentative agenda items for the September 10–11, 2012, meeting include: A discussion regarding recent wildfires, subsequent stabilization and rehabilitation efforts, effected resources and the status of ecosystems of burned areas within the Southeast Oregon RAC jurisdictional boundary; updates on travel management planning in the Lakeview Resource Area, the Chiloquin Ranger District, and the Malheur National Forest; information sharing regarding Cooperative Conservation Agreements (CCA) and CCA's with Assurances; and a partial-day field tour to the Miller Homestead wildfire area near Frenchglen, Oregon. The Southeast Oregon RAC will also hear subcommittee and Federal official reports, receive an update on the RAC's development on questions for analyzing lands with wilderness characteristics, review and approve meeting minutes from the April 2012 session, and develop agenda items for the next meeting. Any other matters that may reasonably come before the Southeast Oregon RAC may also be addressed.

All meetings are open to the public in their entirety. Those interested in participating in the field tour must provide personal transportation. Information to be distributed to the Southeast Oregon RAC is requested prior to the start of each meeting.

Before including your address, phone 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.

Jeff Rose,

BLM Burns Associate District Manager.

[FR Doc. 2012–21834 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM–932000–L1430000–FQ0000; NMNM012273]

Public Land Order No. 7796; Partial Withdrawal Revocation and Transfer of Administrative Jurisdiction, Kirtland Air Force Base; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order partially revokes the withdrawal created by Public Land Order No. 995 insofar as it affects approximately 82.81 acres of public land reserved for military purposes on behalf of the United States Department of the Air Force for the portion now containing the Lovelace Respiratory Research Institute. The land is no longer needed for the purpose for which it was withdrawn. This order also transfers administrative jurisdiction to the Department of Energy to allow for a subsequent conveyance of the land in accordance with the Omnibus Public Land Management Act of 2009.

DATES: *Effective Date:* September 5, 2012.

FOR FURTHER INFORMATION CONTACT: Debby Lucero, Bureau of Land Management, New Mexico State Office, 301 Dinosaur Trail, P.O. Box 27115, Santa Fe, New Mexico 87502–0115, 505–954–2196. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The United States Department of the Air Force has determined that 82.81 acres of public land is excess to its needs and has requested a partial revocation of the withdrawal. Pursuant to Public Law 111–11, the land is found suitable for transfer to the Department of Energy in order to allow for a subsequent conveyance to the Lovelace Respiratory Research Institute.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, and Section 13005 of Public Law 111–11, 123 Stat. 1449 (2009), it is ordered as follows:

1. Public Land Order No. 995 (19 FR 5443 (1954)), which withdrew public land and reserved it for use of the United States Department of the Army in connection with Sandia Base, presently managed by the United States Department of the Air Force in connection with Kirtland Air Force Base, is hereby revoked only insofar as it affects the following described land:

New Mexico Principal Meridian

T. 8 N., R. 4 E.,
Sec. 3, lot 18.
The area described contains approximately 82.81 acres, more or less, in Bernalillo County.

2. Pursuant to Section 13005 of Public Law 111–11, 123 Stat. 1449 (2009), and subject to valid existing rights, administrative jurisdiction of the land described in Paragraph 1 is hereby transferred to the Department of Energy in order to allow for a subsequent conveyance to the Lovelace Respiratory Research Institute for research, scientific, or educational use.

Dated: August 23, 2012.

Rhea S. Suh,

Assistant Secretary—Policy, Management and Budget.

[FR Doc. 2012–21800 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAC069 L1711.0000 AL.0000 025B]

Call for Nominations for the Carrizo Plain National Monument Advisory Council, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) is soliciting nominations from the public to fill three positions on the Carrizo Plain National Monument Advisory Council (MAC). MAC members provide advice and recommendations to the BLM on the management of public lands in the Carrizo Plain National Monument.

DATES: The deadline for submitting nominations is November 5, 2012.

ADDRESSES: Nominations should be sent to Johna Hurl, Monument Manager, Bureau of Land Management, Bakersfield Field Office, 3801 Pegasus Drive, Bakersfield, CA 93308.

FOR FURTHER INFORMATION CONTACT: Johna Hurl, Monument Manager, Bakersfield Field Office, 3801 Pegasus Drive, Bakersfield, CA 93308, 661–391–6093, *jhurl@blm.gov* or John Kelley, Carrizo Program Support Technician, at 661–391–6088, *jtkelley@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The MAC provides representative citizen counsel and advice to the Secretary of the Interior through the BLM with respect to the revision and implementation of the comprehensive plan for the Carrizo Plain National Monument. This notice constitutes an open call to the public to submit nomination applications for the following positions on the MAC:

(1) A member of, or nominated by, the Carrizo Native American Advisory Council;

(2) A member representing individuals or companies authorized to graze livestock within the Monument; and

(3) One member with recognized backgrounds reflecting:

i. The purposes for which the Monument was established; or

ii. The interests of other stakeholders, including the general public, who are affected by or interested in the planning and management of the Monument.

Individuals may nominate themselves or others. Nominees must be residents of the counties or neighboring county in which the MAC has jurisdiction. The BLM will evaluate nominees based on their education, training, experience, and their knowledge of the geographical resource. The Obama Administration prohibits individuals who are currently federally registered lobbyists from being appointed or re-appointed to Federal Advisory Committee Act (FACA) and non-FACA boards, committees, or councils.

The following must accompany nominations received in this call for nominations:

○ Letters of reference from represented interests or organizations;

○ A completed background information nomination form; and

○ Any other information that speaks to the nominee's qualifications.

Nominations will be accepted for a 60-day period beginning the date this notice is published.

Timothy Z. Smith,

Field Manager, Bakersfield Field Office.

[FR Doc. 2012–21669 Filed 9–4–12; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Toxic Substances Control Act

Notice is hereby given that on August 21, 2012, a proposed Consent Decree in *United States* v. *INEOS Chlor Americas, Inc.,* Civil Action No. 1:12–cv–01058, was lodged with the United States District Court for the District of Delaware.

In this action, the United States sought injunctive relief from Defendant INEOS Chlor Americas, Inc., (''INEOS Chlor'') for violations of the Toxic Substances Control Act (''TSCA''), Section 15, 15 U.S.C. 2614. The Complaint alleges that INEOS Chlor manufactured and continues to manufacture multiple ''new chemical substances'' as defined in TSCA Section 3(9), 15 U.S.C. 2602 (9), while failing to comply with the manufacturing and processing notices required under TSCA Section 5, 15 U.S.C. 2604. The violations alleged in the Complaint occurred and continue to occur at INEOS Chlor's headquarters located in Wilmington, Delaware.

Under the proposed Consent Decree, INEOS Chlor will cease importing chlorinated paraffin products unless and until it submits the requisite premanufacture notices (''PMNs'') and such substances are placed on the TSCA Inventory. The proposed Consent Decree also requires INEOS Chlor to pay a civil penalty of $175,000.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to this Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either emailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *INEOS Chlor Americas, Inc.,* D.J. Ref. 90–5–1–1–10159.

During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, U.S. Department of Justice, P.O. Box 7611, Washington, DC 20044–7611 or by faxing or emailing a request to ''Consent Decree Copy'' (*EESCDCopy.ENRD@usdoj.gov*), fax number (202) 514–0097, phone confirmation number (202) 514–5271. If

requesting a copy from the Consent Decree Library, please enclose a check in the amount of $ 6.50 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by email or fax, forward a check in that amount to the Consent Decree Library at the address given above.

Maureen Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division, United States Department of Justice.

[FR Doc. 2012–21716 Filed 9–4–12; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0095]

Agency Information Collection Activities: Proposed collection; Comments Requested: Student and Supervisor Training Validation Surveys

ACTION: 30-Day notice of information collection under review.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 127, page 39262 on July 2, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until October 5, 2012. This process is conducted in accordance with 5 CFR 1320.10.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. The best way to ensure your comments are received is to email them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285. All comments should reference the eight digit OMB number or the title of the collection.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Summary of Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Student and Supervisor Training Validation Surveys.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: None. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: State, Local or Tribal Government. Other: None.

Need for Collection

The information will help ATF determine whether the training programs are meeting objectives and impacting the performance of the individuals in their work place. Also, the information will provide performance measure data and meet Federal law enforcement training accreditation requirements.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 1,400 respondents will complete a 10 minute survey.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 233.34 annual total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, Room 2E–508, 145 N Street NE., Washington, DC 20530.

Dated: August 30, 2012.

Jerri Murray,

Department Clearance Officer, U.S. Department of Justice.

[FR Doc. 2012–21796 Filed 9–4–12; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0096]

Agency Information Collection Activities: Proposed Collection; Comments Requested: Environmental Information

ACTION: 30-Day Notice of Information Collection:

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 127, page 39263 on July 2, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until October 5, 2012. This process is conducted in accordance with 5 CFR 1320.10.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. The best way to ensure your comments are received is to email them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285. All comments should reference the eight digit OMB number or the title of the collection.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Summary of Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Environmental Information.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: ATF Form 5000.29. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. Other: None.

Need for Collection

The information will help ATF identify any waste product(s) generated as a result of the operations by the applicant and the disposal of the products. The information will help determine if there is any adverse impact on the environment.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 680 respondents will complete the form in 30 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 340 annual total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, Room 2E–508, 145 N Street NE., Washington, DC 20530.

Dated: August 30, 2012.

Jerri Murray,

Department Clearance Officer, U.S. Department of Justice.

[FR Doc. 2012–21797 Filed 9–4–12; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—IMS Global Learning Consortium, Inc.

Notice is hereby given that, on July 16, 2012, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), IMS Global Learning Consortium, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Antioch University, Yellow Springs, OH; Courseload, Indianapolis, IN; Psydev, Sheffield, UNITED KINGDOM; and Samsung Electronics, Gyeonngi-do, REPUBLIC OF KOREA, have been added as parties to this venture.

Also, Cambridge Assessment, Cambridge, UNITED KINGDOM; Iowa Community College Online Consortium (ICCOC), W. Burlington, IA; and Lightbox Education, Cheadle, UNITED KINGDOM, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and IMS Global Learning Consortium, Inc. intends to file additional written notifications disclosing all changes in membership.

On April 7, 2000, IMS Global Learning Consortium, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on September 13, 2000 (65 FR 55283).

The last notification was filed with the Department on May 2, 2012. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 8, 2012 (77 FR 34069).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2012–21781 Filed 9–4–12; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—National Warheads and Energetics Consortium

Notice is hereby given that, on August 7, 2012, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), National Warheads and Energetics Consortium (''NWEC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Control Solutions, LLC, Aurora, IL; Tiburon Associates, Inc., Alexandria, VA; Streamline Automation, LLC (dba C3 Propulsion), Huntsville, AL; L–3 Communications Corporation-Brashear Division, Pittsburgh, PA; Knight's Armament Company, Titusville, FL; and JAK Tool and Model LLC, Cranberry, NJ, have been added as parties to this venture.

Also, Cyber Research, Inc., Belle Mead, NJ, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and NWEC intends to file additional written notifications disclosing all changes in membership.

On May 2, 2000, NWEC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 30, 2000 (65 FR 40693).

The last notification was filed with the Department on May 7, 2012. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 8, 2012 (77 FR 34067).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2012–21780 Filed 9–4–12; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Petroleum Environmental Research Forum

Notice is hereby given that, on July 5, 2012, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Petroleum Environmental Research Forum (''PERF'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Phillips 66, Houston, TX, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PERF intends to file additional written notifications disclosing all changes in membership.

On February 10, 1986, PERF filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 14, 1986 (51 FR 8903).

The last notification was filed with the Department on June 8, 2012. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 6, 2012 (77 FR 40086).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2012–21778 Filed 9–4–12; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—ODVA, INC.

Notice is hereby given that, on July 18, 2012, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 301 *et seq.* (''the Act''), ODVA, Inc. (''ODVA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Sine Systems Corporation, Clinton Township, MI; Ecava Sdn Bhd, Kuala Lumpur, Malaysia; SERRA soldadura S.A.U., Barcelona, Spain; Tri-Tronics Company, Inc., Tampa, FL; IEP GmbH, Langenhagen, Germany; Monduran Pty Ltd., Southport, Queensland, Australia; Chi Mei Electronics Co., Ltd., Hong Kong, Hong Kong-China; and Lenze SE., Aerzen, Germany, have been added as parties to this venture.

Also, Samsung Electronics Co., Ltd., Gyeonggi-Do, Republic of Korea; and Lenze AC Tech Corporation, Uxbridge, MA, have withdrawn as a parties to this venture.

In addition, Syron Engineering & Manufacturing, Inc. has changed its name to Norgren Automation Solutions, LLC, Saline, MI.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and ODVA intends to file additional written notifications disclosing all changes in membership.

On June 21, 1995, ODVA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on February 15, 1996 (61 FR 6039).

The last notification was filed with the Department on April 20, 2012. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on May 24, 2012 (77 FR 31041).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2012–21758 Filed 9–4–12; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Executive Office for Immigration Review

[OMB Number 1125–0010]

Agency Information Collection Activities: Proposed Collection; Comments Requested: Notice of Appeal to the Board of Immigration Appeals From a Decision of a DHS Officer

ACTION: 30-Day notice of information collection.

The Department of Justice (DOJ), Executive Office for Immigration Review (EOIR) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77 Number 127, page 39261, on July 2, 2012, allowing for a 60 day comment period. The purpose of this notice is to allow for an additional 30 days for public comment until October 5, 2012. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530. Additionally, comments may also be submitted to OMB via facsimile to (202) 395–7285.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Notice of Appeal to the Board of Immigration Appeals from a Decision of a DHS Officer.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form EOIR 29, Executive Office for Immigration Review, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: A party who appeals a decision of a DHS Officer to the Board of Immigration Appeals (Board). Other: None. Abstract: A party affected by a decision of a DHS Officer may appeal that decision to the Board, provided that the Board has jurisdiction pursuant to 8 CFR 1003.1(b). The party must complete the Form EOIR–29 and submit it to the DHS office having administrative control over the record of proceeding in order to exercise the regulatory right to appeal.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 7,215 respondents will complete the form annually with an average of thirty minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 3,607.5 total burden hours associated with this collection annually.

If additional information is required, contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 2E–508, Washington, DC 20530.

Dated: August 30, 2012.

Jerri Murray,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 2012–21798 Filed 9–4–12; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 07–12]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR Part 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:

Thursday, September 13, 2012: 11 a.m.—Issuance of Proposed Decisions in claims against Libya; 2 p.m.—Oral hearings on Objection to Commission's Proposed Decisions in Claim No. LIB–II–116; 3 p.m.—LIB–II–122, LIB–II–153; 4:30 p.m.—LIB–II–170.

Friday, September 14, 2012: 9 a.m.—LIB–II–017, LIB–II–018, LIB–II–019, LIB–II–020, LIB–II–021, LIB–II–022 and LIB–II–047; 11 a.m.—LIB–II–189; 2 p.m.—LIB–I–037.

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. 2012–21950 Filed 8–31–12; 4:15 pm]

BILLING CODE 4410–BA–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number 1121–0291]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Census of Juveniles on Probation (Reinstatement, With Change, of a Previously Approved Collection for Which Approval Has Expired)

ACTION: 30-Day notice of information collection under review.

The Department of Justice (DOJ), Office of Justice Programs, Office of Juvenile Justice and Delinquency Prevention, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 127, page 39264, on July 2, 2012, allowing for a 60 day comment period.

Comments are encouraged and will be accepted for thirty days until October 5, 2012. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Brecht Donoghue, (202) 305–1270, Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, US Department of Justice, 810 Seventh Street NW., Washington, DC 20531.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of information collection:* Reinstatement, with change, of a previously approved collection whose approval has expired.

(2) *The title of the form/collection:* Census of Juveniles on Probation.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is CJ–17, Office of Juvenile Justice and Delinquency Prevention, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Federal Government, State, Local or Tribal. Other: Not-for-profit institutions; Business or other for-profit.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 1,600 respondents will complete a 3 hour questionnaire.

(6) *An estimate of the total public burden (in hours) associated with the collection:* Approximately 4,800 hours.

If additional information is required, contact: Jerr Murray, Department Clearance Officer, United States

Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Suite 2E–508, Washington, DC 20530.

Dated: August 30, 2012.

Jerri Murray,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2012–21803 Filed 9–4–12; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c) (2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the revision of the ''The Consumer Expenditure Surveys: The Quarterly Interview and the Diary.'' A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section of this notice on or before November 5, 2012.

ADDRESSES: Send comments to Nora Kincaid, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE., Washington, DC 20212. Written comments also may be transmitted by fax to 202–691–5111 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Nora Kincaid, BLS Clearance Officer, at 202–691–7628 (this is not a toll free number). (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The Consumer Expenditure (CE) Surveys collect data on consumer expenditures, demographic information, and related data needed by the Consumer Price Index (CPI) and other public and private data users. The continuing surveys provide a constant measurement of changes in consumer expenditure patterns for economic analysis and to obtain data for future CPI revisions. The CE Surveys have been ongoing since 1979.

The data from the CE Surveys are used (1) for CPI revisions, (2) to provide a continuous flow of data on income and expenditure patterns for use in economic analysis and policy formulation, and (3) to provide a flexible consumer survey vehicle that is available for use by other Federal Government agencies. Public and private users of price statistics, including Congress and the economic policymaking agencies of the Executive branch, rely on data collected in the CPI in their day-to-day activities. Hence, data users and policymakers widely accept the need to improve the process used for revising the CPI. If the CE Surveys were not conducted on a continuing basis, current information necessary for more timely, as well as more accurate, updating of the CPI would not be available. In addition, data would not be available to respond to the continuing demand from the public and private sectors for current information on consumer spending.

In the Quarterly Interview Survey, each consumer unit (CU) in the sample is interviewed every three months over five calendar quarters. The sample for each quarter is divided into three panels, with CUs being interviewed every three months in the same panel of every quarter. The Quarterly Interview Survey is designed to collect data on the types of expenditures that respondents can be expected to recall for a period of three months or longer. In general the expenses reported in the Interview Survey are either relatively large, such as property, automobiles, or major appliances, or are expenses which occur on a fairly regular basis, such as rent, utility bills, or insurance premiums.

The Diary (or recordkeeping) Survey is completed at home by the respondent family for two consecutive one-week periods. The primary objective of the Diary Survey is to obtain expenditure data on small, frequently purchased items which normally are difficult to recall over longer periods of time.

II. Current Action

Office of Management and Budget clearance is being sought for the proposed revision of the Consumer Expenditure Surveys: The Quarterly Interview and the Diary.

The continuing CE Surveys provide a constant measurement of changes in consumer expenditure patterns for economic analysis and obtain data for future CPI revisions.

The Consumer Expenditure Quarterly Interview Survey has recently undergone a thorough review. The proposed changes from this review fall into two major categories: Streamlining the current questions in several sections and updating several questions and sections to reflect the current marketplace. In the streamlining category, the BLS deleted or collapsed obsolete questions. For example, previously clothing purchases were asked separately for those over and under two years old. These questions were combined into one section for all clothing purchases. Sewing products were moved to 'Miscellaneous Expenditures' after 'arts and crafts.'

To keep the survey current and to fulfill the requirements of the Consumer Price Index (CPI), question wording changed and new items were added. For example, the questions on who is a member of the CU were collapsed from several questions down to one; the number of educational categories were reduced; the residential telephone service category was collapsed with voice over IP; cell phone service was collapsed with prepaid cell phone service; vehicle repair categories were collapsed; sewing item expenditures were collapsed from four questions into one; some appliance categories (e.g. washer and dryer will now be collected together) were collapsed; service contracts were combined with the repair and maintenance of items; clothing items were combined. Lastly, many questions in the income section were collapsed and reworded.

There are no changes to the Diary CAPI instrument since clearance was last received.

A full list of the proposed changes to the Quarterly Interview Survey and Diary Survey are available upon request.

In addition, the Consumer Expenditure program is planning several tests over the next several years in an effort to improve the CE surveys in the areas of both data quality and respondent burden.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Type of Review: Revision.

Agency: Bureau of Labor Statistics.

Title: The Consumer Expenditure Surveys: The Quarterly Interview and the Diary.

OMB Number: 1220–0050.

Affected Public: Individuals or Households.

Form	Total respondents	Frequency	Total responses	Average time per response (minutes)	Estimated total burden
CEQ—Interview	8,825	4	35,300	55	32,358
CEQ—Reinterview	3,800	1	3,800	10	633
CED—Diary (recordkeeping)	7,050	2	14,100	105	24,675
CED—Diary (Interview)	7,050	3	21,150	24	8,460
CED—Diary (Reinterview)	1,400	1	1,400	10	233
Totals			75,750		66,359

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, this 28th day of August 2012.

Kimberley Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2012–21804 Filed 9–4–12; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL SCIENCE FOUNDATION

Astronomy and Astrophysics Advisory Committee #13883; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following Astronomy and Astrophysics Advisory Committee (#13883) meeting:

Date and Time: September 25, 2012, 1 p.m.–2 p.m.

Place: National Science Foundation, Room 1020, Stafford I Building, 4201 Wilson Blvd., Arlington, VA, 22230.

Type of Meeting: Open.

Contact Person: Dr. Jim Ulvestad, Division Director, Division of Astronomical Sciences, Suite 1045, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: 703–292–7165.

Purpose of Meeting: To brief the AAAC on the Portfolio Review report recommendations. The AST portfolio review committee was charged with recommending critical capabilities over the period of 2015 to 2015 with a balance of investments in new and existing grants programs, facilities, and other activities. The briefing will provide the AAAC with information that will assist it in the future in providing its advice to NSF, NASA, and DOE on issues within the field of astronomy and astrophysics that are of mutual interest and concern to the agencies.

Agenda: Brief the AAAC on the Portfolio Review report process and recommendations.

Dated: August 29, 2012.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 2012–21741 Filed 9–4–12; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

Strategic Management Program; Fiscal Year 2013–2016 Strategic Plan

AGENCY: National Transportation Safety Board.

ACTION: Notice: Request for comments.

SUMMARY: This notice is in accordance with OMB Circular A–11, Section 210.3(b), Consultation and Outreach, which requires that the NTSB solicits comments on the proposed strategic plan to be published by October 2012. All interested parties are invited to submit comments regarding this proposed strategic plan.

As background, the NTSB's 2010–2015 strategic plan was published in January 2010. This document updates that plan, incorporating a revised mission statement, expanded core values including diversity and inclusion in the workplace, streamlined strategic goals and objectives, and updated key priority performance indicators to measure overall success of agency objectives.

You can view a copy of the draft strategic plan on the NTSB Web site at *http://www.ntsb.gov/doclib/agency_reports/Strategic-Plan_2013–2016.pdf.*

DATES: Parties should submit comments on or before September 19, 2012.

ADDRESSES: Submit electronic comments to *strategicplan@ntsb.gov* or at *http://regulations.gov.* Submit written comments by regular mail to the National Transportation Safety Board, 490 L'Enfant Plaza SW., Washington, DC 20594. Attn: MD–1, Strategic Management Program.

FOR FURTHER INFORMATION CONTACT: Agency contact, Shamicka Fulson, Program Manager, Strategic Management Program; National Transportation Safety Board, 490 L'Enfant Plaza SW., MD–1, Washington, DC 20594, 202–314–6082.

SUPPLEMENTARY INFORMATION: * * *

Candi R. Bing,

Federal Register Liaison Officer.

[FR Doc. 2012–21820 Filed 9–4–12; 8:45 am]

BILLING CODE 7533–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2012–0176]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection

request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR Part 110 ''Reporting and Recordkeeping Requirements for Export and Import of Nuclear Equipment and Material.''

2. *Current OMB approval number:* 3150–0036.

3. *How often the collection is required:* On occasion.

4. *Who is required or asked to report:* Any person in the U.S. who wishes to export or import nuclear material or equipment subject to the requirements of a general or a specific license issued under NRC authority.

5. *The number of annual respondents:* 136.

6. *The number of hours needed annually to complete the requirement or request:* 809.

7. *Abstract:* Persons in the U.S. who export or import nuclear material or equipment under an NRC general or specific license must comply with certain reporting and recordkeeping requirements under part 110 of Title 10 of the Code of Federal Regulations (10 CFR).

Submit, by November 5, 2012, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/.*

The document will be available on the NRC's home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2012–0176.

You may submit your comments by any of the following methods: Electronic comments: Go to *http://www.regulations.gov* and search for Docket No. NRC–2012–0176. Mail comments to NRC's Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Questions about the information collection requirements may be directed to the NRC's Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6258, or by email: *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 29th day of August 2012.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2012–21789 Filed 9–4–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2012–0148]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR Part 150, ''Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274.''

2. *Current OMB approval number:* 3150–0032.

3. *How often the collection is required:* 10 CFR 150.16(b), 150.17(c), and 150.19(c) require the submission of reports following specified events, such as the theft or unlawful diversion of licensed radioactive material. The source material inventory reports required under 10 CFR 150.17(b) must be submitted annually by certain licensees.

4. *Who is required or asked to report:* Agreement State licensees authorized to possess source or special nuclear material at certain types of facilities, or at any one time and location in greater than specified amounts. In addition, persons engaging in activities in non-Agreement States, in areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters.

5. *The number of annual respondents:* 15.

6. *The number of hours needed annually to complete the requirement or request:* 190.

7. *Abstract:* Part 150 of Title 10 of the Code of Federal Regulations (10 CFR), provides certain exemptions from NRC regulations for persons in Agreement States. Part 150 also defines activities in Agreement States and in offshore waters over which the NRC regulatory authority continues, including certain information collection requirements. The information is needed to permit the NRC to make reports to other governments and the International Atomic Energy Agency in accordance with international agreements. The information is also used to carry out the NRC's safeguards and inspection programs.

Submit, by November 5, 2012, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's

Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/.*

The document will be available on the NRC's home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2012–0148.

You may submit your comments by any of the following methods: Electronic comments: Go to *http://www.regulations.gov* and search for Docket No. NRC–2012–0148. Mail comments to NRC's Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Questions about the information collection requirements may be directed to the NRC's Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone at 301–415–6258, or by email: *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 29th day of August 2012.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2012–21790 Filed 9–4–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2012–0184]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* NRC Form 398, ''Personal Qualification Statement—Licensee.''

2. *Current OMB approval number:* 3150–0090.

3. *How often the collection is required:* Upon application for an initial or upgrade operator license and every six years for the renewal of operator or senior operator licenses.

4. *Who is required or asked to report:* Facility licensees who are tasked with certifying that the applicants and renewal operators are qualified to be licensed as reactor operators and senior reactor operators.

5. *The number of annual respondents:* 1,436.

6. *The number of hours needed annually to complete the requirement or request:* 3,680.25.

7. *Abstract:* NRC Form 398 is used to transmit detailed information required to be submitted to the NRC by a facility licensee on each applicant applying for new and upgraded licenses or license renewals to operate the controls at a nuclear reactor facility. This information is used to determine that each applicant or renewal operator seeking a license or renewal of a license is qualified to be issued a license and that the licensed operator would not be expected to cause operational errors and endanger public health and safety.

Submit, by November 5, 2012, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/.*

The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2012–0184.

You may submit your comments by any of the following methods: Electronic comments; go to *http://www.regulations.gov* and search for Docket No. NRC–2012–0184. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC's Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone at 301–415–6258, or by email: *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 30th day of August, 2012.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2012–21832 Filed 9–4–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2012–0135]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* NRC Form 171, ''Duplication Request.''

2. *Current OMB approval number:* 3150–0066.

3. *How often the collection is required:* Weekly.

4. *Who is required or asked to report:* Individuals, companies, or organizations requesting document duplication.

5. *The number of annual respondents:* 200.

6. *The number of hours needed annually to complete the requirement or request:* 16.67.

7. *Abstract:* This form is utilized by the Public Document Room (PDR) staff members who collect information from the public requesting reproduction of publicly available documents in NRC Headquarters' Public Document Room. Copies of the form are utilized by the reproduction contractor to accompany the orders. One copy of the form is kept by the contractor for their records, one copy is sent to the public requesting the documents, and the third copy (with no credit card data) is kept by the PDR staff for 90 calendar days, and then securely discarded.

Submit, by November 5, 2012, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/.*

The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2012–0135.

You may submit your comments by any of the following methods: Electronic comments: Go to *http://www.regulations.gov* and search for Docket No. NRC–2012–0135. Mail comments to the NRC's Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC's Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone at 301–415–6258, or by email: *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 30th day of August, 2012.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2012–21831 Filed 9–4–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0002]

Sunshine Act Meeting

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATE: Weeks of September 3, 10, 17, 24, October 1, 8, 2012.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of September 3, 2012

There are no meetings scheduled for the week of September 3, 2012.

Week of September 10, 2012—Tentative

Tuesday, September 11, 2012

9 a.m.

Briefing on Economic Consequences (Public Meeting) (Contact: Richard Correia, 301–251–7430)

This meeting will be webcast live at the Web address—*www.nrc.gov.*

Friday, September 14, 2012

11 a.m.

Discussion of Management and Personnel Issues (Closed—Ex. 2 and 6)

Week of September 17, 2012—Tentative

There are no meetings scheduled for the week of September 17, 2012.

Week of September 24, 2012—Tentative

Tuesday, September 25, 2012

9:30 a.m.

Strategic Programmatic Overview of the New Reactors Business Line (Public Meeting) (Contact: Donna Williams, 301–415–1322)

This meeting will be webcast live at the Web address—*www.nrc.gov.*

Week of October 1, 2012—Tentative

Tuesday, October 2, 2012

9:30 a.m.

Strategic Programmatic Overview of the Nuclear Materials Users and Decommissioning and Low-Level Waste Business Lines (Public Meeting) (Contact: Kimyata Morgan Butler, 301–415–0733)

This meeting will be webcast live at the Web address—*www.nrc.gov.*

Week of October 8, 2012—Tentative

There are no meetings scheduled for the week of October 8, 2012.

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* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—301–415–1292. Contact person for more information: Rochelle Bavol, 301–415–1651.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify Bill Dosch, Chief, Work Life and Benefits Branch, at 301–415–6200, TDD: 301–415–2100, or by email at *william.dosch@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed electronically to subscribers. If you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an email to *darlene.wright@nrc.gov.*

Dated: August 30, 2012.

Rochelle C. Bavol,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2012–21940 Filed 8–31–12; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0203; Docket Nos. STN 50–456, STN 50–457, STN 50–454 AND STN 50–455; License Nos. 72, 77, 37, and 66]

Exelon Generation Company, LLC., Receipt of Request for Action

Notice is hereby given that by petition dated April 20, 2012, Mr. Barry Quigley has requested that the U.S. Nuclear Regulatory Commission (NRC, the Commission) take action with regard to Braidwood Station, Units 1 and 2, and Byron Station, Units 1 and 2. The petitioner requests that the NRC require Exelon Generation Company, LLC (Exelon) to shut down immediately, Byron Station, Units 1 and 2, and Braidwood Station, Units 1 and 2, until all turbine building (TB) high-energy line break (HELB) concerns are identified and those important to safety are corrected.

As the basis for this request, the petitioner states the following:

- An adequate supply of combustion air for the diesel generators (DG) is threatened because the combustion air can be diluted with steam. Although the combustion air is drawn from an air shaft (not the TB), it is also the same air shaft that supplies ventilation for the DG room. Under certain conditions, the ventilation damper alignment is such that steam that enters the DG room from the ventilation exhaust can flow back into the inlet air shaft. From there it can be drawn into the engine, potentially starving the engine of air.
- The effects of high temperature in the engineered safety feature (ESF) switchgear rooms on the protective relaying setpoints has not been evaluated. The concern is that high temperatures could alter the setpoints, causing protective actions to occur under normal loading conditions.
- The current method of analysis for TB HELB uses a ''lumped volume'' approach wherein the mass and energy of the ruptured line mixes instantly with the entire volume before flowing into the areas of concern. Since this substantially reduces the energy flow, it does not always give conservative results. For example, a preliminary assessment using the subdivided volume feature in the GOTHIC computer code shows that the structural limits on the block wall between the ESF switchgear rooms would be substantially exceeded.
- There has been no structured and detailed review of the licensing requirements for HELB.

The NRC is treating this request pursuant to Title 10 of the Code of Federal Regulations (10 CFR), Section 2.206. The request has been referred to the Director of the Office of Nuclear Reactor Regulation (NRR). As required by Section 2.206, the NRC will take appropriate action on this petition within a reasonable time. The petitioner met with the petition review board on May 16, 2012, to discuss the petition. The board reviewed the information provided in that meeting in its consideration of the petitioner's request for immediate action and in establishing the schedule for the review of the petition. By letter dated August 23, 2012, the Director of NRR denied the petitioner's request for immediate shutdown of Exelon's Byron Station, Unit Nos. 1 and 2, and Braidwood Station, Units 1 and 2. A copy of the petition is available for inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are accessible electronically through the Agencywide Documents Access and Management System (ADAMS) in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* Those who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by email to *PDR.Resource@nrc.gov.*

Dated at Rockville, Maryland, this 23rd day of August 2012.

For the Nuclear Regulatory Commission.

Eric J. Leeds,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–21811 Filed 9–4–12; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 17Ad–4(b) & (c), OMB Control No. 3235–0341, SEC File No. 270–264.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information provided for in Rule 17Ad–4(b) and (c) (17 CFR 240.17Ad–4(b) and (c)) of the Securities Exchange Act of 1934 (17 U.S.C. 78a *et seq.*).

Rule 17Ad–4(b) & (c) (17 CFR 240.17Ad–4) is used to document when transfer agents are exempt, or no longer exempt, from the minimum performance standards and certain recordkeeping provisions of the Commission's transfer agent rules. Rule 17Ad–4(c) sets forth the conditions under which a registered transfer agent loses its exempt status. Once the conditions for exemption no longer exist, the transfer agent, to keep the appropriate regulatory authority (''ARA'') apprised of its current status, must prepare, and file if the ARA for the transfer agent is the Board of Governors of the Federal Reserve System (''BGFRS'') or the Federal Deposit Insurance Corporation (''FDIC''), a notice of loss of exempt status under paragraph (c). The transfer agent then cannot claim exempt status under Rule 17Ad–4(b) again until it remains subject to the minimum performance standards for non-exempt transfer agents for six consecutive months. The ARAs use the information contained in the notice to determine whether a registered transfer agent qualifies for the exemption, to determine when a registered transfer agent no longer qualifies for the exemption, and to determine the extent to which that transfer agent is subject to regulation.

The BGFRS receives approximately two notices of exempt status and two notices of loss of exempt status annually. The FDIC also receives approximately two notices of exempt status and two notices of loss of exempt status annually. The Commission and the Office of the Comptroller of the Currency (''OCC'') do not require transfer agents to file a notice of exempt status or loss of exempt status. Instead, transfer agents whose ARA is the Commission or OCC need only to prepare and maintain these notices. The Commission estimates that approximately ten notices of exempt status and ten notices of loss of exempt status are prepared annually by transfer agents whose ARA is the Commission. We estimate that the transfer agents for whom the OCC is their ARA prepare and maintain approximately five notices of exempt status and five notices of loss of exempt status annually. Thus, a total of approximately thirty-eight notices of exempt status and loss of exempt status are prepared and maintained by transfer agents annually. Of these thirty-eight

notices, approximately eight are filed with an ARA. Any additional costs associated with filing such notices would be limited primarily to postage, which would be minimal. Since the Commission estimates that no more than one-half hour is required to prepare each notice, the total annual burden to transfer agents is approximately nineteen hours.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management (OMB) control number.

Background documentation for this information collection may be viewed at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to *PRA_Mailbox@sec.gov.* Comments must be submitted within 30 days of this notice.

Dated: August 29, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21770 Filed 9–4–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Form 18, OMB Control No. 3235–0121, SEC File No. 270–105.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form 18 (17 CFR 249.218) is a registration form used by a foreign government or political subdivision to register securities for listing on a U.S. exchange. The information collected is intended to ensure that the information required by the Commission to be filed permits verification of compliance with securities law requirements and assures the public availability of the information. Form 18 takes approximately 8 hours per response and is filed by approximately 5 respondents for a total of 40 annual burden hours. It is estimated that 100% of the total reporting burden is prepared by the company.

Written comments are invited on: (a) Whether this 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 imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: August 29, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21771 Filed 9–4–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Form F–80; OMB Control No. 3235–0404; SEC File No. 270–357.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form F–80 (17 CFR 239.41) is a registration form used by large, publicly-traded Canadian issuers to register securities that will be offered in a business combination, exchange offer or other reorganization requiring the vote of shareholders of the participating companies. The information collected is intended to make available material information upon which shareholders and investors can make informed voting and investment decisions. Form F–80 takes approximately 2 hours per response and is filed by approximately 4 issuers for a total annual burden of 8 hours. The estimated burden of 2 hours per response was based upon the amount of time necessary to compile the registration statement using the existing Canadian prospectus plus any additional information required by the Commission.

Written comments are invited on: (a) Whether this 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 imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: August 29, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21772 Filed 9–4–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–30186; File No. 812–13990]

Pruco Life Insurance Company, *et al;* Notice of Application

August 29, 2012.

AGENCY: Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Notice of application for an order approving the substitution of certain securities pursuant to Section 26(c) of the Investment Company Act of 1940, as amended (the ''1940 Act'' or ''Act'') and an order of exemption pursuant to Section 17(b) of the Act from Section 17(a) of the Act.

APPLICANTS: Pruco Life Insurance Company (''Pruco Life''), Pruco Life Flexible Premium Variable Annuity Account (''Pruco Life Variable Annuity Account''), Pruco Life Insurance Company of New Jersey (''Pruco Life of New Jersey''), Pruco Life of New Jersey Flexible Premium Variable Annuity Account (''PLNJ Variable Annuity Account''), Prudential Annuities Life Assurance Corporation (''Prudential Annuities''), Prudential Annuities Life Assurance Corporation Variable Account B (''Variable Account B''), Allstate Life Insurance Company (''Allstate Life''), Allstate Financial Advisors Separate Account I (''Separate Account I''), Allstate Life Insurance Company of New York (''Allstate New York'' and collectively with Pruco Life, Pruco Life of New Jersey, Prudential Annuities and Allstate Life, the ''Insurance Companies''), Allstate Life of New York Separate Account A (''Separate Account A'' and collectively with Pruco Life Variable Annuity Account, PLNJ Variable Annuity Account, Variable Account B and Separate Account I, the ''Separate Accounts''), and Advanced Series Trust (''AST''). The Insurance Companies and the Separate Accounts are referred to herein collectively as the ''Substitution Applicants.'' Pruco Life, Pruco Life of New Jersey and Prudential Annuities are also referred to herein as the ''Prudential Insurance Companies.'' The Prudential Insurance Companies, Pruco Life Variable Annuity Account, PLNJ Variable Annuity Account, Variable Account B and AST are collectively referred to as the ''Section 17 Applicants.''

SUMMARY OF APPLICATION: The Substitution Applicants seek an order pursuant to Section 26(c) of the 1940 Act, approving the substitution of shares of the AST Franklin Templeton Founding Funds Allocation Portfolio (the ''Replacement Fund'') for shares of the Franklin Templeton VIP Founding Funds Allocation Fund, a series of Franklin Templeton Variable Insurance Products Trust (''Franklin Templeton VIP Trust'') (the ''Existing Fund''), held by the Separate Accounts to fund certain individual variable annuity contracts (collectively, the ''Contracts'') issued by the Insurance Companies. The Section 17 Applicants seek an order pursuant to Section 17(b) of the 1940 Act exempting them from Section 17(a) of the Act to the extent necessary to permit them to engage in certain in-kind transactions in connection with the substitution.

DATES: *Filing Date:* The application was filed on December 9, 2011, and the amended and restated application was filed on August 23, 2012.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving the applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on September 19, 2012, and should be accompanied by proof of service on the applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the requester's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary of the Commission.

ADDRESSES: Secretary, SEC, 100 F Street NE., Washington, DC 20549–1090. Applicants: Pruco Life Insurance Company, Pruco Life Flexible Premium Variable Annuity Account, Pruco Life Insurance Company of New Jersey and Pruco Life of New Jersey Flexible Premium Variable Annuity Account, 751 Broad Street, Newark, NJ 07102; Prudential Annuities Life Assurance Corporation and Prudential Annuities Life Assurance Corporation Variable Account B, One Corporate Drive, Shelton, CT 06484; Advanced Series Trust, Gateway Center Three, 100 Mulberry Street, Newark, New Jersey 07102; Allstate Life Insurance Company and Allstate Financial Advisors Separate Account I, 3100 Sanders Road, Northbrook, IL 60062; Allstate Life Insurance Company of New York and Allstate Life of New York Separate Account A, 100 Motor Parkway, Suite 132, Hauppauge, New York 11788.

FOR FURTHER INFORMATION CONTACT: Sally Samuel, Senior Counsel, or Joyce M. Pickholz, Branch Chief, Office of Insurance Products, Division of Investment Management, at (202) 551–6795.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm,* or by calling (202) 551–8090.

Applicants' Representations

1. The Insurance Companies, on their own behalf and on behalf of their respective separate accounts, propose to substitute shares of the Replacement Fund for shares of the Existing Fund held by the Separate Accounts to fund the Contracts. The Separate Accounts own only Class 4 shares of the Existing Fund.

2. Pruco Life is the depositor and sponsor of Pruco Life Variable Annuity Account. Pruco Life of New Jersey is the depositor and sponsor of PLNJ Variable Annuity Account. Prudential Annuities is the depositor and sponsor of Variable Account B. Allstate Life is the depositor and sponsor of Separate Account I. Allstate New York is the depositor and sponsor of Separate Account A.

3. On June 1, 2006, Allstate Life and Allstate New York entered into an agreement with Prudential Financial, Inc. (''Prudential Financial'') and its subsidiary, The Prudential Insurance Company of North America (''Prudential''), pursuant to which Allstate Life and Allstate New York sold, through a combination of coinsurance and modified coinsurance reinsurance, substantially all of their variable annuity business. Allstate Life and Allstate New York also have entered into an administrative services agreement pursuant to which Prudential or an affiliate administers Separate Account I and Separate Account A.

4. Each of Pruco Life Variable Annuity Account, PLNJ Variable Annuity Account, Variable Account B, Separate Account 1 and Separate Account A is a ''separate account'' as defined by Rule 0–1(e) under the Act and each is registered under the Act as a unit investment trust for the purpose of funding the Contracts. Security interests under the Contracts have been registered under the Securities Act of 1933. The application sets forth the registration statement file numbers for the Contracts and the Separate Accounts.

5. AST and Franklin Templeton VIP Trust are registered open-end management investment companies of

the series type (File Number 033–24962 and 033–23493, respectively).

6. Franklin Templeton Services, LLC (''Existing Fund Administrator'') serves as the administrator to the Existing Fund. Prudential Investments LLC and AST Investment Services, Inc. (together, the ''Investment Managers'') serve as the co-investment managers of the Replacement Fund. Franklin Advisers, Inc. (''Franklin Advisers''), Franklin Mutual Advisers, LLC (''Franklin Mutual''), and Templeton Global Advisors Limited (''Templeton Global'') serve as subadvisers to the Replacement Fund and are affiliates of the Existing Fund Administrator. Franklin Advisers, Franklin Mutual, and Templeton Global are collectively referred to as the ''FT Subadvisers.''

7. The substitution will replace an investment option (i.e., the Existing Fund) administered by an entity (i.e., Franklin Templeton Services, LLC) that is not affiliated with the Substitution Applicants as of the date hereof (other than by way of certain of the Substitution Applicants owning more than 5% of the shares of the Existing Fund) with an investment option (i.e., the Replacement Fund) that is managed by investment managers (i.e., Prudential Investments LLC and AST Investment Services, Inc.) that are affiliated with the Prudential Insurance Companies. The Investment Managers may hire and replace unaffiliated subadvisers with the approval of AST's Board of Trustees. Pursuant to an exemptive order issued to a predecessor Prudential Financial investment adviser, Inv. Co. Rel. No. 22215 (Sept. 11, 1996), (the ''Multi-Manager Order''), the Investment Managers are authorized to enter into and amend sub-advisory agreements without shareholder approval under certain conditions. However, Substitution Applicants and AST represent that the Replacement Fund will not change a subadviser, add a new subadviser, or otherwise rely on the Multi-Manager Order without first obtaining shareholder approval of the change in subadviser, the new subadviser, or the Replacement Fund's ability to add or to replace a subadviser in reliance on the Multi-Manager Order at an AST shareholder meeting, the record date for which shall be after the proposed substitution has been effected. In addition, prior to the substitution, the Substitution Applicants state that each Contract owner will have been provided with the Replacement Fund prospectus describing the existence, substance and effect of the Multi-Manager order.

8. The Contracts are individual and group flexible premium variable, variable with fixed options and variable with fixed and market value adjusted fixed options contracts. The Contracts permit the Insurance Companies to substitute shares of one fund with shares of another, including a fund of a different registered investment company. The prospectuses for the Contracts and the Separate Accounts contain disclosures of this right. The Contracts which offer the Existing Fund securities are registered in the Form N–4 Registration Statements listed in footnotes 1 through 5 of the application.

9. The Existing Fund is a ''fund of funds'' meaning that it seeks to achieve its investment goal by investing its assets in a combination of Class 1 shares of the Franklin Income Securities Fund (''Franklin Income'') (33⅓%), Mutual Shares Securities Fund (''Mutual Shares'') (33⅓%), and Templeton Growth Securities Fund (''Templeton Growth,'' and collectively with Franklin Income and Mutual Shares, the ''Underlying FT Funds''). Franklin Income is managed by Franklin Advisers, Mutual Shares is managed by Franklin Mutual, and Templeton Growth is managed by Templeton Global. The Existing Fund makes equal allocations to each of the Underlying FT Funds on a fixed percentage basis. Although the Replacement Fund will not operate as a ''fund of funds'' like the Existing Fund, its overall investment strategy will be substantially identical to that of the Existing Fund. Franklin Income, Franklin Mutual, and Templeton Global serve as subadvisers to the Replacement Fund. Each FT Subadviser handles the day-to-day investment management of approximately 33⅓% of the Replacement Fund's assets based upon the application of the specific investment strategy that it uses in connection with the corresponding Underlying FT Fund. Like the Existing Fund, the percentage of Replacement Fund assets that is allocated to each investment strategy will be monitored and those allocations will be rebalanced when they are more than 3% above or below the goal of equal allocations to each of the three investment strategies. A comparison of the investing strategies and risks of the Existing Fund and the Replacement Fund is included in the application. The following table compares the fees and expenses of the Existing Fund and the Replacement Fund as of December 31, 2011.[1]

	Existing fund (Class 4)	Replacement Fund
Management fees	None	0.95%
Distribution and service (12b–1) fees	0.35%	None
Other Expenses	0.11%	0.16%
Acquired fund fees and expenses	0.65%	—
Total annual Fund operating expenses	1.11%	1.11%
Fee waiver and/or expense reimbursement	−0.01%	−0.03%
Total annual Fund operating expenses after fee waiver and/or expense reimbursement.	1.10%	1.08%

10. The Existing Fund does not pay a management fee but as a shareholder in the underlying funds, indirectly bears its proportionate share of any management fees and other expenses paid by the underlying funds. The management fees of each of the underlying funds, based on each underlying fund's average net assets for the fiscal year ended December 31, 2011, are: Franklin Income Securities Fund: 0.45%; Mutual Shares Securities Fund: 0.60%; and Templeton Growth Securities Fund: 0.74%.

11. The Substitution Applicants state that the substitutions are expected to benefit Contract owners in a number of ways. The Replacement Fund is a new

[1] The Replacement Fund has no assets and has not yet commenced operations as of the date hereof. The estimated fees and expenses of the Replacement Fund are, however, based in part on assumed average daily net assets of approximately $2.4 billion for the Replacement Fund (i.e., the approximate amount of net assets that would have been acquired from the Existing Fund had the substitution been completed as of December 31, 2011) for the fiscal period ending December 31, 2012.

series of AST, and thus the Replacement Fund is part of the Prudential Annuity family of funds. As such, the Insurance Companies generally expect to learn of any changes affecting the Replacement Fund well in advance of their effectiveness, thereby allowing the Insurance Companies to use the most efficient and least costly means to administer such changes (e.g., by including the changes in other routine filings and planned mailings to contract owners). The Insurance Companies believe that Contract owners will benefit from this streamlining as the Insurance Companies enhance their communication efforts to contract owners and sales representatives regarding investment options. Further, since the Replacement Fund is part of the Prudential Annuity family of funds, the Investment Managers will provide rigorous oversight and monitoring of the Replacement Fund's investment performance and its compliance with investment objectives, policies and restrictions. In addition, the Replacement Fund unlike the Existing Fund is not a ''fund of funds'' and therefore can generally operate with more flexibility. As described in more detail in the application, a portion of the assets attributable to each of the three investment strategies used in connection with the Replacement Fund will be invested in certain types of derivatives and short-term instruments to help maintain adequate portfolio liquidity. Such investments will provide for more effective and efficient fund management and operation during times of market volatility than the current fund-of-funds structure. Further, the Replacement Fund, as a series of AST, will have access to the Prudential Financial fund complex's credit facility which will also serve to potentially create efficiencies and cause less disruption to the orderly investment management of the Replacement Fund in times of market volatility and increased redemption activity. The Insurance Companies will also realize the benefit of reduced production and mailing expenses with respect to the prospectus, given that the Replacement Fund will be a series of AST with all disclosures concerning the Replacement Fund being included in the combined AST prospectus. Contract owners will benefit from consolidated and consistent fund disclosure. The Insurance Company Applicants believe that the Replacement Fund represents the best available match, consistent with the goal of providing Contract owners with a substitute investment option offering a lower expense ratio than the expense ratio of the Existing Fund. Further, Contract owners will be allowed a free transfer out of the Existing Fund (before the substitution) or out of the Replacement Fund (after the substitution) to any other investment option available under the applicable Contract; therefore any Contract owner will be able, without charge, to switch to another investment option.

12. For these reasons and the reasons discussed below, the Substitution Applicants believe that substituting the Replacement Fund for the Existing Fund is appropriate and in the best interest of Contract owners. Because the Existing Fund does not have an investment manager, it does not directly pay any investment management fees. The Existing Fund does, however, indirectly pay investment management fees in connection with its investments in the Underlying FT Funds. In addition, as shown in more detail in the application, the estimated total operating expense ratio for the Replacement Fund will be lower than the net expense ratio for Class 4 shares of the Existing Fund as set forth in its current prospectus. There will be no increase in Contract fees and expenses, including mortality and expense risk fees and administration and distribution fees charged to the Separate Accounts as a result of the substitutions. The Substitution Applicants believe that the Replacement Fund has an investment objective, policies and a risk profile that are substantially the same as the Existing Fund, thus making the Replacement Fund an appropriate candidate as a substitute. In addition, after the substitutions, neither the Investment Managers nor any of their affiliates will receive compensation from the charges to the Separate Accounts related to the Contracts or from revenue sharing from the Replacement Funds in excess of the compensation currently received from the administrator or distributors of the Existing Fund.

13. By a supplement to the prospectuses for the Contracts and the Separate Accounts each Insurance Company has notified all owners of the Contracts affected by the substitutions of its intention to take the necessary actions, including seeking the order requested by the application, to substitute shares of the funds as described herein. The supplement advised Contract owners that from the date of the supplement until the date of the proposed substitution, owners are permitted to make one transfer of Contract value (or annuity unit exchange) out of the Existing Fund sub-account to one or more other sub-accounts without the transfer (or exchange) being treated as one of a limited number of permitted transfers (or exchanges) permitted without a transfer charge. The supplement informed Contract owners that the Insurance Company will not exercise any rights reserved under any Contract to impose additional restrictions on transfers until at least 30 days after the proposed substitution. The supplement also informed Contract owners that for at least 30 days following the proposed substitution, the Insurance Companies will permit Contract owners affected by the substitution to make one transfer of Contract value (or annuity unit exchange) out of the Replacement Fund sub-account to one or more other sub-accounts without the transfer (or exchange) being treated as one of a limited number of permitted transfers (or exchanges) or a limited number of transfers (or exchanges) permitted without a transfer charge.

14. The proposed substitution will take place at relative net asset value with no change in the amount of any Contract owner's Contract value or death benefit or in the dollar value of his or her investment in the Separate Accounts.

15. The substitution will be effected by a combination of in-kind and cash transactions. It is anticipated that the majority of the transactions will be effected in-kind, with the remainder being effected in cash. With respect to in-kind transactions, it is intended that, after receipt of the Insurance Companies' redemption request, the Existing Fund will redeem shares it holds in the FT Underlying Funds, which request will be fulfilled by the FT Underlying Funds primarily in the form of underlying securities. The Existing Fund will then fulfill the Insurance Companies' redemption request with these in-kind securities received from the FT Underlying Funds. These in-kind securities will then be contributed to the Replacement Fund to purchase shares of that Fund. All in-kind redemptions from the Existing Fund of which any of the Substitution Applicants is an affiliated person will be effected in accordance with the conditions set forth in the Commission's no-action letter issued to *Signature Financial Group, Inc.* (available December 28, 1999). To the extent that the redemption request cannot be completed wholly through in-kind securities, the remainder of the substitution will be effected through the Insurance Companies' redeeming shares of the Existing Fund for cash and using the cash to purchase shares of the Replacement Fund.

16. Contract owners will not incur any fees or charges as a result of the proposed substitution, nor will their rights or Insurance Company's obligations under the Contracts be altered in any way. All expenses incurred in connection with the proposed substitution, including brokerage, legal, accounting, and other fees and expenses, will be paid by the Insurance Companies. In addition, the proposed substitution will not impose any tax liability on Contract owners. The proposed substitution will not cause the Contract fees and charges currently being paid by existing Contract owners to be greater after the proposed substitution than before the proposed substitution. No fees will be charged on the transfers made at the time of the proposed substitution because the proposed substitution will not be treated as a transfer for the purpose of assessing transfer charges or for determining the number of remaining permissible transfers in a Contract year.

17. In addition to the prospectus supplements distributed to owners of Contracts, within five business days after the proposed substitution is completed, Contract owners will be sent a written notice informing them that the substitution was carried out and that they may make one transfer of any Contract value invested in the Replacement Fund sub-account on the date of the notice to one or more other sub-accounts available under their Contract at no cost and without regard to the usual limit on the frequency of transfers among sub-accounts or from the variable account options to the fixed account options. The notice will also reiterate that (other than with respect to ''market timing'' activity) the Insurance Companies will not exercise any rights reserved by it under the Contracts to impose additional restrictions on transfers or to impose any charges on transfers until at least 30 days after the proposed substitution. The Insurance Companies will also send each Contract owner a current prospectus for the Replacement Fund to the extent that they have not previously received a copy. Each Insurance Company also is seeking approval of the proposed substitution from any state insurance regulators whose approval may be necessary or appropriate.

Legal Analysis and Conditions:

Section 26(c) Relief:

1. The Substitution Applicants request that the Commission issue an order pursuant to Section 26(c) of the Act approving the proposed substitution. Section 26(c) of the Act requires the depositor of a registered unit investment trust holding the securities of a single issuer to obtain Commission approval before substituting the securities held by the trust.

2. The Contracts permit the applicable Insurance Company, subject to compliance with applicable law, to substitute shares of another investment company for shares of an investment company held by a sub-account of the Separate Accounts. The prospectuses for the Contracts and the Separate Accounts contain disclosure of this right. The Replacement Fund is anticipated to have a lower total expense ratio than the Existing Fund. The Insurance Companies believe that it is in the best interests of the Contract owners to substitute the Replacement Fund for the Existing Fund. The Substitution Applicants believe that the FT Subadvisers will, over the long term, be positioned to provide at least comparable performance to that of the Existing Fund through their equal investments in the Underlying FT Funds because the Underlying FT Funds are managed by the same entities.

3. The proposed substitution is not of the type that Section 26(c) was designed to prevent. Unlike traditional unit investment trusts where a depositor could only substitute an investment security in a manner which permanently affected all the investors in the trust, the Contracts provide each Contract owner with the right to exercise his or her own judgment and transfer Contract or cash values into other sub-accounts. Moreover, the Contracts will offer Contract owners the opportunity to transfer amounts out of the affected sub-accounts into any of the remaining sub-accounts without cost or other disadvantage. The proposed substitution, therefore, will not result in the type of costly forced redemption which Section 26(c) was designed to prevent. The proposed substitution also is unlike the type of substitution which Section 26(c) was designed to prevent in that by purchasing a Contract, Contract owners select much more than a particular investment company in which to invest their account values. They also select the specific type of insurance coverage offered by an insurance company under their Contract as well as numerous other rights and privileges set forth in the Contract.

4. The Substitution Applicants and AST agree that for the two year period commencing on the date of the substitution the total annual Fund operating expenses of the Replacement Fund (net of reimbursement and waivers) will be capped at a level equal to the Existing Fund's total annual Fund operating expenses (net of reimbursement and waivers) of 1.10% of average daily net assets. In addition, the Substitution Applicants and AST have agreed to permanently cap the management fee of the Replacement Fund at .95% of average daily net assets.

5. The Substitution Applicants submit that the proposed substitution meets the standards set forth in Section 26(c) and assert that the replacement of the Existing Fund with the Replacement Fund is consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

Section 17(b) Relief:

1. The Section 17 Applicants request an order under Section 17(b) of the Act exempting them from the provisions of Section 17(a) to the extent necessary to permit the Prudential Insurance Companies to carry out the proposed substitution as described herein.

2. Section 17(a)(1) of the Act, in relevant part, prohibits any affiliated person of a registered investment company, or any affiliated person of such person, acting as principal, from knowingly selling any security or other property to that company. Section 17(a)(2) of the Act generally prohibits the persons described above, acting as principals, from knowingly purchasing any security or other property from the registered company.

3. Because shares held by a separate account of an insurance company are legally owned by the insurance company, the Prudential Insurance Companies and their affiliates collectively own of record substantially all of the shares of each of the various series of AST (and will also own such with respect to the Replacement Fund upon its commencement of operations). Therefore, AST and each of its respective series could be deemed to be under the control of the Prudential Insurance Companies for purposes of the Act, notwithstanding the fact that Contract owners may be considered the beneficial owners of those shares held in the Separate Accounts for certain purposes. If AST and each of its respective series are deemed to be under the control of the Prudential Insurance Companies for purposes of the Act, then each Prudential Insurance Company could be deemed to be an affiliated person of AST and each of its respective series within the meaning of Section 2(a)(3) of the Act. Likewise if the Prudential Insurance Companies are deemed to control AST and each of its respective series for purposes of the Act, then AST and each of its respective series, could be deemed to be affiliated persons of the Prudential Insurance

Companies within the meaning of Section 2(a)(3) of the Act. Regardless of whether or not the Prudential Insurance Companies are considered to control AST and each of its respective series within the meaning of Section 2(a)(9) of the Act, because the Prudential Insurance Companies own of record more than 5% of the shares of each series of AST, the Prudential Insurance Companies could be deemed to be affiliated persons of AST and each of its respective series within the meaning of Section 2(a)(3) of the Act. Notwithstanding the foregoing, because the Prudential Insurance Companies and the Investment Managers are under the common control of Prudential Financial, the Prudential Insurance Companies could be deemed to be affiliated persons of an affiliated person (i.e., the Investment Managers) of a registered investment company (i.e., AST and each of its respective series) for purposes of Section 17(a) of the Act. Because the substitution may be effected, in whole or in part, by means of in-kind redemptions of shares of the Existing Fund and in-kind purchases of shares of the Replacement Fund, the substitution may be deemed to involve one or more purchases or sales of securities or property between affiliated persons. The proposed transactions could be deemed to involve the transfer of portfolio securities held by the Underlying FT Funds through the Existing Fund to the Prudential Insurance Companies and the simultaneous purchase by the Prudential Insurance Companies of shares of the Replacement Fund using such portfolio securities as consideration. As a practical matter, the custodian for the Replacement Fund will receive such transferred assets from the custodians for the Existing Fund and Underlying FT Funds. Accordingly, as the Prudential Insurance Companies and the Existing Fund, and the Prudential Insurance Companies and the Replacement Fund, could be viewed as first-tier or second-tier affiliates of one another under Section 2(a)(3) of the Act, it is conceivable that this aspect of the substitutions could be viewed as being prohibited by Section 17(a) of the Act. As a result, the Section 17 Applicants have determined that it is prudent to seek relief from Section 17(a) in the context of this application for the in-kind purchases of Replacement Fund shares by the Prudential Insurance Companies and the in-kind sales of Replacement Fund shares to the Prudential Insurance Companies.

4. The Section 17 Applicants submit that for all the reasons stated in the application, the terms of the proposed in-kind purchases of shares of the Replacement Fund by the Prudential Insurance Companies, including the consideration to be paid and received, as described in this application, are reasonable and fair and do not involve overreaching on the part of any person concerned. The Section 17 Applicants also submit that the proposed in-kind purchases by the Prudential Insurance Companies of Replacement Fund shares are consistent with the policies of AST and the Replacement Fund as recited in their current registration statements and reports filed under the Act. Finally, the Section 17 Applicants submit that the proposed substitution is consistent with the general purposes of the Act. To the extent that the in-kind purchases by the Prudential Insurance Companies of the Replacement Fund's shares are deemed to involve principal transactions among first-tier or second-tier affiliates for purposes of Section 17(a) of the Act, the procedures described below should be sufficient to assure that the terms of the proposed transactions are reasonable and fair to all participants. The Section 17 Applicants maintain that the terms of the proposed in-kind purchase transactions, including the consideration to be paid and received by each fund involved, are reasonable, fair and do not involve overreaching principally because the transactions will conform with all but one of the conditions enumerated in Rule 17a–7. The one condition of Rule 17a–7 that the Section 17 Applicants will not comply with is the condition requiring that the transaction be a purchase or sale for no consideration other than cash payment against prompt delivery of a security for which market quotations are readily available. The proposed transactions will take place at relative net asset value in conformity with the requirements of Section 22(c) of the Act and Rule 22c–1 thereunder with no change in the amount of any Contract owner's contract value or death benefit or in the dollar value of his or her investment in any of the Separate Accounts. Contract owners will not suffer any adverse tax consequences as a result of the substitution. The fees and charges under the Contracts will not increase because of the substitution. Even though the Separate Accounts, the Prudential Insurance Companies, and AST may not rely on Rule 17a–7, the Section 17 Applicants believe that the Rule's conditions outline the type of safeguards that result in transactions that are fair and reasonable to registered investment company participants and preclude overreaching in connection with an investment company by its affiliated persons. The Section 17 Applicants assert that where, as here, they or the relevant investment company would comply with all but one of the conditions of the Rule as described above, the Commission should consider the extent to which they would meet these or other similar conditions and issue an order if the protections of the Rule would be provided in substance.

5. The board of AST has adopted procedures, as required by paragraph (e)(1) of Rule 17a–7 under the Act, pursuant to which the Replacement Fund may purchase and sell securities to and from its affiliates. The board of AST will conduct its review of the transactions in the same manner that it normally would follow in accordance with Rule 17a–7 under the Act. The Section 17 Applicants will carry out the proposed Prudential Insurance Companies' in-kind purchases in conformity with all of the conditions of Rule 17a–7 and AST's procedures thereunder, except that the consideration paid for the securities being purchased or sold may not be entirely cash. Nevertheless, the circumstances surrounding the proposed substitution will be such as to offer the same degree of protection to the Replacement Fund from overreaching that Rule 17a–7 provides to it generally in connection with its purchase and sale of securities under that Rule in the ordinary course of its business. In particular, the Prudential Insurance Companies (or any of their affiliates) cannot effect the proposed transactions at a price that is disadvantageous to the Replacement Fund. Although the transactions may not be entirely for cash, each will be effected based upon (1) the independent market price of the portfolio securities valued as specified in paragraph (b) of Rule 17a–7, and (2) the net asset value per share of each fund involved valued in accordance with the procedures disclosed in its respective investment company registration statement and as required by Rule 22c–1 under the Act. No brokerage commission, fee, or other remuneration will be paid to any party in connection with the proposed in-kind purchase transactions.

6. The sale of shares of the Replacement Fund for investment securities, as contemplated by the proposed Prudential Insurance Companies' in-kind purchases, is consistent with the investment policies and restrictions of the Replacement Fund because (1) the shares are sold at their net asset value, (2) each of the FT Subadvisers also serves as the

investment manager for the relevant Underlying FT Fund, (3) each of the FT Subadvisers will implement the same investment strategy for the Replacement Fund that it uses to manage the corresponding Underlying FT Fund, and (4) the assets of the Replacement Fund will be equally divided among the three relevant investment strategies in exactly the same manner as the Existing Fund equally divides its assets among the three Underlying FT Funds. The portfolio securities are of the type and quality that the Replacement Fund would have acquired with the proceeds from the sale of shares of the Existing Fund had the shares of the Existing Fund been sold for cash. To assure that this condition is met, as applicable, the Investment Managers and the subadvisers for the Replacement Fund will examine the portfolio securities being offered to the Replacement Fund and accept only those securities as consideration for shares that it would have acquired for each such fund in a cash transaction.

Conclusion:

For the reasons and upon the facts set forth above and in the application, the Substitution Applicants and the Section 17 Applicants believe that the requested orders meet the standards set forth in Section 26(c) of the Act and Section 17(b) of the Act, respectively, and should therefore, be granted.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21773 Filed 9–4–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, September 6, 2012 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Walter, as duty officer, voted to consider the items listed for the Closed Meeting in a closed session.

The subject matter of the Closed Meeting scheduled for Thursday, September 6, 2012 will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551–5400.

Dated: August 30, 2012.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–21910 Filed 8–31–12; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67752; File No. SR–CBOE–2012–043]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Approving a Proposed Rule Change Relating to Spread Margin Rules

August 29, 2012.

I. Introduction

On May 29, 2012, the Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend CBOE Rule 12.3 to propose universal spread margin rules. The proposed rule change was published for comment in the **Federal Register** on June 7, 2012.[3] The Commission received no comment letters on the proposed rule change. This order approves the proposed rule change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 67086 (May 31, 2012), 77 FR 33802.

II. Description of the Proposal

An option spread is typically characterized by the simultaneous holding of a long and short option of the same type (put or call) where both options involve the same security or instrument, but have different exercise prices and/or expirations. To be eligible for spread margin treatment, the long option may not expire before the short option. These long put/short put or long call/short call spreads are known as two-legged spreads.

Since the inception of the Exchange, the margin requirements for two-legged spreads have been specified in CBOE margin rules.[4] The margin requirement for a two-legged spread that is eligible for spread margin treatment is its maximum risk based on the intrinsic values of the options, exclusive of any net option premiums paid or received when the positions were established.[5] For example, consider the following equity option spread:

Long 1 XYZ May2011 60 call
Short 1 XYZ May2011 50 call

The maximum potential loss (*i.e.,* risk) for this particular spread would be a scenario where the price of the underlying stock (XYZ) is $60 or higher. If the market price of XYZ is $60, the May2011 60 call would have an intrinsic value of zero, because the right to buy at $60 when XYZ can be purchased in the market for $60 has no intrinsic value. The May2011 50 call would have an intrinsic value of $10 because of the $10 advantage gained by being able to buy at $50 when it costs $60 to purchase XYZ in the market. Because each option contract controls 100 shares of the underlying stock, the intrinsic value, which was calculated on a per share basis, is multiplied by 100, resulting in an aggregate intrinsic value of $1,000 for the May2011 50 call.[6] However, because the May2011 50 call is short, the $1,000 intrinsic value is a loss, because it represents the cost to close (*i.e.,* buy-back) the short option. At an assumed XYZ market price of $60, netting the intrinsic values of the options results in a loss of $1,000 (−$1,000 + $0).[7] Therefore, the

[4] CBOE Rules Chapter 12; CBOE Rule 12.3(c)(5)(C)(4).

[5] Any net credit received for establishing a spread may be applied to the margin requirement, if any. In the case of a spread that is established for a net debit, the net debit must be paid for in full.

[6] The result would be multiplied by the number of contracts when more than a one-by-one contract spread is involved.

[7] At an assumed market price of $50, both the May2011 50 call and May2011 60 call would have no intrinsic value. Thus, there is no risk (provided any net debit is paid for in full) at an assumed market price of $50.

maximum risk of, and margin requirement for, this spread is $1,000. If there is no maximum risk (*i.e.,* there is no loss calculated at any of the exercise prices found in the spread), no margin is required, but under Exchange margin rules, any net debit incurred to establish the spread would be required to be paid for in full. Current CBOE Rule 12.3(c)(5)(C)(4) provides that, when the exercise price of the long call (or short put) is less than or equal to the exercise price of the offsetting short call (or long put), no margin is required; and that when the exercise price of the long call (or short put) is greater than the exercise price of the offsetting short call (or long put), the amount of margin required is the lesser of the margin requirement on the short option, if treated as uncovered, or the difference in the aggregate exercise prices. The intrinsic value calculation described above is essentially expressed, in different words, in the current rule language.

The maximum risk remains constant at $1,000 for XYZ market prices higher than $60 because for each incremental increase in the assumed market price of XYZ above $60, the loss on the short option is equally offset by a gain on the long option in terms of their intrinsic values. By calculating the net intrinsic value of the options at each exercise price found in the spread, as in the computation exemplified above, the maximum risk of, and margin requirement for, any two-legged spread can be determined.

On July 27, 1999, the Commission approved the Exchange's implementation of specific definitions and margin requirements for butterfly spreads and box spreads.[8] In a butterfly spread, a two-legged spread is combined with a second two-legged spread (same type—put or call—and same underlying security or instrument) as in the following example:

Long 1 XYZ May2011 50 call
Short 1 XYZ May2011 60 call

Long 1 XYZ May2011 70 call
Short 1 XYZ May2011 60 call

Note that a short XYZ May2011 60 call option is common to both two-legged spreads. Therefore, by adding the May2011 60 call options together, the two spreads can be combined to form a butterfly spread as follows:

Long 1 XYZ May2011 50 call
Short 2 XYZ May2011 60 calls
Long 1 XYZ May2011 70 call[9]

The margin requirement for a butterfly spread is its maximum risk. The maximum risk can be determined in the same manner as demonstrated above for two-legged spreads. In this example, the net intrinsic values would be calculated at assumed prices for the underlying security or instrument of $50, $60 and $70, which are the exercise prices found in the butterfly spread. The greatest loss, if any, from among the net intrinsic values is the margin requirement. For this particular butterfly spread, there is no loss in terms of net intrinsic values at any of the assumed underlying prices ($50, $60 or $70). Therefore, there is no margin requirement. However, the net debit incurred to establish this butterfly spread must be paid for in full.

In a box spread, a two-legged call spread is combined with a two-legged put spread. The exercise prices of the long and short put options are the reverse of the call spread. All options have the same underlying security or instrument and expiration date. An example is as follows:

Long 1 XYZ May2011 50 call
Short 1 XYZ May2011 60 call

Long 1 XYZ May2011 60 put
Short 1 XYZ May2011 50 put[10]

The margin requirement for a box spread, unless all options are European style, is its maximum risk. The maximum risk of a box spread can be determined in the same manner as demonstrated above for two-legged spreads and butterfly spreads. In this example, the net intrinsic values would be calculated at assumed prices for the underlying security or instrument of $50 and $60, which are the exercise prices found in the box spread. The greatest loss, if any, from among the net intrinsic values is the margin requirement. For this particular box spread (long box spread), there is no loss in terms of net intrinsic values at either of the assumed underlying prices ($50 or $60). Therefore, there is no margin requirement. However, the net debit incurred to establish this box spread must be paid for in full. In the case of a long box spread where all options are European style, the margin requirement is 50% of the difference in the exercise prices (in aggregate).[11]

On August 13, 2003, the Exchange issued a Regulatory Circular (RG03–066) to define additional types of multi-leg option spreads, and to set margin requirements for these spreads through interpretation of Exchange margin rules. The Regulatory Circular had been filed with the Commission and was approved on August 8, 2003, on a one year pilot basis.[12] The Regulatory Circular was reissued as RG04–90 (dated August 16, 2004) and RG05–37 (dated April 6, 2005) pursuant to one year extensions of the pilot granted by the Commission on August 6, 2004, and March 22, 2005, respectively.[13]

The Regulatory Circular identified seven spread strategies by presenting an example of each spread's configuration, and numbering each configuration, rather than designating the configurations by names commonly used in the industry. The seven configurations would be referred to in the industry as:

Long Condor Spread,
Short Iron Butterfly Spread,
Short Iron Condor Spread,
Long Calendar Butterfly Spread,
Long Calendar Condor Spread,
Short Calendar Iron Butterfly Spread and
Short Calendar Iron Condor Spread.

On July 30, 2004, the Exchange filed proposed rule amendments with the Commission to codify the provisions of the Regulatory Circular in Exchange margin rules. Included in the proposal were definitions of Long Condor Spread (which includes a Long Calendar Condor Spread), Short Iron Butterfly Spread (which includes a Short Calendar Iron Butterfly Spread), and Short Iron Condor Spread (which includes a Short Calendar Iron Condor Spread). In addition, it was proposed that the existing definition of Long Butterfly Spread be amended to include a Long Calendar Butterfly Spread. The margin requirements, specific to each type of spread, as had been set-forth in the Regulatory Circulars, were also proposed for inclusion in Exchange

[8] The butterfly and box spread margin rules, and various other CBOE margin rule changes, were approved by the Commission on July 27, 1999. See Securities Exchange Act Release No. 41658 (July 27, 1999), 64 FR 42736 (SR–CBOE–97–67).

[9] This configuration represents a long butterfly spread. The opposite (*i.e.,* short 1 XYZ May2011 50 call, long 2 XYZ May2011 60 calls and short 1 XYZ May2011 70 call) would be a short butterfly spread.

[10] This configuration represents a long box spread. The opposite (*i.e.,* short 1 XYZ May2011 50 call, long 1 XYZ May2011 60 call, short 1 XYZ May2011 60 put and long 1 XYZ May2011 50 put) would be a short box spread.

[11] A 50% margin requirement is allowed because a long box spread has an intrinsic value at expiration equal to the difference in the exercise prices (in aggregate), which will more than cover the net debit incurred to establish the spread. A long box spread is, essentially, a riskless position. The difference between the value of the long box spread realizable at expiration and the lower cost to establish the spread represents a risk-free rate of return.

[12] *See* Securities Exchange Act Release No. 48306 (Aug. 8, 2003), 68 FR 48974 (Aug. 15, 2003) (SR–CBOE–2003–24).

[13] *See* Securities Exchange Act Release No. 50164 (Aug. 6, 2004), 69 FR 50405 (Aug. 16, 2004) and Securities Exchange Act Release No. 51407 (Mar. 22, 2005), 70 FR 15669 (Mar. 28, 2005).

margin rules.[14] Contemporaneously, the New York Stock Exchange filed similar margin rule proposals with the Commission.[15] CBOE's proposed rule amendment was approved by the Commission on December 14, 2005.[16]

Because a number of variations are possible for each basic type of multi-leg option spread strategy, it is problematic to maintain margin rules specific to each.[17] It becomes difficult to continually designate each variation by name, and define and specify a margin requirement for it in the rules. For example, consider the following spreads:

Long 10 XYZ May2011 50 call
Short 10 XYZ May2011 55 call

Long 5 XYZ May2011 70 call
Short 5 XYZ May2011 60 call

These two spreads combined are a variation of a condor spread. In a basic condor spread, the number of option contracts would be equal across all option series and the interval between the exercise prices of each spread would be equal. In the above variation, there is a 10-by-10 contract spread vs. a 5-by-5 contract spread, and a spread with a 5 point interval between exercise prices vs. a spread with a 10 point interval between exercise prices. The two spreads in the above example offset each other in terms of risk, and no margin requirement is necessary. However, margin of $5,000 is required under the Exchange's current margin rules, because this variation of the condor spread is not specified in the rules. Because it is not recognized in Exchange margin rules, the two spreads must be treated as separate, unrelated spread strategies for margin purposes. As a result, spread margin of $5,000 is required (on the May2011 70/May2011 60 call spread) versus no requirement (other than pay for the net debit in full), if the two spreads could be recognized as one strategy.

The Exchange proposed a single, universal definition of a spread and one spread margin requirement that consists of a universal margin requirement computation methodology. In this manner, the margin requirement for all types of option spreads would be covered by a single rule, without regard to the number of option series involved or the term commonly used in the industry to refer to the spread. This would eliminate the need to define, and refer to, particular spreads by monikers commonly used in the industry. Therefore, this rule filing would eliminate definitions of each particular spread strategy (*e.g.,* butterfly, condor, iron butterfly, iron condor, etc.), with one exception.

The one exception would be ''Box Spreads.'' A definition for ''Box Spread'' would be retained because loan value is permitted under Exchange margin rules for box spreads. Box spreads are the only type of spread that is eligible for loan value. They, therefore, need to be specially identified in the rules.

Additionally, the proposed rule changes would automatically enable variations not currently recognized in Exchange margin rules (because only a limited number of specific spread strategies are defined) to receive spread margin treatment.

The Exchange proposed a new definition of a spread as CBOE Rule 12.3(a)(5). The key to the definition is that it designates a spread as being an equivalent long and short position in different call option series and/or equivalent long and short positions in different put option series, or a combination thereof.[18] With respect to equivalency of long and short positions, the definition further requires that the long and short positions be equal in terms of the aggregate value of the underlying security or instrument covered by each leg. The aggregate value equivalency is included so that it is clear that a spread composed of one standard option contract and one reduced value option contract covering the same underlying security or instrument would be permissible. For example, if reduced value options, equal to 1/10th the value of a standard option contract are trading, a spread consisting of 10 reduced value contracts vs. one standard contract would be permissible.[19] As with spreads under the current rule, the proposed rule further requires that the long option(s) expire after, or at the same time as, the short option(s). Additionally, under the proposed rule definition, all options in a spread must have the same exercise style (American or European) and either be composed of all listed options or all over-the-counter (OTC) options. Spreads that do not conform to the definition would be ineligible for spread margin treatment.

Amendments to CBOE Rule 12.3(c)(5)(C)(4) would implement language specifying how a margin requirement is to be computed for any spread that meets the definition, and limit eligibility for spread margin treatment to spreads that meet the definition. The computational method would require that the intrinsic value of each option series contained in a spread be calculated for assumed prices of the underlying security or instrument. The exercise prices of the option series contained in the spread would be required to be used as the assumed prices of the underlying security or instrument. For each assumed price of the underlying, the intrinsic values would be netted. The greatest loss from among the netted intrinsic values would be the spread margin requirement. As an example, consider the following spread:

Long 1 XYZ May2011 50 put
Short 1 XYZ May2011 60 put
Short 1 XYZ May2011 65 call
Long 1 XYZ May2011 70 call

This spread is a variation of an iron condor spread. It consists of a put spread and a call spread, with all options covering the same underlying security or instrument. There are an equal number of contracts long and short in both the put spread and call spread. The short options expire with or after the long options (with, in this case). It is assumed that all options are of the same exercise style (American or European). This spread would, therefore, be eligible for the spread margin requirement computation in this proposed rule amendment.

Note that in this example, the interval between the exercise prices in the put spread is greater than the interval in the call spread. In a basic iron condor spread, these intervals are equal. This particular configuration is not recognized under current Exchange margin rules. Therefore the component put spread and call spread must be viewed as separate, unrelated strategies for margin purposes. Under current Exchange margin rules, there is a $1,000

[14] *See* Securities Exchange Act Release No. 52739 (Nov. 4, 2005), 70 FR 69173 (Nov. 14, 2005) (SR–CBOE–2004–53). This release also noticed a partial amendment (Amendment No. 1) that was filed on August 23, 2005 (in coordination with the New York Stock Exchange).

[15] *See* Securities Exchange Act Release No. 52738 (Nov. 4, 2005), 70 FR 68501 (Nov. 10, 2005) (SR–NYSE–2004–39). For approval order, *see* Securities Exchange Act Release No. 52951 (Dec. 14, 2005), 70 FR 75523 (Dec. 20, 2005).

[16] *See* Securities Exchange Act Release 52950 (Dec. 14, 2005), 70 FR 75512 (Dec. 20, 2005).

[17] A long calendar butterfly spread is an example of a variation. The basic type would be a butterfly spread. In a long calendar butterfly spread, one of the long options expires after the other two options expire concurrently, whereas in the basic butterfly spread, all options expire concurrently. Another example of a variation of a butterfly spread would be a configuration where the intervals between the exercise prices involved are not equal. In a basic butterfly spread, the intervals are equal (*i.e.,* symmetric).

[18] An option series means particular exercise price *and* expiration date with respect to a put or call option.

[19] Currently, spreads consisting of standard contracts and reduced value contracts are permitted by the rules, although the current rule does not go into detail to require equivalent aggregate underlying value between the long and short legs.

margin requirement on the put spread and $500 margin requirement on the call spread. However, there are offsetting properties between the two spreads, and, if viewed collectively, a total margin requirement of $1,500 is not necessary. Using the proposed computational methodology, a margin requirement would be calculated as follows:

INTRINSIC VALUES FOR ASSUMED PRICES OF THE UNDERLYING SPREAD

	$50	$60	$65	$70
Long 1 XYZ May2011 50 put	0	0	0	0
Short 1 XYZ May2011 60 put	$(1,000)	0	0	0
Short 1 XYZ May2011 65 call	0	0	0	$(500)
Long 1 XYZ May2011 70 call	0	0	0	0
Net intrinsic values	$(1,000)	0	0	$(500)

The greatest loss from among the netted intrinsic values is $1,000.[20] Under the proposed rule amendments, this would be the margin requirement. This spread margin requirement is $500 less than that required under current Exchange margin rules. Note that under both the current and proposed rules, any net debit incurred when establishing the spread is required to be paid for in full.

It can be intuitively shown that the put spread and call spread in the example do not have $1,500 of risk when viewed collectively. If the price of the underlying security or instrument is at or above $60, the put spread would have no intrinsic value. At or below $65, the call spread would have no intrinsic value. Thus, both spreads would never be at risk at any given price of the underlying security or instrument. Therefore, margin need be required on only one of the spreads—the one with the highest risk. In this example, the put spread has the highest risk ($1,000), and that is the risk (and margin requirement) that would be rendered by the proposed computational methodology.

In summary, the proposed rule amendments would enable the Exchange, for margin purposes, to accommodate the many types of spread strategies utilized in the industry today in a fair and efficient manner.

III. Discussion and Commission's Findings

After careful review of the proposed rule change, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[21] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[22] which requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest. More specifically, the Commission believes that the proposed rule change modernizes the treatment of option spread strategies while maintaining margin requirements that are commensurate with the risk of those strategies. Further, because it is consistent with changes being made to FINRA Rule 4210,[23] the proposed rule change will provide for a more uniform application of margin requirements for similar products.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[24] that the proposed rule change (SR–CBOE–2012–043) is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21765 Filed 9–4–12; 8:45 am]

BILLING CODE 8011–01–P

[20] Again, depending on the type of spread strategy, there may be no loss among the netted intrinsic values, in which case there would be no margin requirement.

[21] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[22] 15 U.S.C. 78f(b)(5).

[23] *See* Securities Exchange Act Release No. 67751 (Aug. 29, 2012) (SR–FINRA–2012–024) (order approving changes to FINRA Rule 4210 relating to spread margin requirements).

[24] 15 U.S.C. 78s(b)(2).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67754; File No. SR–ISE–2012–33]

Self-Regulatory Organizations; International Securities Exchange, LLC; Order Granting Approval of Proposed Rule Change, as Modified by Amendment No. 1, Regarding Strike Price Intervals for Certain Option Classes

August 29, 2012.

I. Introduction

On May 21, 2012, the International Securities Exchange, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to modify its Short Term Option Series Program (''STOS Program'') to permit, during the expiration week of an option class that is selected for the STOS Program (''STOS Option''), the strike price intervals for the related non-STOS option that is in the same class as a STOS Option (''Related non-STOS Option'') to be the same as the strike price interval for the STOS Option. The Exchange also proposed to adopt a rule to open for trading Short Term Option Series at $0.50 strike price intervals for option classes that trade in one dollar increments and are in the STOS Program (''Eligible Option Classes''). The proposed rule change was published for comment in the **Federal Register** on June 6, 2012.[3] The Commission received one comment letter on the proposal.[4] On July 26,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 67083 (June 6, 2012), 76 FR 33543 (''Notice'').

[4] *See* letter from Jenny L. Klebes, Senior Attorney, Legal Division, Chicago Board Options Exchange, Incorporated (''CBOE''), to Elizabeth M. Murphy, Secretary, Commission, dated June 27, 2012

Continued

2012, ISE filed Amendment No.1 to the proposed rule change.[5] This order approves the proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposal

The Exchange proposed to amend ISE Rules 504 (Series of Options Contracts Open for Trading) and 2009 (Terms of Index Options Contracts) to indicate that, during the expiration week, the strike price intervals for the Related non-STOS Option shall be the same as the strike price interval for the STOS Option. The Exchange also proposed to adopt a rule that would permit ISE to list Short Term Option Series at $0.50 strike price intervals for Eligible Option Classes.

In the Notice, the Exchange stated that the principal reason for the proposed expansion is in response to market and customer demand to list actively traded products in more granular strike price intervals and to provide Exchange members and their customers increased trading opportunities in the STOS Program.[6] ISE also represented that there are substantial benefits to market participants in the ability to trade the Eligible Option Classes at more granular strike price intervals and that the instant proposal has the support of several of its market makers and was developed in consultations with one such market-making firm.[7] Furthermore, the Exchange also argued that allowing it to open Related non-STOS Options at the more granular strike price intervals the week before expiration would ensure conformity between STOS options and Related non-STOS Options.

The Exchange stated that it has analyzed its capacity, and represented that it and the Options Price Reporting Authority (''OPRA'') have the necessary systems capacity to handle the potential additional traffic associated with trading the Eligible Option Classes in narrower strike price intervals.[8] The Exchange also represented that the proposal, if approved, would not increase the number of listed short-term series.[9]

III. Discussion and Commission Findings

After careful review of the proposed rule change and the CBOE Letter, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[10] Specifically, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[11] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission believes that the proposal strikes a reasonable balance between the Exchange's desire to offer a wider array of investment opportunities and the need to avoid unnecessary proliferation of options series.

In approving this proposal, the Commission notes that the Exchange has represented that it and OPRA have the necessary systems capacity to handle the potential additional traffic associated with trading the expanded number of strike price intervals available to the Eligible Option Classes and Related non-STO Options. The Commission expects the Exchange to monitor the trading volume associated with the additional options series listed as a result of this proposal and the effect of these additional series on market fragmentation and on the capacity of the Exchange's, OPRA's, and vendors' automated systems.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[12] that the proposed rule change (SR–ISE–2012–33) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21767 Filed 9–4–12; 8:45 am]

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(''CBOE Letter''). CBOE sought further clarification on how the proposed rule change would be implemented and suggested that the proposed rule change be revised to indicate which, if any, day(s) during the week of expiration for standard options the related non-STOS options could be added. *See* CBOE Letter at 2.

[5] Amendment No. 1 clarified the timing of when additional series of non-STOS, or standard options, may be opened. Because Amendment No. 1 is technical in nature, the Commission is not required to publish it for public comment.

[6] *See* Notice, *supra* note 3 at 33544.

[7] *Id.* at 33545.

[8] *Id.* The Exchange also stated that, while liquidity levels at each individual option series could decrease as a result of listing short term options series at more granular strike price intervals, it did not expect that the proposed rule change would result in a significant change in liquidity or otherwise cause liquidity in the Eligible Options Classes products to decline.

[9] *See* Notice, *supra* note 3 at 33545

[10] In approving this 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).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67755; File No. SR–BYX–2012–012]

Self-Regulatory Organizations; BATS–Y Exchange, Inc.; Order Approving Proposed Rule Change, as Modified by Amendment No. 1, To Adopt a New Market Maker Peg Order Available to Exchange Market Makers

August 29, 2012.

I. Introduction

On June 26, 2012, BATS–Y Exchange, Inc. (''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt a new Market Maker Peg Order to provide similar functionality as the automated functionality provided to market makers under Rule 11.8(e). The proposed rule change was published for comment in the **Federal Register** on July 16, 2012.[3] The Commission received no comment letters regarding the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

II. Background

BYX is proposing to adopt a new Market Maker Peg Order to provide a similar functionality presently available to Exchange market makers under Rule 11.8(e). [4] BYX adopted Rule 11.8(e) as

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 67382 (July 10, 2012), 77 FR 41842 (''Notice''). The Commission notes that on July 6, 2012, the Exchange submitted Amendment No. 1 to the proposed rule change to make certain amendments that, in part, clarified that it is expected that market makers will perform the necessary checks to comply with Regulation SHO prior to entry of a Market Maker Peg Order.

[4] BYX will continue to offer the present automated quote management functionality provided to market makers under Rule 11.8(e) for a period of 3 months after the implementation of the proposed Market Maker Peg Order. The purpose of this transition period, during which both the present automated quote management functionality under Rule 11.8(e) and the Market Maker Peg Order will operate concurrently, is to afford market makers with the opportunity to adequately test the

part of an effort to address issues uncovered by the aberrant trading that occurred on May 6, 2010.[5] According to the Exchange, the automated quote management functionality offered by these rules is designed to help Exchange market makers meet the enhanced market maker obligations adopted post May 6, 2010,[6] and avoid execution of market maker ''stub quotes'' in instances of aberrant trading.[7] As part of these obligations, BYX requires market makers for each stock in which they are registered to continuously maintain a two-sided quotation within a designated percentage of the National Best Bid and National Best Offer,[8] as appropriate. According to BYX, the market maker quoter functionality presents difficulties to market makers in meeting their obligations under Rule 15c3–5 under the Act (the ''Market Access Rule'')[9] and Regulation SHO.[10] Specifically, the current market maker quoter functionality offered to market makers reprices and ''refreshes'' a market maker's quote when it is executed against, without any action required by the market maker. When a market maker's quote is refreshed by the Exchange, however, the market maker has an obligation to ensure that the requirements of the Market Access Rule and Regulation SHO are met. To meet these obligations, a market maker must actively monitor the status of its quotes and ensure that the requirements of the Market Access Rule and Regulation SHO are being satisfied.

Market Maker Peg Order

In an effort to simplify market maker compliance with the requirements of the Market Access Rule and Regulation SHO, BYX proposes to adopt a new order type available only to Exchange market makers, which offers functionality similar to the market maker quoter functionality, but also allows a market maker to comply with the requirements of the Market Access Rule and Regulation SHO. Specifically, BYX proposes to replace the market maker quoter functionality with the Market Maker Peg Order. The Market Maker Peg Order would be a one-sided limit order and similar to other peg orders available to market participants in that the order is tied or ''pegged'' to a certain price,[11] but it would not be eligible for routing pursuant to Rule 11.13(a)(2) and would always be displayed. The Market Maker Peg Order would be limited to market makers and would have its price automatically set and adjusted, both upon entry and any time thereafter, in order to comply with the Exchange's rules regarding market maker quotation requirements and obligations.[12] It is expected that market makers will perform the necessary checks to comply with Regulation SHO, as discussed above, prior to entry of a Market Maker Peg Order. Upon entry and at any time the order exceeds either the ''Defined Limit,'' as described in Rule 11.8(d)(2)(E), or moves a specified number of percentage points away from the Designated Percentage towards the then current National Best Bid or National Best Offer, the Market Maker Peg Order would be priced by the Exchange at the Designated Percentage[13] away from the then current National Best Bid and National Best Offer. Where there is no National Best Bid or National Best Offer, the Market Maker Peg Order would, by default, be priced at the Designated Percentage away from the last reported sale from the responsible single plan processor, unless instructed by the market maker upon entry to cancel or reject where there is no National Best Bid or National Best Offer. According to BYX, in the absence of a National Best Bid or National Best Offer and last reported sale, the order will be cancelled or rejected. Adjustment to the Designated Percentage is designed to avoid an execution against a Market Maker Peg Order that would initiate an individual stock trading pause. In the event of an execution against a Market Maker Peg Order that reduces the size of the Market Maker Peg Order below one round lot, the market maker would need to enter a new order, after performing the regulatory checks discussed above, to satisfy their obligations under Rule 11.8.[14] In the event that pricing the Market Maker Peg Order at the Designated Percentage away from the then current National Best Bid and National Best Offer, or, if no National Best Bid or National Best Offer, to the Designated Percentage away from the last reported sale from the responsible single plan processor would result in the order exceeding its limit price, the order will be cancelled or rejected.

BYX is also proposing to allow a market maker to designate an offset more aggressive (*i.e.,* smaller) than the Designated Percentage for any given Market Maker Peg Order. This functionality will allow a market maker to quote at price levels that are closer to the National Best Bid and National Best Offer if it elects to do so. To use this functionality, a market maker, upon entry, must designate the desired offset and a percentage away from the National Best Bid or National Best Offer at which the price of such bid or offer will be adjusted back to the desired offset (the ''Reprice Percentage'').[15]

new Market Maker Peg Order and migrate away from the present automated quote management functionality under Rule 11.8(e). Prior to the end of this three month period, BYX represents that it will submit a rule filing to retire the automated quote management functionality under Rule 11.8(e). *See* Notice, *supra* note 3 at 41843.

[5] Securities Exchange Act Release No. 63342 (November 18, 2010), 75 FR 71768 (November 24, 2010) (SR–BYX–2010–001).

[6] *Id.*

[7] For each issue in which a market maker is registered, the market maker quoter functionality optionally creates a quotation for display to comply with market making obligations. Compliant displayed quotations are thereafter allowed to rest and are not adjusted unless the relationship between the quotation and its related national best bid or national best offer, as appropriate, either: (a) Shrinks to a specified number of percentage points away from the Designated Percentage (as defined below) towards the then current national best bid or national best offer, which number of percentage points will be determined and published in a circular distributed to Members from time to time, or (b) expands to within 0.5% of the applicable percentage necessary to trigger an individual stock trading pause, whereupon such bid or offer will be cancelled and re-entered at the Designated Percentage away from the then current national best bid and national best offer, or if no national best bid or national best offer, at the Designated Percentage away from the last reported sale from the responsible single plan processor. Quotations independently entered by market makers are allowed to move freely towards the national best bid or national best offer, as appropriate, for potential execution. In the event of an execution against a quote generated pursuant to the market maker quoter functionality, the market maker's quote is refreshed on the executed side of the market at the applicable Designated Percentage away from the then national best bid (offer), or if no national best bid (offer), the last reported sale. *See* Rule 11.8(e).

[8] As defined by Regulation NMS Rule 600(b)(42). 17 CFR 242.600.

[9] *See* Notice, *supra* note 3 at 41843.

[10] 17 CFR 242.200 through 204.

[11] Rule 11.9(c)(8).

[12] The Market Maker Peg Order is one-sided so a market maker seeking to use Market Maker Peg Orders to comply with the Exchange's rules regarding market maker quotation requirements would need to submit both a bid and an offer using the order type.

[13] The ''Designated Percentage'' is the individual stock pause trigger percentage listed in Interpretations and Policies .01 to Rule 11.8, less either: (i) Two percentage points for securities that are included in the S&P 500® Index, Russell 1000® Index, and a pilot list of Exchange Traded Products and for all other NMS stocks with a price equal to or greater than $1 per share; or (ii) twenty percentage points for all NMS stocks with a price less than $1 per share that are not included in the S&P 500® Index, Russell 1000® Index, and a pilot list of Exchange Traded Products. *See* Rule 11.8(d)(2)(D).

[14] Rule 11.8 generally sets forth BYX's market maker requirements, which include quotation and pricing obligations.

[15] If a market maker wishes, it can designate a more aggressive bid while using the Defined Percentage and Defined Limit for its offer, or vice versa.

Thereafter,[16] a Market Maker Peg Order with a market maker-designated offset will have its price automatically adjusted to the market maker-designated offset from the National Best Bid or National Best Offer or last reported sale upon reaching the Reprice Percentage.[17] Identical to the behavior of Market Maker Peg Orders using the Defined Percentage and Defined Limit, in the absence of a National Best Bid or National Best Offer, Market Maker Peg Orders with a market maker-designated offset will, by default, have their price adjusted to the Market Maker-designated offset from the price of the last reported sale from the responsible single plan processor, or, if otherwise instructed by the Market Maker, will be cancelled or rejected. In the absence of a National Best Bid or National Best Offer and a last reported sale, Market Maker Peg Orders with a market maker-designated offset will be cancelled or rejected. In the event that pricing the Market Maker Peg Order at the market maker-designated offset away from the then current National Best Bid and National Best Offer or last reported sale would result in the order exceeding its limit price, the order will be cancelled or rejected.[18]

BYX claims that this order-based approach is superior in terms of the ease in complying with the requirements of the Market Access Rule and Regulation SHO while also providing similar quote adjusting functionality to its market makers.[19] BYX also states that market makers would have control of order origination, as required by the Market Access Rule, while also allowing market makers to make marking and locate determinations prior to order entry, as required by Regulation SHO. The Exchange claims that this will allow market makers to fully comply with the requirements of the Market Access Rule and Regulation SHO, as they would when placing any order, while also meeting their Exchange market making obligations.[20]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[21] Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[22] which requires, among other things, the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The Commission finds that the proposed rule change also is designed to support the principles of Section 11A(a)(1)[23] of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets.

The Commission finds that the Exchange's proposal is consistent with the Act because it provides a means through which market makers may meet their minimum quoting requirements, which may assist in the maintenance of fair and orderly markets, provide additional liquidity to the Exchange, and prevent excessive volatility. The Commission notes, however, that notwithstanding the availability of the Market Maker Peg Order functionality, the market maker remains responsible for meeting its obligations under Rule 11.8, including entering, monitoring, and re-submitting, as applicable, compliant quotations. At the same time, the Commission finds that the proposal is reasonably designed to assist market makers in complying with the regulatory requirements of the Market Access Rule and Regulation SHO. The Commission notes, however, that the Market Maker Peg Order, like the current market maker quoter functionality, does not ensure that the market maker is satisfying the requirements of the Market Access Rule or Regulation SHO, including the satisfaction of the locate requirement of Rule 203(b)(1) or an exception thereto. The Commission also notes that, in the event a Market Maker Peg Order is executed against such that the Market Maker Peg Order is reduced in size to below one round lot, the market maker would need to perform the necessary regulatory checks pursuant to the Market Access Rule and Regulation SHO prior to entering a new Market Maker Peg Order.

The Commission also believes that providing Exchange market makers with a transition period will serve to minimize the potential market impact caused by the implementation of the Market Maker Peg Order. In addition, by allowing market makers to enter a Market Maker Peg Order that is priced more aggressively than the Designated Percentage, the proposed rules are reasonably designed to provide that quotations submitted by market makers to the Exchange, and displayed to market participants, bear some relationship to the prevailing market price.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[24] that the proposed rule change, as modified by Amendment No. 1, (SR–BYX–2012–012) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Kevin M. O'Neill,

Deputy Secretary.

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[16] In the absence of an offset designation and/or Reprice Percentage, a Market Maker Peg Order will default to using the Defined Percentage and Defined Limit, and the repricing process whereby, upon reaching the Defined Limit, the price of a Market Maker Peg Order bid or offer will be adjusted by the System to the Designated Percentage away from the then current National Best Bid or National Best Offer, or, if no National Best Bid or National Best Offer, to the Designated Percentage away from the last reported sale from the responsible single plan processor.

[17] Market Maker Peg Orders with a market maker-designated offset may be able to qualify as bona-fide market making for purposes of Regulation SHO, depending on the facts and circumstances. A market maker entering such an order must consider the factors set forth by the Commission in determining whether reliance on the exception from the ''locate'' requirement of Rule 203 for bona-fide market making is appropriate with respect to the particular Market Maker Peg Order and its designated offset. *See* 17 CFR 242.203(b)(1).

[18] The Market Maker Peg Order will be accepted during Regular Trading Hours and the Pre-Opening and After Hours Trading Sessions. The Pre-Opening Session means the time between 8 a.m. and 9:30 a.m. Eastern Time. The After Hours Trading Session means the time between 4 p.m. and 5 p.m. Eastern Time. By default, the Market Maker Peg Order will be priced at 9:30 a.m. and will only be executable during Regular Trading Hours, however, upon entry, a User may direct the Exchange to automatically price and execute a Market Maker Peg Order during the Pre-Opening Session and After Hours Trading Session (''Extended Hours Market Maker Peg Orders''). During the Pre-Opening Session and After Hours Trading Session, the wider Designated Percentage and Defined Limit associated with the 9:30 am–9:45 am and 3:35 pm–4 pm periods under Rule 11.8(e) will be applied to Extended Hours Market Maker Peg Orders for which the market maker has not designated an offset more aggressive than the Designated Percentage.

[19] *See* Notice, *supra* note 3 at 41845.

[20] *See id.*

[21] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78k–1(a)(1).

[24] 15 U.S.C. 78s(b)(2).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67756; File No. SR–BATS–2012–026]

Self-Regulatory Organizations; BATS Exchange, Inc.; Order Approving Proposed Rule Change, as Modified by Amendment No. 1, To Adopt a New Market Maker Peg Order Available to Exchange Market Makers

August 29, 2012.

I. Introduction

On June 26, 2012, BATS Exchange, Inc. (''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt a new Market Maker Peg Order to provide similar functionality as the automated functionality provided to market makers under Rule 11.8(e). The proposed rule change was published for comment in the **Federal Register** on July 16, 2012.[3] The Commission received no comment letters regarding the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

II. Background

BATS is proposing to adopt a new Market Maker Peg Order to provide a similar functionality presently available to Exchange market makers under Rule 11.8(e).[4] BATS adopted Rule 11.8(e) as part of an effort to address issues uncovered by the aberrant trading that occurred on May 6, 2010.[5] According to the Exchange, the automated quote management functionality offered by these rules is designed to help Exchange market makers meet the enhanced market maker obligations adopted post May 6, 2010,[6] and avoid execution of market maker ''stub quotes'' in instances of aberrant trading.[7] As part of these obligations, BATS requires market makers for each stock in which they are registered to continuously maintain a two-sided quotation within a designated percentage of the National Best Bid and National Best Offer,[8] as appropriate. According to BATS, the market maker quoter functionality presents difficulties to market makers in meeting their obligations under Rule 15c3–5 under the Act (the ''Market Access Rule'') [9] and Regulation SHO.[10] Specifically, the current market maker quoter functionality offered to market makers reprices and ''refreshes'' a market maker's quote when it is executed against, without any action required by the market maker. When a market maker's quote is refreshed by the Exchange, however, the market maker has an obligation to ensure that the requirements of the Market Access Rule and Regulation SHO are met. To meet these obligations, a market maker must actively monitor the status of its quotes and ensure that the requirements of the Market Access Rule and Regulation SHO are being satisfied.

Market Maker Peg Order

In an effort to simplify market maker compliance with the requirements of the Market Access Rule and Regulation SHO, BATS proposes to adopt a new order type available only to Exchange market makers, which offers functionality similar to the market maker quoter functionality, but also allows a market maker to comply with the requirements of the Market Access Rule and Regulation SHO. Specifically, BATS proposes to replace the market maker quoter functionality with the Market Maker Peg Order. The Market Maker Peg Order would be a one-sided limit order and similar to other peg orders available to market participants in that the order is tied or ''pegged'' to a certain price,[11] but it would not be eligible for routing pursuant to Rule 11.13(a)(2) and would always be displayed. The Market Maker Peg Order would be limited to market makers and would have its price automatically set and adjusted, both upon entry and any time thereafter, in order to comply with the Exchange's rules regarding market maker quotation requirements and obligations.[12] It is expected that market makers will perform the necessary checks to comply with Regulation SHO, as discussed above, prior to entry of a Market Maker Peg Order. Upon entry and at any time the order exceeds either the ''Defined Limit'', as described in Rule 11.8(d)(2)(E), or moves a specified number of percentage points away from the Designated Percentage towards the then current National Best Bid or National Best Offer, the Market Maker Peg Order would be priced by the Exchange at the Designated Percentage [13] away from the then current National Best Bid and National Best Offer. Where there is no National

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 67381 (July 10, 2012), 77 FR 41829 (''Notice''). The Commission notes that on July 6, 2012, the Exchange submitted Amendment No. 1 to the proposed rule change to make certain amendments that, in part, clarified that it is expected that market makers will perform the necessary checks to comply with Regulation SHO prior to entry of a Market Maker Peg Order.

[4] BATS will continue to offer the present automated quote management functionality provided to market makers under Rule 11.8(e) for a period of 3 months after the implementation of the proposed Market Maker Peg Order. The purpose of this transition period, during which both the present automated quote management functionality under Rule 11.8(e) and the Market Maker Peg Order will operate concurrently, is to afford market makers with the opportunity to adequately test the new Market Maker Peg Order and migrate away from the present automated quote management functionality under Rule 11.8(e). Prior to the end of this three month period, BATS represents that it will submit a rule filing to retire the automated quote management functionality under Rule 11.8(e). *See* Notice, *supra* note 3 at 41829.

[5] Securities Exchange Act Release No. 63255 (November 5, 2010), 75 FR 69484 (November 12, 2010) (SR–BATS–2010–25).

[6] *Id.*

[7] For each issue in which a market maker is registered, the market maker quoter functionality optionally creates a quotation for display to comply with market making obligations. Compliant displayed quotations are thereafter allowed to rest and are not adjusted unless the relationship between the quotation and its related national best bid or national best offer, as appropriate, either: (a) Shrinks to a specified number of percentage points away from the Designated Percentage (as defined below) towards the then current national best bid or national best offer, which number of percentage points will be determined and published in a circular distributed to Members from time to time, or (b) expands to within 0.5% of the applicable percentage necessary to trigger an individual stock trading pause, whereupon such bid or offer will be cancelled and re-entered at the Designated Percentage away from the then current national best bid and national best offer, or if no national best bid or national best offer, at the Designated Percentage away from the last reported sale from the responsible single plan processor. Quotations independently entered by market makers are allowed to move freely towards the national best bid or national best offer, as appropriate, for potential execution. In the event of an execution against a quote generated pursuant to the market maker quoter functionality, the market maker's quote is refreshed on the executed side of the market at the applicable Designated Percentage away from the then national best bid (offer), or if no national best bid (offer), the last reported sale. *See* Rule 11.8(e).

[8] As defined by Regulation NMS Rule 600(b)(42). 17 CFR 242.600.

[9] *See* Notice, *supra* note 3 at 41830.

[10] 17 CFR 242.200 through 204.

[11] Rule 11.9(c)(8).

[12] The Market Maker Peg Order is one-sided so a market maker seeking to use Market Maker Peg Orders to comply with the Exchange's rules regarding market maker quotation requirements would need to submit both a bid and an offer using the order type.

[13] The ''Designated Percentage'' is the individual stock pause trigger percentage listed in Interpretations and Policies .01 to Rule 11.8, less either: (i) Two percentage points for securities that are included in the S&P 500® Index, Russell 1000® Index, and a pilot list of Exchange Traded Products and for all other NMS stocks with a price equal to or greater than $1 per share; or (ii) twenty percentage points for all NMS stocks with a price less than $1 per share that are not included in the S&P 500® Index, Russell 1000® Index, and a pilot list of Exchange Traded Products. *See* Rule 11.8(d)(2)(D).

Best Bid or National Best Offer, the Market Maker Peg Order would, by default, be priced at the Designated Percentage away from the last reported sale from the responsible single plan processor, unless instructed by the market maker upon entry to cancel or reject where there is no National Best Bid or National Best Offer. According to BATS, in the absence of a National Best Bid or National Best Offer and last reported sale, the order will be cancelled or rejected. Adjustment to the Designated Percentage is designed to avoid an execution against a Market Maker Peg Order that would initiate an individual stock trading pause. In the event of an execution against a Market Maker Peg Order that reduces the size of the Market Maker Peg Order below one round lot, the market maker would need to enter a new order, after performing the regulatory checks discussed above, to satisfy their obligations under Rule 11.8.[14] In the event that pricing the Market Maker Peg Order at the Designated Percentage away from the then current National Best Bid and National Best Offer, or, if no National Best Bid or National Best Offer, to the Designated Percentage away from the last reported sale from the responsible single plan processor would result in the order exceeding its limit price, the order will be cancelled or rejected.

BATS is also proposing to allow a market maker to designate an offset more aggressive (*i.e.,* smaller) than the Designated Percentage for any given Market Maker Peg Order. This functionality will allow a market maker to quote at price levels that are closer to the National Best Bid and National Best Offer if it elects to do so. To use this functionality, a market maker, upon entry, must designate the desired offset and a percentage away from the National Best Bid or National Best Offer at which the price of such bid or offer will be adjusted back to the desired offset (the ''Reprice Percentage'').[15] Thereafter,[16] a Market Maker Peg Order with a market maker-designated offset will have its price automatically adjusted to the market maker-designated offset from the National Best Bid or National Best Offer or last reported sale upon reaching the Reprice Percentage.[17] Identical to the behavior of Market Maker Peg Orders using the Defined Percentage and Defined Limit, in the absence of a National Best Bid or National Best Offer, Market Maker Peg Orders with a market maker-designated offset will, by default, have their price adjusted to the Market Maker-designated offset from the price of the last reported sale from the responsible single plan processor, or, if otherwise instructed by the Market Maker, will be cancelled or rejected. In the absence of a National Best Bid or National Best Offer and a last reported sale, Market Maker Peg Orders with a market maker-designated offset will be cancelled or rejected. In the event that pricing the Market Maker Peg Order at the market maker-designated offset away from the then current National Best Bid and National Best Offer or last reported sale would result in the order exceeding its limit price, the order will be cancelled or rejected.[18]

BATS claims that this order-based approach is superior in terms of the ease in complying with the requirements of the Market Access Rule and Regulation SHO while also providing similar quote adjusting functionality to its market makers.[19] BATS also states that market makers would have control of order origination, as required by the Market Access Rule, while also allowing market makers to make marking and locate determinations prior to order entry, as required by Regulation SHO. The Exchange claims that this will allow market makers to fully comply with the requirements of the Market Access Rule and Regulation SHO, as they would when placing any order, while also meeting their Exchange market making obligations.[20]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[21] Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[22] which requires, among other things, the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The Commission finds that the proposed rule change also is designed to support the principles of Section 11A(a)(1)[23] of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets.

The Commission finds that the Exchange's proposal is consistent with the Act because it provides a means through which market makers may meet their minimum quoting requirements, which may assist in the maintenance of fair and orderly markets, provide additional liquidity to the Exchange, and prevent excessive volatility. The Commission notes, however, that notwithstanding the availability of the Market Maker Peg Order functionality, the market maker remains responsible for meeting its obligations under Rule 11.8, including entering, monitoring, and re-submitting, as applicable, compliant quotations. At the same time, the Commission finds that the proposal is reasonably designed to assist market makers in complying with the regulatory requirements of the Market Access Rule and Regulation SHO. The Commission notes, however, that the Market Maker Peg Order, like the

[14] Rule 11.8 generally sets forth BATS's market maker requirements, which include quotation and pricing obligations.

[15] If a market maker wishes, it can designate a more aggressive bid while using the Defined Percentage and Defined Limit for its offer, or vice versa.

[16] In the absence of an offset designation and/or Reprice Percentage, a Market Maker Peg Order will default to using the Defined Percentage and Defined Limit, and the repricing process whereby, upon reaching the Defined Limit, the price of a Market Maker Peg Order bid or offer will be adjusted by the System to the Designated Percentage away from the then current National Best Bid or National Best Offer, or, if no National Best Bid or National Best Offer, to the Designated Percentage away from the last reported sale from the responsible single plan processor.

[17] Market Maker Peg Orders with a market maker-designated offset may be able to qualify as bona-fide market making for purposes of Regulation SHO, depending on the facts and circumstances. A market maker entering such an order must consider the factors set forth by the Commission in determining whether reliance on the exception from the ''locate'' requirement of Rule 203 for bona-fide market making is appropriate with respect to the particular Market Maker Peg Order and its designated offset. *See* 17 CFR 242.203(b)(1).

[18] The Market Maker Peg Order will be accepted during Regular Trading Hours and the Pre-Opening and After Hours Trading Sessions. The Pre-Opening Session means the time between 8 a.m. and 9:30 a.m. Eastern Time. The After Hours Trading Session means the time between 4 p.m. and 5 p.m. Eastern Time. By default, the Market Maker Peg Order will be priced at 9:30 a.m. and will only be executable during Regular Trading Hours, however, upon entry, a User may direct the Exchange to automatically price and execute a Market Maker Peg Order during the Pre-Opening Session and After Hours Trading Session (''Extended Hours Market Maker Peg Orders''). During the Pre-Opening Session and After Hours Trading Session, the wider Designated Percentage and Defined Limit associated with the 9:30 a.m.–9:45 a.m. and 3:35 p.m.–4 p.m. periods under Rule 11.8(e) will be applied to Extended Hours Market Maker Peg Orders for which the market maker has not designated an offset more aggressive than the Designated Percentage.

[19] *See* Notice, *supra* note 3 at 41831.

[20] *See id.*

[21] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78k–1(a)(1).

current market maker quoter functionality, does not ensure that the market maker is satisfying the requirements of the Market Access Rule or Regulation SHO, including the satisfaction of the locate requirement of Rule 203(b)(1) or an exception thereto. The Commission also notes that, in the event a Market Maker Peg Order is executed against such that the Market Maker Peg Order is reduced in size to below one round lot, the market maker would need to perform the necessary regulatory checks pursuant to the Market Access Rule and Regulation SHO prior to entering a new Market Maker Peg Order.

The Commission also believes that providing Exchange market makers with a transition period will serve to minimize the potential market impact caused by the implementation of the Market Maker Peg Order. In addition, by allowing market makers to enter a Market Maker Peg Order that is priced more aggressively than the Designated Percentage, the proposed rules are reasonably designed to provide that quotations submitted by market makers to the Exchange, and displayed to market participants, bear some relationship to the prevailing market price.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[24] that the proposed rule change, as modified by Amendment No.1, (SR–BATS–2012–026) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21769 Filed 9–4–12; 8:45 am]

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[24] 15 U.S.C. 78s(b)(2).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67753; File No. SR–Phlx–2012–78]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Order Granting Approval of Proposed Rule Change Regarding Strike Price Intervals in the Short Term Options Program

August 29, 2012.

I. Introduction

On July 2, 2012, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to indicate that the interval between strike prices on short term options series (''STOs'') listed in accordance with its Short Term Option Series Program (''STO Program'') shall be $0.50 or greater where the strike price is less than $75 and $1 or greater where the strike price is between $75 and $150. The proposal would also provide that, during the expiration week of an option that is in the same class as an STO but has a longer expiration cycle (''Related non-STO'') the strike price interval for the STO and such Related non-STO shall be the same and that a Related non-STO shall be opened for trading in STO intervals in the same manner as the STO. The proposed rule change was published for comment in the **Federal Register** on July 20, 2012.[3] The Commission received one comment letter on the proposal.[4] On August 16, 2012, the Exchange filed a response to the CBOE Letter (''Phlx Response'').[5] This order approves the proposed rule change.

II. Description of the Proposal

The Exchange proposed to amend Phlx Rules 1012 (Series of Options Open for Trading) and 1101A (Terms of Options Contracts) to indicate that the interval between strike prices on STOs shall be $0.50 or greater where the strike price is less than $75 and $1 or greater where the strike price is between $75 and $150 (''STO Intervals''). The proposal would amend Phlx's rules to indicate that, during expiration week of a Related non-STO, the strike price intervals for the STO and Related non-STO shall be the same. Phlx also proposed to amend its rules to indicate that, during the week before the expiration week of the Related non-STO, such Related non-STO shall be opened for trading in the STO Intervals and in the same manner as the STO.

In the Notice, the Exchange stated that the principal reason for the proposed expansion is market demand for weekly options and continuing strong customer demand to use STOs to effectively execute hedging and trading strategies.[6] Conversely, Phlx contended that inadequately narrow STO intervals can impact trading and hedging opportunities.[7] Phlx also stated that listing Related non-STOs at the same strike prices intervals as STOs will ensure conformity and give investors and traders the ability to maximize trading and hedging opportunities and minimize associated costs.[8]

The Exchange stated that it has analyzed its capacity, and represented that it and the Options Price Reporting Authority (''OPRA'') have the necessary systems capacity to handle the potential additional traffic associated with trading in STOs at $0.50 or greater where the strike price is less than $75 and $1 or greater where the strike price is between $75 and $150. In addition, Phlx stated that it believes that the proposed rule change will not raise a capacity issue with its members.[9]

III. Discussion and Commission Findings

After careful review of the proposed rule change and the CBOE Letter, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[10] Specifically, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[11] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission believes that the proposal strikes a reasonable balance between the Exchange's desire to offer a wider array of investment opportunities and the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 67446 (July 20, 2012), 77 FR 42780 (''Notice'').

[4] *See* letter from Jenny L. Klebes-Golding, Senior Attorney, Legal Division, Chicago Board Options Exchange, Incorporated (''CBOE''), to Elizabeth M. Murphy, Secretary, Commission, dated August 10, 2012 (''CBOE Letter''). CBOE sought, in part, further clarification on whether the current 30 series per-class limitation set forth in the STO Program would apply to the Related non-STOs when the STO strike price intervals are added in accordance with this proposal.

[5] In its response, Phlx confirmed that the 30 series limitation CBOE identified applies to STOs only and would not restrict the ability to open additional series of Related non-STOs in accordance with the proposed rule change. *See* Phlx Response at 2–3.

[6] *See* Notice, *supra* note 3 at 42781.

[7] *Id.* at 42782–42783.

[8] *Id.* at 42783.

[9] *Id.*

[10] In approving this 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).

[11] 15 U.S.C. 78f(b)(5).

need to avoid unnecessary proliferation of options series.

In approving this proposal, the Commission notes that Exchange has represented that it and OPRA have the necessary systems capacity to handle the potential additional traffic associated with trading STOs and Related non-STOs at more granular strike price intervals. The Commission expects the Exchange to monitor the trading volume associated with the additional options series listed as a result of this proposal and the effect of these additional series on market fragmentation and on the capacity of the Exchange's, OPRA's, and vendors' automated systems.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[12] that the proposed rule change (SR–Phlx–2012–78) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

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[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67751; File No. SR–FINRA–2012–024]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1, Relating to FINRA Rule 4210 (Margin Requirements)

August 29, 2012.

I. Introduction

On May 23, 2012, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend FINRA Rule 4210 (Margin Requirements). The proposed rule was published for comment in the **Federal Register** on June 6, 2012.[3] The Commission received one comment on the proposed rule change.[4] On July 13, 2012, FINRA extended the time period for Commission action until September 4, 2012.[5] FINRA filed Amendment No. 1 to the proposed rule change and responded to the comment letter on August 13, 2012.[6] The Commission is publishing this notice and order to solicit comment on Amendment No. 1 and to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposal

FINRA has proposed to amend FINRA Rule 4210 (Margin Requirements) to: (1) Revise the definitions and margin treatment of option spread strategies; (2) clarify the maintenance margin requirement for non-margin eligible equity securities; (3) clarify the maintenance margin requirements for non-equity securities; (4) eliminate the current exemption from the free-riding prohibition for designated accounts; (5) conform the definition of ''exempt account''; and (6) eliminate the requirement to stress test portfolio margin accounts in the aggregate. In addition, the proposed rule change would amend FINRA Rule 4210 to make non-substantive technical and stylistic changes.

Option Spread Strategies

Basic option spreads can be paired in such ways that they offset each other in terms of risk. The total risk of the combined spreads is less than the sum of the risk of both spread positions if viewed as stand-alone strategies. FINRA Rule 4210(f)(2) currently recognizes several specific option spread strategies.[7] These strategies consist of either a ''long'' and a ''short'' option contract or two ''long'' and two ''short'' option contracts. The ''long'' and ''short'' option contracts have the same underlying security or instrument and the ''long'' option contracts must expire on or after the expiration of the ''short'' option contracts.

While the strategies recognized under FINRA Rule 4210 are the most common types of option spread strategies used by investors, there are other combinations of calls and/or puts that are similar in terms of their risk profile. Accordingly, FINRA proposed a broader definition of a spread in FINRA Rule 4210(f)(2)(A)(xxxii) to mean a ''long'' and ''short'' position in different call option series, different put option series, or a combination of call and put option series, that collectively have a limited risk/reward profile, and meet the following conditions: (1) All options must have the same underlying security or instrument; (2) all ''long'' and ''short'' option contracts must be either all American-style or all European-style; [8] (3) all ''long'' and ''short'' option contracts must be either all listed or all over-the-counter (''OTC''); [9] (4) the aggregate underlying contract value of ''long'' versus ''short'' contracts within option type(s) must be equal; and (5) the ''short'' option(s) must expire on or before the expiration date of the ''long'' option(s).

The proposed revised margin requirements set forth in FINRA Rule 4210(f)(2)(H) would require that the ''long'' option contracts within such spreads must be paid for in full. The margin required for the ''short'' option contracts within such spreads would be the lesser of: (1) The margin required pursuant to FINRA Rule 4210(f)(2)(E); or (2) the maximum potential loss. The maximum potential loss would be determined by computing the intrinsic value of the options at price points for the underlying security or instrument that are set to correspond to every exercise price present in the spread. The intrinsic values are netted at each price point, and the maximum potential loss is the greatest loss, if any. The proceeds of the ''short'' options may be applied towards the cost of the ''long'' options and/or any margin requirement. FINRA Rule 4210(f)(2)(H)(iv) would also make clear that OTC option contracts that comprise a spread must be issued and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 67088 (May 31, 2012), 77 FR 33527 (''Notice'').

[4] Letter to Elizabeth M. Murphy, Secretary, Commission from David Aman, Esq., Cleary Gottlieb Steen & Hamilton LLP, dated June 27, 2012 (''Aman Letter'').

[5] *See http://www.finra.org/web/groups/industry/@ip/@reg/@rulfil/documents/rulefilings/p135885.pdf.*

[6] Amendment No. 1 and response to Aman Letter, dated Aug. 13, 2012 (''Amendment No. 1''). The text of Amendment No. 1 is available on FINRA's Web site at http://www.finra.org, at the principal office of FINRA, and at the Commission's Public Reference Room. *See* section III. below (describing Amendment No. 1).

[7] *See* FINRA Rule 4210(f)(2)(A) that currently recognizes the following spread strategies: box spread, butterfly spread, calendar (or time) spread, ''long'' calendar butterfly spread, ''long'' calendar condor spread, ''long'' condor spread, ''short'' calendar iron butterfly spread, ''short'' calendar iron condor spread, ''short'' iron butterfly spread and ''short'' iron condor spread.

[8] American-style options can be exercised or assigned at any time during the life of the contract. European-style options can only be exercised or assigned at the time of expiration.

[9] *See* FINRA Rule 4210(f)(2)(A)(xxvi) (renumbered as 4210(f)(2)(A)(xxiv)) that defines a listed option as an option contract that is traded on a national securities exchange and is issued and guaranteed by a registered clearing agency. *See also* FINRA Rule 4210(f)(2)(A)(xxxii) (renumbered as 4210(f)(2)(A)(xxvii)) that defines an OTC option as an over-the-counter option contract that is not traded on a national securities exchange and is issued and guaranteed by the carrying broker-dealer.

guaranteed by the same carrying broker-dealer and the carrying broker-dealer must also be a FINRA member. If the OTC option contracts are not issued and guaranteed by the same carrying broker-dealer, or if the carrying broker-dealer is not a FINRA member, then the ''short'' option contracts must be margined separately pursuant to FINRA Rule 4210(f)(2)(E)(iii) or (E)(iv). In addition, FINRA proposes to amend FINRA Rule 4210(f)(2)(N) to similarly conform the margin requirements for spreads that are permitted in a cash account.

FINRA proposed to eliminate the definitions for the option spread strategies currently recognized within the rule, along with the specific margin requirements associated with each spread, with the exception of a ''long'' box spread consisting of European-style options.[10] FINRA Rule 4210(f)(2)(H)(v)g.[11] currently allows a margin requirement equal to 50% of the aggregate difference in the exercise prices. This is the only spread strategy that allows loan value, and FINRA believes that retaining this provision is appropriate.

Non-Margin Eligible Equity Securities

FINRA proposed to clarify the maintenance margin requirement for non-margin eligible equity securities. FINRA Rule 4210(c)(1) prescribes a maintenance margin requirement of 25% of the current market value of all securities (except for security futures contracts) held ''long'' in an account. FINRA believes that non-margin eligible equity securities should be subject to more stringent margin requirements in light of the nature of such securities. Accordingly, FINRA proposed to amend FINRA Rule 4210(c)(1) regarding securities held ''long'' to clarify that the maintenance margin requirement of 25% of the current market value would apply only to margin securities as defined in Regulation T.[12] Consequently, non-margin eligible equity securities would be excluded from such margin treatment and the maintenance margin requirement for non-margin eligible equity securities would be 100% of the current market value.[13] This maintenance margin requirement of 100% for non-margin eligible equity securities is consistent with the requirement outlined in *Regulatory Notice* 11–16. However, FINRA noted that two provisions of *Regulatory Notice* 11–16 would be superseded. Firms may no longer extend maintenance loan value on non-margin eligible equity securities either to satisfy maintenance margin deficiencies or when used to collateralize non-purpose loans, except as otherwise provided by FINRA in writing. To this end, FINRA would allow a firm to extend credit on a non-margin eligible security[14] only to the extent: (1) The security is collateralizing a non-purpose loan debit; and (2) such security can be liquidated in a period not exceeding 20 business days, based on a rolling 20 business day median trading volume. The maintenance loan value for the non-margin eligible security would be calculated based on the applicable maintenance margin requirements for a margin eligible security. If the security fails to meet the trading volume requirement, then the security would no longer be entitled to maintenance loan value, and a 100% maintenance margin requirement would be applied together with a deduction to net capital pursuant to Rule 15c3–1 and, if applicable, FINRA Rule 4110(a). Notwithstanding the foregoing, FINRA would allow that in the case of offshore mutual funds, a firm may extend maintenance loan value, based on a 25% maintenance margin requirement, to collateralize a non-purpose loan, provided that the fund has an affiliation with a U.S.-based fund registered with the SEC under the Investment Company Act of 1940, and the fund shares can be liquidated or redeemed daily.

Similar to the treatment above, FINRA also proposed to amend Rule 4210(f)(8)(B)(iii) to clarify that the special maintenance margin requirement for day traders, based on the cost of all day trades made during the day, would be 25% for margin eligible equity securities, and 100% for non-margin eligible equity securities.[15]

In addition, FINRA proposed to adopt new paragraph (g)(7)(E) of FINRA Rule 4210 regarding the margin requirements for non-margin eligible equity securities held in a portfolio margin account. Consistent with the margin treatment above, the provision would clarify that non-margin eligible equity securities held ''long'' in a portfolio margin account would have a maintenance margin requirement equal to 100% of the current market value at all times.[16] Paragraph (g)(7)(E) would also provide that non-margin eligible equity securities held ''short'' in a portfolio margin account would have a maintenance margin requirement equal to 50% of the current market value at all times.[17] FINRA believes that setting this specific requirement is necessary to help ensure that customers do not attempt to circumvent the initial margin requirements of Regulation T and place all short sales in a portfolio margin account to obtain lower margin requirements.[18]

FINRA also proposed to amend paragraph (g)(7)(D) of FINRA Rule 4210 to clarify that although non-margin eligible equity securities are not eligible for portfolio margin treatment, they may be carried in a portfolio margin account, provided that the member uses strategy-based margin requirements unless such securities are subject to other provisions of paragraph (g). For example, non-margin eligible equity securities may be carried in a portfolio margin account, but the amendment would clarify that they would be subject to the margin treatment set forth in FINRA Rule 4210(g)(7)(E), rather than FINRA Rule 4210(c).

Non-Equity Securities[19]

In the Notice, FINRA proposed to further amend FINRA Rule 4210 to clarify the appropriate maintenance margin requirement for non-equity securities in a margin account. Paragraph (c)(4) stipulates a maintenance margin requirement for each bond held ''short'' in a margin account. Paragraph (e)(2)(C) stipulates the maintenance margin requirements on any positions in specified non-equity

[10] *See* FINRA Rule 4210(f)(2)(A)(vi). A box spread means an aggregation of positions in a ''long'' call and ''short'' put with the same exercise price (''buy side'') coupled with a ''long'' put and ''short'' call with the same exercise price (''sell side'') structured as: (1) A ''long'' box spread in which the sell side exercise price exceeds the buy side exercise price; or (2) a ''short'' box spread in which the buy side exercise price exceeds the sell side exercise price, all of which have the same contract size, underlying component or index and time of expiration, and are based on the same aggregate current underlying value.

[11] FINRA Rule 4210(f)(2)(H)(v)g. would be renumbered as FINRA Rule 4210(f)(2)(H)(v)e.

[12] *See* Federal Reserve Regulation T (''Regulation T'') section 200.2 for the definition of margin security.

[13] *See Regulatory Notice* 11–16 (April 2011) and *Regulatory Notice* 11–30 (June 2011) (*Regulatory Notice* 11–30 delayed the effective date of *Regulatory Notice* 11–16 until October 3, 2011).

[14] The exception to permit firms to extend maintenance loan value would apply to both equity and non-equity non-margin eligible securities.

[15] The special maintenance margin requirement for non-margin eligible equity securities for day traders is consistent with the margin requirements outlined in *Regulatory Notice* 11–16.

[16] The maintenance margin requirement for non-margin eligible equity securities held ''long'' in a portfolio margin account is consistent with the margin requirements outlined in *Regulatory Notice* 11–16.

[17] The maintenance margin requirement for ''short'' non-margin eligible equity securities held in a portfolio margin account would supersede the maintenance margin requirement for such securities specified in *Regulatory Notice* 11–16.

[18] *See* Rule 4210(g)(7).

[19] *See* section III. below (describing Amendment No. 1).

securities [20] that are inconsistent with the requirements in paragraph (c)(4). FINRA received several inquiries as to the appropriate maintenance margin requirement for any ''short'' non-equity security. Accordingly, in the Notice, FINRA proposed to amend FINRA Rule 4210 to clarify that the margin requirements in paragraph (c)(4) would apply to non-margin eligible, non-equity securities held ''short'' [21] while the margin requirements in paragraph (e)(2)(C) would apply to the specified margin-eligible non-equity securities held ''short'' or ''long.'' [22] FINRA also proposed to add a reference to ''short'' or ''long'' to each of paragraphs (e)(2)(B), (F) and (G) to further clarify that such provisions apply to securities held short or long.

''Free-Riding''

''Free-riding'' is the purchase of a security and the selling of the same security in the cash account, using the proceeds of the sale to satisfy the purchase. Such activity is prohibited under section 220.8(a)(1)(ii) of Regulation T. FINRA Rule 4210(f)(9) addresses free-riding in the cash account and currently exempts broker-dealers and ''designated accounts.'' [23] While the term ''designated account'' generally includes banks, savings associations, insurance companies, investment companies, states or political subdivisions, and ERISA pension or profit sharing plans, FINRA believes that it is appropriate to treat such accounts as any other customer regarding this activity. Accordingly, FINRA proposed to eliminate this exemption for designated accounts consistent with Regulation T.

''Exempt Account''

Certain non-equity securities such as exempted securities, mortgage related securities, highly rated foreign sovereign debt securities, and investment grade debt securities may be subject to reduced maintenance margin requirements (or require no margin be deposited) for an ''exempt account,'' as defined in FINRA Rule 4210(a)(13).[24] FINRA Rule 4210(f)(2)(E)(iv) regarding reduced maintenance margin requirements for OTC put and call options on certain U.S. Government and U.S. Government Agency debt securities retained an earlier definition of ''exempt account'' that was not updated in 2003 when the New York Stock Exchange and National Association of Securities Dealers amended the definition of ''exempt account'' by raising the dollar threshold in paragraph (a)(13) for all other purposes in their respective margin rules.[25] The definition of ''exempt account'' currently referenced in paragraph (f)(2)(E)(iv) was retained as a result of comment letters received by the SEC in 2003, expressing concern that customers who no longer qualified as ''exempt accounts'' in the amended paragraph (a)(13) definition would be subject to higher maintenance margin requirements for the securities addressed in paragraph (f)(2)(E)(iv). Therefore, such definition was maintained only for the provision in paragraph (f)(2)(E)(iv) to allow existing customers to continue to avail themselves of the reduced margin requirements. However, the SEC noted that exempt accounts that met the requirements for exempt account status would be ''grandfathered'' on the existing credit transactions but that the new requirements (the current paragraph (a)(13) ''exempt account'' requirements) would apply to any new credit transactions or roll-overs of existing transactions.[26] In light of the application of the 2003 exempt account definition to new and roll-over transactions and the significant passage of time, FINRA believes that maintaining these separate definitions is no longer necessary and proposes to delete the definition of ''exempt account'' contained in paragraph (f)(2)(E)(iv) and require an exempt account to satisfy the definition of ''exempt account'' in paragraph (a)(13) to qualify for the reduced margin on such options.

Portfolio Margin

FINRA proposed to eliminate the monitoring requirement contained in FINRA Rule 4210(g)(1)(D) that stress testing of accounts must be done in the aggregate for portfolio margin accounts. The rule would continue to require firms to stress test portfolio margin accounts on an individual account basis. FINRA has been reviewing the portfolio margin program and believes that the stress testing on an individual account basis is sufficient from a risk perspective.

Technical Changes

Finally, the proposed rule change would amend FINRA Rule 4210 to make non-substantive technical and stylistic changes to encourage consistency throughout the rule and enhance readability.

FINRA stated that it would announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The effective date would be no later than 90 days following publication of the *Regulatory Notice* announcing Commission approval.

III. Summary of Comment Received, FINRA's Response and Description of Amendment No. 1

As stated above, the Commission received one comment letter in response to the proposed rule change generally supporting the proposal, particularly the modernization of the treatment of option spread strategies.[27] The commenter stated, however, that the consequences of the proposed changes to the margin requirements for ''non-margin eligible, non-equity securities'' have not been fully considered and recommended that FINRA investigate the extent to which FINRA members presently extend credit against these securities and withdraw or modify this element of the proposed amendments. The commenter stated that the securities that would become unmarginable would include any non-investment grade debt securities that are not registered under Section 5 of the Securities Act of 1933. The commenter explained that since the high-yield debt market is to a great extent an institutional market, where it is usual for debt to trade under Rule 144A, the proposal would cut off credit to a substantial part of the high yield debt market, and could have significant adverse effects on FINRA members, investors and issuers.

The commenter also recommended technical changes to the proposal, including: (1) That the 100% maintenance margin requirement on non-margin eligible equity securities be

[20] Paragraph (e)(2)(C) provides the maintenance margin requirements for (1) investment grade debt securities and (2) all other listed non-equity securities and all other margin eligible non-equity securities as defined in FINRA Rule 4210(a)(16).

[21] Non-margin eligible non-equity securities held ''long'' would be excluded from such margin treatment, and the maintenance margin requirement for such securities would be 100% of the current market value.

[22] *See also* FINRA Rule 4210(e)(2)(A), which establishes the maintenance margin requirements for long or short positions on obligations issued or guaranteed by the United States or obligations that are highly rated foreign sovereign debt securities.

[23] *See* FINRA Rule 4210(a)(4) for the definition of ''designated account.''

[24] *See* FINRA Rule 4210(e)(2)(F), (G) and (H).

[25] *See* Securities Exchange Act Release No. 48407 (August 25, 2003), 68 FR 52259 (September 2, 2003) (Order Approving File No. SR–NASD–00–08) (''NASD Order''); Securities Exchange Act Release No. 48365 (August 19, 2003), 68 FR 51314 (August 26, 2003) (Order Approving File No. SR–NYSE–98–14); and Securities Exchange Act Release No. 48133 (July 7, 2003), 68 FR 41672 (July 14, 2003) (Notice of Filing of File No. SR–NYSE–98–14) (''NYSE Notice of Filing'').

[26] *See* note 20, page 52261 of the NASD Order and page 41676 of NYSE Notice of Filing.

[27] Aman Letter, *supra* note 4.

set forth in a new subsection to FINRA Rule 4210; (2) that the margin requirements for certain non-equity securities be moved from FINRA Rule 4210(e) to FINRA Rule 4210(c); and (3) that FINRA define ''non-margin eligible, non-equity security.''

In response to the comment regarding the 100% maintenance margin requirement for non-margin eligible, non-equity securities, FINRA proposes to further analyze the impact of this proposed change on member firms and the market. Accordingly, Amendment No. 1 would eliminate the requirements applicable to non-margin eligible, non-equity securities from the proposed rule. To effectuate this change, FINRA proposes to delete the exclusion of non-equity securities from FINRA Rule 4210(c)(1) as originally proposed in the Notice. In addition, FINRA proposes to delete in FINRA Rule 4210(c)(4) the reference to non-margin eligible, non-equity securities as originally proposed in the Notice. The margin requirement for non-equities held ''long'' in an account would be margined as provided in FINRA Rule 4210(c)(1) unless they otherwise meet an exception for the type of non-equity security provided in FINRA Rule 4210(e).

In response to the technical comments in the Aman Letter, FINRA agrees that amending the proposed rule further to clarify the 100% maintenance margin requirement for non-margin eligible equity securities held ''long'' would be beneficial. In Amendment No. 1, FINRA proposes to add a new subparagraph (6) to FINRA Rule 4210(c) to effectuate this clarification. Also in response to technical comments, with regard to the margin requirements for non-equity securities and the exceptions provided in FINRA Rule 4210(e), FINRA proposes in Amendment No. 1 to modify Rule 4210(c) by prefacing that the margin provisions are as stated except as set forth in Rule 4210(e) as well as Rule 4210(f) (the margin requirements for options and warrants) and Rule 4210(g) (portfolio margin requirements).

In response to the comment that FINRA define ''non-margin eligible, non-equity securities,'' Amendment No. 1 would delete that term in FINRA Rule 4210(c)(4) in light of the elimination of the proposal to amend the margin requirements for such securities. Finally, and unrelated to any specific comment, Amendment No. 1 would make certain clarifying changes to Rule 4210(c) to eliminate the reference to ''plus'' as the maintenance margin provisions are not additive.

IV. Discussion and Commission's Findings

After careful review of the proposed rule change, the comment received, and Amendment No. 1, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.[28] In particular, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Act, which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.[29] More specifically, the Commission believes that the proposed rule change modernizes the treatment of option spread strategies while maintaining margin requirements that are commensurate with the risk of those strategies. Further, because it is consistent with changes being approved to Chicago Board Options Exchange, Incorporated, Rule 12.3,[30] the proposed rule change will provide for a more uniform application of margin requirements for similar products. The Commission believes that FINRA has adequately responded to the concerns raised in the Aman Letter by deleting the 100% maintenance margin requirement for non-margin eligible, non-equity securities until such time as FINRA has had additional opportunity to more fully evaluate the effects of such a change. In addition, the Commission believes that FINRA has adequately responded to the technical comments by making the changes described in Amendment No. 1.

V. Accelerated Approval

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[31] for approving the proposed rule change, as modified by Amendment No. 1, prior to the 30th day after publication of Amendment No. 1 in the **Federal Register**. In response to certain concerns raised in the Aman Letter, FINRA proposed in Amendment No. 1 to eliminate the increase in the margin requirement applicable to long positions in non-margin eligible, non-equity securities to 100%. In Amendment No. 1, FINRA also proposed other technical changes responsive to the comments made in the Aman Letter. Accordingly, the Commission finds that good cause exists to approve the proposal, as modified by Amendment No. 1, 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. 1 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–2012–024 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–2012–024. 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

[28] In approving this rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[29] 15 U.S.C. 78*o*–3(b)(6).

[30] *See* Securities Exchange Act Release No. 67752 (Aug. 29, 2012) (SR–CBOE–2012–043) (order approving changes to CBOE Rule 12.3 relating to spread margin rules).

[31] 15 U.S.C. 78s(b)(2).

submissions should refer to File Number SR–FINRA–2012–024 and should be submitted on or before September 26, 2012.

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[32] that the proposed rule change (SR–FINRA–2012–024), as modified by Amendment No. 1, be and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21761 Filed 9–4–12; 8:45 am]

BILLING CODE 8011–01–P

[32] 15 U.S.C. 78s(b)(2).

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67750; File No. SR–NASDAQ–2012–098]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change Relating to the Listing and Trading of Shares of the WisdomTree Global Corporate Bond Fund of the WisdomTree Trust

August 29, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 15, 2012, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to list and trade the shares of the WisdomTree Global Corporate Bond Fund (''Fund'') of the WisdomTree Trust (''Trust'') under Nasdaq Rule 5735 (''Managed Fund Shares''). The shares of the Fund are collectively referred to herein as the ''Shares.''

The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com/,* at Nasdaq's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change. The text of these statements may be examined at the places specified in Item IV below, and is set forth in Sections A, B, and C below.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares of the Fund under Nasdaq Rule 5735, which governs the listing and trading of Managed Fund Shares on the Exchange.[3] The Fund will be an actively managed exchange traded fund (''ETF''). The Shares will be offered by the Trust, which was established as a Delaware statutory trust on December 15, 2005. The Fund is registered with the Commission as an investment company and has filed a registration statement on Form N–1A (''Registration Statement'') with the Commission.[4]

Description of the Shares and the Fund

WisdomTree Asset Management, Inc. (''WisdomTree Asset Management'') is the investment adviser (''Adviser'') to the Fund.[5] Western Asset Management Company serves as sub-adviser for the Fund (''Sub-Adviser'').[6] The Bank of New York Mellon is the administrator, custodian, and transfer agent for the Trust. ALPS Distributors, Inc. (''Distributor'') serves as the distributor for the Trust.[7]

Paragraph (g) of Rule 5735 provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[8] In addition,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission approved Nasdaq Rule 5735 in Securities Exchange Act Release No. 57962 (June 13, 2008) 73 FR 35175 (June 20, 2008) (SR–NASDAQ–2008–039). The Fund would not be the first actively-managed fund listed on the Exchange. *See* Securities Exchange Act Release No. 66175 (February 29, 2012), 77 FR 13379 (March 6, 2012) (SR–NASDAQ–2012–004) (order approving listing and trading of WisdomTree Emerging Markets Corporate Bond Fund). Additionally, the Commission has previously approved the listing and trading of a number of actively managed WisdomTree funds on NYSE Arca, Inc. pursuant to Rule 8.600 of that exchange. *See, e.g.,* Securities Exchange Act Release Nos. 64643 (June 10, 2011), 76 FR 35062 (June 15, 2011) (SR–NYSEArca–2011–21) (order approving listing and trading of WisdomTree Global Real Return Fund); 65458 (September 30, 2011), 76 FR 62112 (October 6, 2011) (SR–NYSE–Arca–2011–54) (order approving listing and trading of WisdomTree Dreyfus Australia and New Zealand Debt Fund); 66342 (February 7, 2012), 77 FR 7623 (February 13, 2012) (SR–NYSEArca–2011–82) (order approving listing and trading of WisdomTree Emerging Markets Inflation Protection Bond Fund); and 67054 (May 24, 2012), 77 FR 32161 (May 31, 2012) (SR–NYSEArca–2012–25) (order approving listing and trading of WisdomTree Brazil Bond Fund). The Exchange believes the proposed rule change raises no significant issues not previously addressed in those prior Commission orders.

[4] *See* Post-Effective Amendment No. 56 to Registration Statement on Form N–1A for the Trust, dated July 1, 2011 (File Nos. 333–132380 and 811–21864). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement.

[5] WisdomTree Investments, Inc. (''WisdomTree Investments'') is the parent company of WisdomTree Asset Management.

[6] The Sub-Adviser is responsible for day-to-day management of the Fund and, as such, typically makes all decisions with respect to portfolio holdings. The Adviser has ongoing oversight responsibility.

[7] The Commission has issued an order granting certain exemptive relief to the Trust under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act''). *See* Investment Company Act Release No. 28171 [sic] (October 27, 2008) (File No. 812–13458). In compliance with NASDAQ Rule 5735(b)(5), which applies to Managed Fund Shares based on an international or global portfolio, the Trust's application for exemptive relief under the 1940 Act states that the Fund will comply with the federal securities laws in accepting securities for deposits and satisfying redemptions with redemption securities, including that the securities accepted for deposits and the securities used to satisfy redemption requests are sold in transactions that would be exempt from registration under the Securities Act of 1933 (15 U.S.C. 77a).

[8] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser and Sub-Adviser and their related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual

paragraph (g) further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the open-end fund's portfolio. Rule 5735(g) is similar to Nasdaq Rule 5705(b)(5)(A)(i); however, paragraph (g) in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. Neither WisdomTree Asset Management nor Western Asset Management Company is affiliated with any broker-dealer. In the event (a) the Adviser or the Sub-Adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes affiliated with a broker-dealer, it will implement a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding such portfolio.

WisdomTree Global Corporate Bond Fund

According to the Registration Statement, the Fund seeks to provide a high level of total return consisting of both income and capital appreciation. To achieve its objective, the Fund will invest in debt securities of corporations that are domiciled or economically tied to countries throughout the world.

The Fund intends to qualify each year as a regulated investment company (''RIC'') under Subchapter M of the Internal Revenue Code of 1986, as amended.[9] The Fund will invest its assets, and otherwise conduct its operations, in a manner that is intended to satisfy the qualifying income, diversification, and distribution requirements necessary to establish and maintain RIC qualification under Subchapter M. The Subchapter M diversification tests generally require that (1) the Fund invest no more than 25% of its total assets in securities (other than securities of the U.S. government or other RICs) of any one issuer or two or more issuers that are controlled by the Fund and that are engaged in the same, similar, or related trades or businesses, and (2) at least 50% of the Fund's total assets consist of cash and cash items, U.S. government securities, securities of other RICs, and other securities, with investments in such other securities limited in respect of any one issuer to an amount not greater than 5% of the value of the Fund's total assets and 10% of the outstanding voting securities of such issuer.

In addition to satisfying the above referenced RIC diversification requirements, no portfolio security held by the Fund (other than U.S. government securities) will represent more than 30% of the weight of the Fund's portfolio, and the five highest weighted portfolio securities of the Fund (other than U.S. government securities and/or non-U.S. government securities) will not in the aggregate account for more than 65% of the weight of the Fund's portfolio. For these purposes, the Fund may treat repurchase agreements collateralized by U.S. government securities or non-U.S. government securities as U.S. or non-U.S. government securities, as applicable.

Global Corporate Debt

The Fund intends to achieve its investment objectives through direct and indirect investments in Global Corporate Debt. For these purposes, Global Corporate Debt includes fixed-income securities, such as bonds, notes, or other debt obligations, including loan participation notes (''LPNs''),[10] as well as other debt instruments denominated in U.S. dollars or local currencies. Global Corporate Debt also includes fixed income securities or debt obligations that are issued by companies or agencies that may receive financial support or backing from local government. Fixed income securities include Money Market Securities as defined below. Fixed income securities do not include derivatives.

Under normal circumstances,[11] the Fund will invest at least 80% of its net assets in Global Corporate Debt that are fixed income securities.

The Fund intends to provide exposure across geographic regions and countries world-wide. The Fund intends to invest in Global Corporate Debt originating in the following regions/countries: North America, South America, Asia, Australia and New Zealand, Latin America, Europe, Africa, and the Middle East. The Fund intends to invest primarily in countries with developed markets in corporate debt. The Fund intends to invest up to 25% of its assets in emerging market countries, though this may change from time to time in response to economic events and changes to the credit ratings of the Global Corporate Debt of such countries.[12] The Fund's credit exposures are consistently monitored from a risk perspective, and may be modified, reduced, or eliminated. The Fund's exposure to any single issuer generally will be limited to 10% of the Fund's assets. The percentage of the Fund's assets in a specific region, country, or issuer will change from time to time. The Fund's exposure to any one country (other than the United States) generally will be limited to 30% of the Fund's assets, though this percentage may change from time to time in response to economic events and changes to the credit ratings of the Global Corporate Debt of such countries.

The universe of Global Corporate Debt currently includes securities that are rated ''investment grade'' as well as ''non-investment grade.''[13] The Fund intends to provide a broad exposure to Global Corporate Debt and therefore will invest in both investment grade and

(who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[9] 26 U.S.C. 851.

[10] The Fund may invest in LPNs with a minimum outstanding principal amount of $200 million that the Adviser or Sub-Adviser deems to be liquid.

[11] The term ''under normal circumstances'' includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

[12] According to the Adviser, while there is no universally accepted definition of what constitutes an ''emerging market,'' in general, emerging market countries are characterized by developing commercial and financial infrastructure with significant potential for economic growth and increased capital market participation by foreign investors. The Adviser and Sub-Adviser look at a variety of commonly-used factors when determining whether a country is an ''emerging'' market. In general, the Adviser and Sub-Adviser consider a country to be an emerging market if:

(1) It is either (a) classified by the World Bank in the lower middle or upper middle income designation for one of the past 5 years (*i.e.,* per capita gross national product of less than U.S. $9,385), (b) has not been a member of OECD for the past five years or (c) classified by the World Bank as high income and a member in OECD in each of the last five years, but with a currency that has been primarily traded on a non-delivered basis by offshore investors (*e.g.,* Korea and Taiwan); and

(2) the country's debt market is considered relatively accessible by foreign investors in terms of capital flow and settlement considerations.

This definition could be expanded or exceptions made depending on the evolution of market and economic conditions.

[13] According to the Adviser, ''investment grade'' means securities rated in the Baa/BBB categories or above by one or more nationally recognized securities rating organizations (''NRSROs''). If a security is rated by multiple NRSROs and receives different ratings, the Fund will treat the security as being rated in the highest rating category received from an NRSRO. Rating categories may include sub-categories or gradations indicating relative standing.

non-investment grade securities. The Fund intends to have 55% or more of its assets invested in investment grade securities, though this percentage may change from time to time in response to economic events and changes to the credit ratings of such issuers. Within the non-investment grade category, some issuers and instruments are considered to be of lower credit quality and at higher risk of default. In order to limit its exposure to these more speculative credits, the Fund will not invest more than 15% of its assets in securities rated B or below by Moody's, or equivalently rated by S&P or Fitch. The Fund does not intend to invest in unrated securities. However, it may do so to a limited extent, such as where a rated security becomes unrated, if such security is determined by the Adviser and Sub-Adviser to be of comparable quality. In determining whether a security is of ''comparable quality,'' the Adviser and Sub-Adviser will consider, for example, whether the issuer of the security has issued other rated securities.

The Fund will invest only in corporate bonds that the Adviser or Sub-Adviser deems to be sufficiently liquid. The Fund will only buy performing debt securities and not distressed debt. Generally, a corporate bond must have $200 million or more par amount outstanding and significant par value traded to be considered as an eligible investment. Economic and other conditions may, from time to time, lead to a decrease in the average par amount outstanding of bond issuances. Therefore, although the Fund does not intend to do so, the Fund may invest up to 5% of its net assets in corporate bonds with less than $200 million par amount outstanding if (1) the Adviser or Sub-Adviser deems such security to be sufficiently liquid based on its analysis of the market for such security (based on, for example, broker-dealer quotations or its analysis of the trading history of the security or the trading history of other securities issued by the issuer), (2) such investment is deemed by the Adviser or Sub-Adviser to be in the best interest of the Fund, and (3) such investment is deemed consistent with the Fund's goal of providing exposure to a broad range of countries and issuers.

The Fund may invest in Global Corporate Debt with effective or final maturities of any length. According to the Registration Statement, the Fund will seek to keep the average effective duration of its portfolio between 2 and 10 years under normal market conditions. Effective duration is an indication of an investment's interest rate risk or how sensitive an investment or a fund is to changes in interest rates. Generally, a fund or instrument with a longer effective duration is more sensitive to interest rate fluctuations, and, therefore, more volatile, than a fund with a shorter effective duration. The Fund's actual portfolio duration may be longer or shorter depending on market conditions.

The Fund intends to invest in Global Corporate Debt of at least 13 non-affiliated issuers. The Fund will not concentrate 25% or more of the value of its total assets (taken at market value at the time of each investment) in any one industry, as that term is used in the 1940 Act (except that this restriction does not apply to obligations issued by the U.S. government or their respective agencies and instrumentalities or government-sponsored enterprises).[14]

Money Market Securities

The Fund intends to invest in Money Market Securities in order to help manage cash flows in and out of the Fund, such as in connection with payment of dividends or expenses, to satisfy margin requirements, to provide collateral, or to otherwise back investments in derivative instruments. Under normal circumstances,[15] the Fund may invest up to 25% of its net assets in Money Market Securities, although it may exceed this amount where the Adviser or Sub-Adviser deems such investment to be necessary or advisable, due to market conditions. For these purposes ''Money Market Securities'' include: short-term, high quality obligations issued or guaranteed by the U.S. Treasury or the agencies or instrumentalities of the U.S. government; short-term, high quality securities issued or guaranteed by non-U.S. governments, agencies and instrumentalities; repurchase agreements backed by U.S. government and non-U.S. government securities; money market mutual funds; and deposit and other obligations of U.S. and non-U.S. banks and financial institutions. All Money Market Securities acquired by the Fund will be rated investment grade,[16] except that the Fund may invest in unrated Money Market Securities that are deemed by the Adviser or Sub-Adviser to be of comparable quality to money market securities rated investment grade.

The Fund Reserves the right to invest in U.S. government securities, money market instruments, and cash, without limitation, as determined by the Adviser or Sub-Adviser in response to adverse market, economic, political, or other conditions. The Fund may also ''hedge'' or minimize its exposure to one or more foreign currencies in response to such conditions. In the event the Fund engages in these temporary defensive strategies that are inconsistent with its investment strategies, the Fund's ability to achieve its investment objectives may be limited.

Derivative Instruments and Other Investments

The Fund may use derivative instruments that are fully-collateralized as part of its investment strategies. Examples of derivative instruments include forward currency contracts,[17] interest rate swaps,[18] total return swaps,[19] credit linked notes,[20] and combinations of investments that provide similar exposure to local currency debt, such as investment in U.S. dollar denominated bonds combined with forward currency positions or swaps.[21] Forward currency contracts and swap positions can be incorporated with bonds denominated in non-U.S. currencies to hedge bond exposures back into U.S. dollars. Conversely, forward currency contracts and swap positions can be implemented in combination with U.S. dollar denominated bonds to create local currency bond exposures. Additionally, the Fund's use of forward contracts and swaps will be combined with investments in short-term, high quality U.S. money market instruments in a manner designed to provide exposure to

[14] *See* Form N–1A, Item 9. The Commission has taken the position that a fund is concentrated if it invests more than 25% of the value of its total assets in any one industry. *See, e.g.,* Investment Company Act Release No. 9011 (Oct. 30, 1975), 40 FR 54241 (November 21, 1975).

[15] *See* note 11, *supra.*

[16] The term ''investment grade,'' for purposes of Money Market Securities only, is intended to mean securities rated A1 or A2 by one or more NRSROs.

[17] A forward currency contract is an agreement to buy or sell a specific currency on a future date at a price set at the time of the contract.

[18] An interest rate swap involves the exchange of a floating interest rate payment for a fixed interest rate payment.

[19] A total return swap is an agreement between two parties in which one party agrees to make payments of the total return of a reference asset in return for payments equal to a rate of interest on another reference asset.

[20] A credit linked note is a type of structured note whose value is linked to an underlying reference asset or entity. Credit linked notes typically provide periodic payments of interest as well as payment of principal upon maturity.

[21] To the extent practicable, the Fund will invest in swaps cleared through the facilities of a centralized clearing house. The Fund may also invest in Money Market Securities that may serve as collateral for the futures contracts and swap agreements.

similar investments in local currency deposits.[22]

The Fund expects that no more than 20% of the value of the Fund's net assets will be invested in derivative instruments. Such investments will be consistent with the Fund's investment objective and will not be used to enhance leverage. For example, the Fund may engage in swap transactions that provide exposure to corporate debt or interest rates. The Fund also may buy or sell listed currency futures contracts.[23]

With respect to certain kinds of derivative transactions entered into by the Fund that involve obligations to make future payments to third parties, including, but not limited to, futures and forward contracts, swap contracts, the purchase of securities on a when-issued or delayed delivery basis, or reverse repurchase agreements, the Fund, in accordance with applicable federal securities laws, rules, and interpretations thereof, will ''set aside'' liquid assets, or engage in other measures to ''cover'' open positions with respect to such transactions.[24]

The Fund may engage in foreign currency transactions, and may invest directly in foreign currencies in the form of bank and financial institution deposits, and certificates of deposit denominated in a specified non-U.S. currency. The Fund may enter into forward currency contracts in order to ''lock in'' the exchange rate between the currency it will deliver and the currency it will receive for the duration of the contract.[25]

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid securities (calculated at the time of investment), including (1) Rule 144A securities, and (2) loan interests (such as loan participations and assignments, but not including LPNs). The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid securities. Illiquid securities include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.[26]

The Fund will not invest in any non-U.S. equity securities.

The Shares

The Fund will issue and redeem Shares on a continuous basis at net asset value (''NAV'')[27] only in large blocks of Shares (''Creation Units'') in transactions with Authorized Participants. Creation Units generally will consist of 100,000 Shares, though this may change from time to time. Creation Units are not expected to consist of less than 50,000 Shares. The Fund will issue and redeem Creation Units in exchange for a portfolio of Global Corporate Debt and other instruments closely approximating the holdings of the Fund or a designated basket of non-U.S. currency and/or an amount of U.S. cash. Once created, Shares of the Fund trade on the secondary market in amounts less than a Creation Unit.

Creations and redemptions must be made by an Authorized Participant or through a firm that is either a member of the National Securities Clearing Corporation or a Depository Trust Company participant, and in each case, must have executed an agreement with the Distributor with respect to creations and redemptions of Creation Unit aggregations.

Additional information regarding the Shares and the Fund, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, distributions, and taxes is included in the Registration Statement.

Availability of Information

The Fund's Web site (*www.wisdomtree.com*), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Web site will include additional quantitative information updated on a daily basis, including, for the Fund: (1) The prior business day's reported NAV, mid-point of the bid/ask spread at the time of calculation of such NAV (''Bid/Ask Price''),[28] and a calculation of the premium and discount of the Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the

[22] The Adviser or Sub-Adviser will also attempt to mitigate the Fund's credit risk by transacting only with large, well-capitalized institutions using measures designed to determine the creditworthiness of the counterparty. The Adviser or Sub-Adviser will take various steps to limit counterparty credit risk which will be described in the Registration Statement. The Fund will enter into swap agreements only with financial institutions that meet certain credit quality standards and monitoring policies. The Fund may also use various techniques to minimize credit risk, including early termination or reset and payment, using different counterparties, and limiting the net amount due from any individual counterparty. The Fund generally will collateralize swap agreements with cash and/or certain securities. Such collateral will generally be held for the benefit of the counterparty in a segregated tri-party account at the custodian to protect the counterparty against non-payment by the Fund. In the event of a default by the counterparty, and the Fund is owed money in the swap transaction, the Fund will seek withdrawal of the collateral from the segregated account and may incur certain costs exercising its right with respect to the collateral.

[23] The exchange-listed futures contracts in which the Fund may invest will be listed on exchanges in the U.S., London, Hong Kong, or Singapore. Each of the United Kingdom's primary financial markets regulator, the Financial Services Authority, Hong Kong's primary financial markets regulator, the Securities and Futures Commission, and Singapore's primary financial markets regulator, the Monetary Authority of Singapore, are signatories to the International Organization of Securities Commissions (''IOSCO'') Multilateral Memorandum of Understanding (''MMOU''), which is a multi-party information sharing arrangement among financial regulators. Both the Commission and the Commodity Futures Trading Commission are signatories to the IOSCO MMOU.

[24] *See* 15 U.S.C. 80a–18; Investment Company Act Release No. 10666 (April 18, 1979), 44 FR 25128 (April 27, 1979); *Dreyfus Strategic Investing,* Commission No-Action Letter (June 22, 1987); *Merrill Lynch Asset Management, L.P.,* Commission No-Action Letter (July 2, 1996).

[25] The Fund will invest only in currencies, and instruments that provide exposure to such currencies, that have significant foreign exchange turnover and are included in the Bank for International Settlements Triennial Central Bank Survey, December 2010 (''BIS Survey''). The Fund may invest in currencies, and instruments that provide exposure to such currencies, selected from the top 40 currencies (as measured by percentage share of average daily turnover for the applicable month and year) included in the BIS Survey.

[26] The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), at footnote 34. *See also* Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding ''Restricted Securities''); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act) and Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

[27] The NAV of the Fund's Shares generally is calculated once daily Monday through Friday as of the close of regular trading on the New York Stock Exchange, generally 4 p.m. Eastern time (''NAV Calculation Time''). NAV per Share is calculated by dividing the Fund's net assets by the number of Fund Shares outstanding. For more information regarding the valuation of Fund investments in calculating the Fund's NAV, *see* the Registration Statement.

[28] The Bid/Ask Price of the Fund will be determined using the mid-point of the highest bid and the lowest offer on the Exchange as of the time of calculation of such Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund and its service providers.

NAV, within appropriate ranges, for each of the four previous calendar quarters. On each business day, before commencement of trading in Shares in the Regular Market Session [29] on the Exchange, the Trust will disclose on its Web site the identities and quantities of the portfolio of securities and other assets (''Disclosed Portfolio'') held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the business day.[30] The Disclosed Portfolio will include, as applicable, the names, quantity, percentage weighting, and market value of fixed income securities and other assets held by the Fund, and the characteristics of such assets. The Web site and information will be publicly available at no charge.

In addition, for the Fund, an estimated value, defined in Rule 5735 as the ''Intraday Indicative Value,'' that reflects an estimated intraday value of the Fund's portfolio, will be disseminated. Moreover, the Intraday Indicative Value, available on the NASDAQ OMX Information LLC proprietary index data service,[31] will be based upon the current value for the components of the Disclosed Portfolio and will be updated and widely disseminated by one or more major market data vendors at least every 15 seconds during the Regular Market Session. In addition, during hours when the markets for local debt in the Fund's portfolio are closed, the Intraday Indicative Value will be updated at least every 15 seconds during the Regular Market Session to reflect currency exchange fluctuations.

The dissemination of the Intraday Indicative Value, together with the Disclosed Portfolio, will allow investors to determine the value of the underlying portfolio of the Fund on a daily basis and to provide a close estimate of that value throughout the trading day.

Intra-day, executable price quotations on Global Corporate Debt, as well as derivative instruments, are available from major broker-dealer firms. Intra-day price information is available through subscription services, such as Bloomberg and Thomson Reuters, which can be accessed by Authorized Participants and other investors.

Information regarding market price and volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last-sale information for the Shares will be available via UTP Level 1, as well as Nasdaq proprietary quote and trade services.

Initial and Continued Listing

The Shares will be subject to Rule 5735, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares. The Exchange represents that, for initial and/or continued listing, the Fund must be in compliance with Rule 10A–3 under the Act.[32] A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. Nasdaq will halt trading in the Shares under the conditions specified in Nasdaq Rules 4120 and 4121; for example, the Shares of the Fund will be halted if the ''circuit breaker'' parameters in Nasdaq Rule 4120(a)(11) are reached. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments comprising the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 5735(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted.

Trading Rules

Nasdaq deems the Shares to be equity securities, thus rendering trading in the Shares subject to Nasdaq's existing rules governing the trading of equity securities. Nasdaq will allow trading in the Shares from 7 a.m. until 8 p.m. Eastern time. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in Nasdaq Rule 5735(b)(3), the minimum price variation for quoting and entry of orders in Managed Fund Shares traded on the Exchange is $0.01.

Surveillance

Nasdaq believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on Nasdaq during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through Nasdaq will be subject to FINRA's surveillance procedures for derivative products, including Managed Fund Shares.[33] The Exchange may obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges who are members or affiliates of the ISG.[34] The Exchange prohibits the distribution of material, non-public information by its employees.

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) Nasdaq Rule 2310, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (3) how information regarding the Intraday Indicative Value is disseminated; (4) the risks involved in trading the Shares during the Pre-Market and Post-Market Sessions when an updated Intraday

[29] *See* Nasdaq Rule 4120(b)(4) (describing the three trading sessions on the Exchange: (1) Pre-Market Session from 7 a.m. to 9:30 a.m. Eastern time; (2) Regular Market Session from 9:30 a.m. to 4 p.m. or 4:15 p.m. Eastern time; and (3) Post-Market Session from 4 p.m. or 4:15 p.m. to 8 p.m. Eastern time).

[30] Under accounting procedures to be followed by the Fund, trades made on the prior business day (''T'') will be booked and reflected in NAV on the current business day (''T+1''). Notwithstanding the foregoing, portfolio trades that are executed prior to the opening of the Exchange on any business day may be booked and reflected in NAV on such business day. Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

[31] Currently, the NASDAQ OMX Global Index Data Service (''GIDS'') is the NASDAQ OMX global index data feed service, offering real-time updates, daily summary messages, and access to widely followed indexes and ETFs. GIDS provides investment professionals with the daily and historical information needed to track or trade NASDAQ OMX indexes, listed ETFs, or third-party partner indexes and ETFs.

[32] *See* 17 CFR 240.10A–3.

[33] FINRA surveils trading on Nasdaq pursuant to a regulatory services agreement. Nasdaq is responsible for FINRA's performance under this regulatory services agreement.

[34] For a list of the current members and affiliate members of ISG, *see www.isgportal.com. See supra* note 23.

Indicative Value will not be calculated or publicly disseminated; (5) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Fund. Members purchasing Shares from the Fund for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act.

Additionally, the Information Circular will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Information Circular will also disclose the trading hours of the Shares of the Fund and the applicable NAV Calculation Time for the Shares. The Information Circular will disclose that information about the Shares of the Fund will be publicly available on the Fund's Web site.

2. Statutory Basis

Nasdaq believes that the proposal is consistent with Section 6(b) of the Act [35] in general and Section 6(b)(5) of the Act [36] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Nasdaq Rule 5735. The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on Nasdaq during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Neither WisdomTree Asset Management nor Western Asset Management Company is affiliated with any broker-dealer. In the event (a) the Adviser or the Sub-Adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes affiliated with a broker-dealer, they will implement a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to a portfolio, and will be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding such portfolio. The Exchange may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. Under normal circumstances, the Fund will invest at least 80% of its assets in fixed income securities. The Fund's exposure to any single issuer generally will be limited to 10% of the Fund's assets. The Fund's exposure to any single country (other than the United States) generally will be limited to 30% of the Fund's assets. The Fund expects to have 55% or more of its assets invested in investment grade securities, though this percentage may change from time to time in response to economic events and changes to the credit ratings of such issuers. The Fund will not invest more than 15% of its assets in securities rated B or below by Moody's, or equivalently rated by S&P or Fitch. The Fund will not invest in unrated securities. The Fund will invest only in corporate bonds that the Adviser or Sub-Adviser deems to be sufficiently liquid and, generally, a corporate bond must have $200 million or more par amount outstanding and significant par value traded to be considered as an eligible investment. The Fund intends to invest in Global Corporate Debt of at least 13 non-affiliated issuers. The Fund intends to invest up to 25% of its assets in emerging market countries, though this may change from time to time in response to economic events and changes to the credit ratings of the Global Corporate Debt of such countries. The Fund expects that no more than 20% of the value of the Fund's net assets will be invested in derivative instruments. Such investments will be consistent with the Fund's investment objective. Such investments also will not be used to enhance leverage. Under normal circumstances, the Fund also may invest up to 25% of its net assets in Money Market Securities, although it may exceed this amount where the Adviser or Sub-Adviser deems such investment to be necessary or advisable, due to market conditions. Also, the Fund may hold up to an aggregate amount of 15% of its net assets in illiquid securities, Rule 144A securities and loan interests (such as loan participations and assignments, but not including LPNs). The Fund will not invest in any non-U.S. equity securities. Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. The Fund's portfolio holdings will be disclosed on its Web site daily after the close of trading on the Exchange and prior to the opening of trading on the Exchange the following day. Moreover, the Intraday Indicative Value, available on the NASDAQ OMX Information LLC proprietary index data service will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Regular Market Session. On each business day, before commencement of trading in Shares in the Regular Market Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day. Information regarding market price and trading volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last-sale information for the Shares will be available via UTP Level 1, as well as Nasdaq proprietary quote and trade services. Intra-day, executable price quotations on Global Corporate Debt, as well as derivative instruments are available from major broker-dealer firms. Intra-day price information is available through subscription services, such as Bloomberg and Thomson Reuters, which can be accessed by authorized participants and other investors.

The Web site for the Fund will include a form of the prospectus for the Fund, and additional data relating to NAV and other applicable quantitative information. Trading in Shares of the Fund will be halted if the circuit breaker parameters in Nasdaq Rule 4120(a)(11) have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in

[35] 15 U.S.C. 78f(b).

[36] 15 U.S.C. 78f(b)(5).

the Shares inadvisable, and trading in the Shares will be subject to Nasdaq Rule 5735(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last-sale information for the Shares.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last-sale information for the Shares.

For the above reasons, Nasdaq believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change 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–NASDAQ–2012–098 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2012–098. 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 at *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 the filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2012–098 and should be submitted on or before September 26, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21815 Filed 9–4–12; 8:45 am]

BILLING CODE 8011–01–P

[37] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2012–0046]

Social Security Acquiescence Ruling (AR) 12–1(8); Correction; Petersen v. Astrue, 633 F.3d 633 (8th Cir. 2011): Whether a National Guard Technician Who Worked in Noncovered Employment is Exempt From the Windfall Elimination Provision (WEP)—Title II of the Social Security Act

AGENCY: Social Security Administration.

ACTION: Notice of Social Security Acquiescence Ruling; Correction.

SUMMARY: The Social Security Administration published a document in the **Federal Register** of August 27, 2012, in FR Doc. 2012–21065, in the first column, correct the ''title'' to read:

Social Security Acquiescence Ruling (AR) 12–1(8); Petersen v. Astrue, 633 F.3d 633 (8th Cir. 2011); Whether a National Guard Technician Who Worked in Noncovered Employment is Exempt From the Windfall Elimination Provision (WEP)—Title II of the Social Security Act.

Also, in the second column, correct the heading to read:

Acquiescence Ruling 12–1(8)

Paul Kryglik,

Director, Office of Regulations, Social Security Administration.

[FR Doc. 2012–21799 Filed 9–4–12; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 8013]

Culturally Significant Objects Imported for Exhibition Determinations: ''Becoming Van Gogh''

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 included in the exhibition ''Becoming Van Gogh,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Denver Art Museum, Denver, Colorado, from on or about October 21, 2012, until on or about January 20, 2013, 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: 202–632–6469). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: August 28, 2012.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2012–21884 Filed 9–4–12; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8010]

Culturally Significant Objects Imported for Exhibition Determinations: ''Sicily: Art and Invention Between Greece and Rome''

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 included in the exhibition ''Sicily: Art and Invention Between Greece and Rome,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The J. Paul Getty Museum in Los Angeles, California from on or about April 3, 2013, until on or about August 19, 2013; and then at the Cleveland Museum of Art in Cleveland, Ohio from September 29, 2013 to January 5, 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 Ona M. Hahs, 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: August 27, 2012.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2012–21862 Filed 9–4–12; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8011]

Culturally Significant Objects Imported for Exhibition Determinations: ''African Art, New York, and the Avant-Garde''

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 included in the exhibition ''African Art, New York, and the Avant-Garde,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art in New York, New York from on or about November 26, 2012, until on or about April 14, 2013, 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 Ona M. Hahs, 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: August 27, 2012.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2012–21858 Filed 9–4–12; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8012]

Culturally Significant Objects Imported for Exhibition Determinations: ''Manet: Portraying Life''

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 included in the exhibition ''Manet: Portraying Life,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Toledo Museum of Art in Toledo, Ohio from on or about October 4, 2012, until on or about January 1, 2013, 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 Ona M. Hahs, 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: August 28, 2012.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2012–21886 Filed 9–4–12; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8014]

Shipping Coordinating Committee; Notice of Committee Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting for the International Maritime Organization's Marine Environment Protection Committee (MEPC).

The meeting will be held at 9:30 a.m. on Friday, September 21, 2012, in Room 2501 of the United States Coast Guard Headquarters Building, 2100 Second Street SW., Washington, DC 20593. The primary purpose of the meeting is to prepare for the sixty-fourth session of the International Maritime Organization's Marine Environment Protection Committee (MEPC 64) to be held at the International Maritime Organization in London, United Kingdom from October 1st to 5th, 2012.

The primary matters to be considered include:

—Harmful aquatic organisms in ballast water;
—Recycling of ships;
—Air pollution and energy efficiency;
—Reduction of GHG emissions from ships;
—Consideration and adoption of amendments to mandatory instruments;
—Interpretation of, and amendments to, MARPOL and related instruments;
—Implementation of the OPRC Convention and the OPRC–HNS Protocol and relevant Conference resolutions;
—Identification and protection of Special Areas and Particularly Sensitive Sea Areas;
—Inadequacy of reception facilities;
—Reports of sub-committees;
—Work of other bodies;
—Status of conventions;
—Harmful anti-fouling systems for ships;
—Promotion of implementation and enforcement of MARPOL and related instruments;
—Technical co-operation activities for the protection of the marine environment;
—Role of the human element;
—Noise from commercial shipping and its adverse impacts on marine life;
—Work program of the Committee and subsidiary bodies;
—Application of the Committees' Guidelines;
—Election of the Chairman and Vice-Chairman for 2013;

Members of the public may attend this meeting up to the seating capacity of the room. To facilitate the building security process and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, Ms. Regina Bergner not later than September 11, 2012, 10 days prior to the meeting. Contact should be made by email at *Regina.R.Bergner@uscg.mil;* by phone at (202) 372–1431; or in writing to Ms. Regina Bergner, Commandant (CG–OES–3), U.S. Coast Guard Headquarters, 2100 2nd Street SW., STOP 7126, Washington, DC 20593–7126. Requests made after September 11, 2012 might not be able to be accommodated. Please note that due to security considerations, two valid government-issued photo identifications must be presented to gain entrance to the Headquarters building. The Headquarters building is accessible by taxi and privately owned conveyance (public transportation is not generally available). Public parking is available in the vicinity of the Headquarters building. Additional information regarding this and other IMO SHC public meetings may be found at: *www.uscg.mil/imo.* Hard copies of documents associated with the 64th Session of MEPC will be available at this meeting. To request further copies of documents please contact Ms. Regina Bergner using the contact information above.

Dated: August 29, 2012.

Brian W. Robinson,

Executive Secretary, Shipping Coordinating Committee.

[FR Doc. 2012–21881 Filed 9–4–12; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Research, Engineering and Development Advisory Committee

Pursuant to section 10(A)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. 2), notice is hereby given of a meeting of the FAA Research, Engineering and Development (R, E&D) Advisory Committee.

AGENCY: Federal Aviation Administration.

ACTION: Notice of Meeting.

NAME: Research, Engineering & Development Advisory Committee.

TIME AND DATE: September 26, 2012—9 a.m. to 4 p.m.

PLACE: JMA Solutions, 600 Maryland Avenue SW., Suite 400E, Washington, DC 20024.

PURPOSE: The meeting agenda will include receiving from the Committee guidance for FAA's research and development investments in the areas of air traffic services, airports, aircraft safety, human factors and environment and energy. Attendance is open to the interested public but seating is limited. Persons wishing to attend the meeting or obtain information should contact Gloria Dunderman at (202) 267–8937 of *gloria.dunderman@faa.gov.* Members of the public may present a written statement to the Committee at any time.

Issued in Washington, DC, on August 27, 2012.

Catherine A. Bigelow,

Manager, Research and Development Management Division.

[FR Doc. 2012–21546 Filed 9–4–12; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Seventh Meeting: RTCA NextGen Advisory Committee (NAC)

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

ACTION: Meeting Notice of RTCA NextGen Advisory Committee (NAC).

SUMMARY: The FAA is issuing this notice to advise the public of the seventh meeting of the RTCA NextGen Advisory Committee (NAC).

DATES: The meeting will be held October 4, 2012, from 9 a.m.–3 p.m.

ADDRESSES: The meeting will be held at the secured facilities at the United States Air Force (USAF), Wright-Patterson Air Force Base, Dayton, OH, 45433.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, Andy Cebula, 1150 18th Street NW., Suite 910, Washington, DC, 20036, or by telephone at (202) 330–0652/(202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the NextGen Advisory Committee Meeting. The agenda will include the following:

October, 4, 2012

Special Facility Access Instructions

The meeting is being held at the secured facilities of the United States Air Force (USAF),

Wright-Patterson AFB, OH. All members of the public are required to register in advance by contacting HQ Air Force Operations NextGen Lead Service Office via email at *NextGen@pentagon.af.mil* not later than September 28, 2012 and provide the following:

- U.S. Citizens without current/valid DoD-issued Identification in their possession must provide the following information:
  - Last name, First name (as it appears on your State Issued Drivers' License or ID)
  - State-issued drivers' license/State-issued ID Card Number and State of Issuance
  - Company
  - Phone number contact
- Non-U.S. Citizens must provide the following information:
  - Full Name as it appears on Passport
  - Country of Citizenship
  - Birthdate and Place of Birth (city and country)
  - Passport and Visa Numbers, I–94 Stamp and Expiration Date
  - Employer and Address—Identify whether U.S. or foreign owned
  - Phone number contact

Note: Attendees must arrive no later than 1 hour prior to the start of the meeting for identification and security screening at Wright-Patterson AFB, Gate 19B.

Agenda

- Opening of Meeting—Chairman Dave Barger, President and CEO JetBlue Airways
- Welcome and Facility Overview—Major General James Jones, NAC Meeting Host
- Official Statement of Designated Federal Official—The Honorable Michael Huerta, FAA Acting Administrator.
- Review and Approval of May 24, 2012 Meeting Summary
- Chairman's Report—Chairman Barger
- FAA Report—Mr. Huerta
- Review and Approve Recommendation for Submission to FAA NextGen Implementation Metrics—a recommendation for:
  - Executive-level set of metrics that capture an overall status of NextGen Implementation
  - Key City Pairs that can be used for NextGen Metrics
- Data Sources for Measuring NextGen Fuel Impact
  - A discussion of a preliminary report on a critical data source to track and analyze the impact of NextGen
- Non-Technical Barriers to NextGen Implementation
  - Open discussion of issues that will affect the FAA Tasking on Implementing Metroplex capabilities
- Environmental Issues Impacting NextGen Implementation
  - A background briefing by FAA Environmental Office on the Environmental review process for NextGen capabilities and the impacts on this process by the ''FAA Modernization and Reform Act of 2012,'' followed by an open discussion by the Committee.
- Anticipated Issues for NAC consideration and action at the next meeting, February 2013
- Other business
- Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on August 28, 2012.

David Sicard,

Manager, Business Operations Group, Federal Aviation Administration.

[FR Doc. 2012–21836 Filed 9–4–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2012–35]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATE: Comments on this petition must identify the petition docket number and must be received on or before September 25, 2012.

ADDRESSES: You may send comments identified by Docket Number FAA–2012–0606 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mark Forseth, ANM–113, (425) 227–2796, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356, or Frances Shaver, (202) 267–4059, Office of Rulemaking (ARM–200), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 30, 2012.

Lirio Liu,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2012–0606.

Petitioner: L–3 Communications Integrated System, L.P.

Sections of 14 CFR Affected: §§ 25.791(d) and 25.853(g).

Description of Relief Sought: The petitioner requests relief from the requirements that lavatories must have ''No-Smoking'' placards located on or adjacent to each side of the lavatory door and ashtrays outside lavatory doors on the Boeing model 747–8 airplanes designated for use as VVIP/Government/Head of State.

[FR Doc. 2012–21835 Filed 9–4–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2012–34]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 25, 2012.

ADDRESSES: You may send comments identified by Docket Number FAA–2012–0302 using any of the following methods:

- *Government-wide rulemaking web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mark Forseth, ANM–113, (425) 227–2796, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356, or Frances Shaver, (202) 267–4059, Office of Rulemaking (ARM–200), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 30, 2012.

Lirio Liu,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2012–0302

Petitioner: Embraer S.A.

Section of 14 CFR Affected: § 25.809(a)

Description of Relief Sought: The petitioner requests partial relief from requirements relating to the outside-viewing means on Type III overwing exits on the Embraer Model EMB–550 airplanes.

[FR Doc. 2012–21833 Filed 9–4–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Intent To Rule on Request To Release Airport Property at the El Paso International Airport, El Paso, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to release airport property.

SUMMARY: The FAA proposes to rule and invite public comment on the release of land at the El Paso International Airport.

DATES: Comments must be received on or before October 5, 2012.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Mr. Mike Nicely, Manager, Federal Aviation Administration, Southwest Region, Airports Division, Texas Airports Development Office, ASW–650, Fort Worth, Texas 76137–0650.

In addition, one copy of any comments submitted to the FAA must mailed or delivered to the FAA at the following: Ms. Monica Lombraña, Director of Aviation, El Paso International Airport, 6701 Convair Rd., EI Paso, Texas 79925–1091.

FOR FURTHER INFORMATION CONTACT: Mr. Guillermo Y. Villalobos, Program Manager, Federal Aviation Administration, Texas Airports Development Office, ASW–650, 2601 Meacham Boulevard, Fort Worth, Texas 76137, Telephone: (817) 222–5657, Email: *Guillermo.Villalobos@faa.gov,* Fax: (817) 222–5989.

The request to release property may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release property at El Paso International Airport under the provisions of Title 49, U.S.C. Section 47107(h).

The following is a brief overview of the request:

The El Paso International Airport request the release of 3.881 acres of airport property. The release of property will allow for continued use of the property as a pool and park. The sale is estimated to provide $155,000.00.

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

In addition, any person may, upon request, inspect the application, notice and other documents relevant to the application in person at: The El Paso International Airport, Telephone: (915) 780–4793.

Issued in Fort Worth, Texas on August 21, 2012.

Kelvin L. Solco,

Airports Division.

[FR Doc. 2012–21146 Filed 9–4–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Study on the Use of Cell Phones On Board Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of availability and request for comments.

SUMMARY: The FAA Modernization and Reform Act of 2012 (Pub. L. 112–95) directed the Administrator of the FAA to conduct a study on the impact of the use of cell phones for voice communications in an aircraft during a flight in scheduled air transportation. A draft report on this study is currently available for review and public comment at *http://www.faa.gov/aircraft/draft_docs/.*

DATES: Written comments must be received on or before November 5, 2012.

ADDRESSES: Send comments identified as Cell Phone Study Comments using any of the following methods:

- *E-Mail:* Send comments to *CELLPHONEcomment@faa.gov.*
- *Mail:* Send comments to Avionics Maintenance Branch, AFS–360, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.
- *Fax:* Fax comments to (202) 385–6474.

FOR FURTHER INFORMATION CONTACT: For questions concerning this action, contact David B. Walen, Chief Scientific and Technical Advisor for Aircraft Electromagnetic Compatibility, Aviation Safety, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, Washington 98057; telephone (425) 917–6586; facsimile (425) 917–6590; email *dave.walen@faa.gov.*

Background

The FAA Modernization and Reform Act of 2012 [1] directed the Federal Aviation Administration (FAA) to conduct a study on the impact of the use of cell phones for voice communications in scheduled passenger air transportation and provide a 60-day opportunity for public comment. The Act also requires the FAA to report to Congress on the results of the study by Nov 10, 2012. Air carriers do not allow the use of cell phones on their airplanes in flight in US airspace, because Federal Communications Commission regulations prohibit the use of certain classes of cell phones while airborne.[2] FAA guidance [3] supports this airborne restriction because of the potential for cell phone interference to aircraft systems and equipment.

The FAA Modernization and Reform Act of 2012 section 410 directed the FAA to conduct a study on the impact of the use of cell phones for voice communications in scheduled passenger air transportation. The study included—

(1) A review of foreign government and air carrier policies on the use of cell phones during flight;

(2) A review of the extent to which passengers use cell phones for voice communications during flight; and

(3) A summary of any impacts of cell phone use during flight on safety, the quality of the flight experience of passengers, and flight attendants.

FAA requested information on these subjects from the national aviation authorities that have approved the installation of on-board cell phone base stations, and allowed the use of cell phones in flight on aircraft equipped with these base stations. The responses from these national aviation authorities were documented in the FAA report to address the requirements of FAA Modernization and Reform Act section 410.

In accordance with the Congressional direction, a report on this study is available for review and public comment at *http://www.faa.gov/aircraft/draft_docs/.*

Considerations for Comment

The FAA Modernization and Reform Act section 410 does not direct FAA or FCC to change the existing policies and regulations that govern the use of cell phones in flight. However, this study provides factual information on the experience of airlines and the national aviation authorities that allow the use of cell phones in flight. Any future rulemaking related to airborne cell phone use will consider this study.

The FAA is interested in obtaining comments on the report that documents the study on the use of cell phones on passenger aircraft. We are soliciting comments in the following general areas:

- Information from aircraft operators that may not have been provided in the responses from the national aviation authorities;
- Flight attendant and pilot experience with cell phone use on aircraft equipped with on-board cell phone base stations;
- Passenger experience on aircraft equipped with on-board cell phone base stations.

Request for Comments

The FAA invites interested persons to submit written comments, data, or views. The agency also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from changes in our current policy. The most helpful comments reference a specific area of concern, explain the reason for any recommended change, and include supporting data. Commenters should submit their comment(s) only once, in either written or electronic form, to ensure there is no duplication.

The FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA will summarize the comments received in a final revision of the cell phone study.

Proprietary or Confidential Business Information: Proprietary or confidential business information must be sent or delivered directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document, and marked as proprietary or confidential. If submitting information on a disk or CD ROM, mark the outside of the disk or CD ROM, and identify electronically within the disk or CD ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), the FAA is aware of proprietary information filed with a comment and does not make it publically available. It is held in a separate file to which the public does not have access. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under Department of Transportation procedures found in 49 CFR part 7.

Issued in Washington, DC on August 30, 2012.

Susan J. M. Cabler,

Asst. Manager, Aircraft Engineering Division, Aircraft Certification Service.

[FR Doc. 2012–21826 Filed 9–4–12; 8:45 am]

BILLING CODE 4910–13–P

[1] FAA Modernization and Reform Act of 2012, H.R. 658.

[2] 47 CFR 22.925.

[3] FAA Advisory Circular 91.21–1B, *Use of Portable Electronic Devices Aboard Aircraft,* August 25, 2006.

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2012–0075]

Draft Program Comment for Common Post-1945 Concrete and Steel Bridges

AGENCIES: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent to issue Program Comment for Common Post-1945 Concrete and Steel Bridges; request for comments.

SUMMARY: The Advisory Council on Historic Preservation (ACHP) is considering issuing a Program Comment at the request of the Federal Highway Administration setting forth the way in which FHWA will comply with Section 106 of the National Historic Preservation Act with regard to the effects of undertakings on common post-1945 concrete and steel bridges. The FHWA is requesting comments on the proposed Program Comment.

DATES: Submit comments on or before September 26, 2012.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, 1200 New Jersey Avenue SE., Washington, DC 20590, or submit electronically at *www.regulations.gov* or fax comments to (202) 493–2251. All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or may print the acknowledgment page that appears after submitting comments electronically. Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Page 19477–78) or you may visit *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: MaryAnn Naber, FHWA Office of Planning, Environment, and Realty, (202) 366–2060, *maryann.naber@dot.gov* or Carol Legard, ACHP Office of Federal Permitting, Licensing, and Assistance, (202) 606–8522, *clegard@achp.gov.* For legal questions contact Diane Mobley, FHWA Office of the Chief Counsel, (202) 366–1366, *diane.mobley@dot.gov*. Office hours for the FHWA are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

This document may be viewed online through the Federal eRulemaking portal at: *http://www.regulations.gov* under docket ID FHWA–2012–0075. 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. It is also available on FHWA's Web site at: *http://www.fhwa.dot.gov*. In addition, a hard copy may be viewed and copied at the U.S. Department of Transportation, Dockets Management Facility, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, 20590.

Background

Section 106 of the National Historic Preservation Act requires Federal agencies to consider the effects of their undertakings on historic properties and to provide ACHP a reasonable opportunity to comment with regard to such undertakings. The ACHP has issued the regulations that set forth the process through which Federal agencies comply with these duties. Those regulations are codified under 36 CFR part 800 (Section 106 regulations).

Under Section 800.14(e) of those regulations, agencies can request ACHP to provide a ''Program Comment'' on a particular category of undertakings in lieu of conducting individual reviews of each individual undertaking under such category, as set forth in 36 CFR 800.4 through 800.7. An agency can meet its Section 106 responsibilities with regard to the effects of particular aspects of those undertakings by taking into account ACHP's Program Comment and following the steps set forth in that comment.

The ACHP is now considering issuing a Program Comment at the request of FHWA that would streamline the way in which FHWA and other agencies may comply with Section 106 of the National Historic Preservation Act with regard to common post-1945 concrete and steel bridges.

The FHWA is taking steps to inform the public and historic preservation organizations about this proposed Program Comment and to solicit their views. These efforts include an email distribution to all FHWA Division offices, State transportation agencies, the Historic Bridge Foundation, the Historic Bridge Alliance, the National Register of Historic Places, the National Trust for Historic Preservation, State Historic Preservation Offices (SHPOs) and others. In addition, FHWA will post the proposed Program Comment on the agency Web site.

As explained in the Program Comment itself, every year FHWA funds the rehabilitation and replacement of hundreds of bridges, many of which are of common types constructed by State transportation agencies after 1945, using reinforced concrete or steel beams and designs that quickly became standardized. These common bridge types are generally undistinguished, have little value for preservation in place, and are rarely viable candidates for relocation.

The FHWA proposes the following Program Comment in accordance with 36 CFR 800.14(e) in order to waive case-by-case Section 106 review of common post-1945 bridges. This program comment would apply to effects of undertakings on common concrete and steel bridges lacking distinctive treatments, of little value for preservation in place, and not located within or adjacent to historic districts.

Under the Program Comment, for undertakings affecting the specified common bridge types, FHWA or another Federal agency official would have the option of following the requirements of the Program Comment in lieu of case-by-case consultation with regard to the effects of proposed work on that bridge. However, the Program Comment would not be a waiver from Section 106 for Federal undertakings that may affect common bridges. For bridges which meet any of the considerations designated in Section IV of the Program Comment, individual consultation would continue to be required. In addition, Federal agency officials would still have to complete Section 106 review and consider effects of the undertaking on historic properties other than the bridge itself.

The Program Comment proposes two types of programmatic mitigation to resolve potential adverse effects: Historic American Engineering Record documentation of at least one example of each of the common post-1945 bridge types included in the Program Comment, and encouragement of State departments of transportation to carry out bridge inventories. The ACHP is specifically requesting that commenters propose any additional ideas they may have for appropriate programmatic mitigation measures.

Public comments on this proposed Program Comment will be accepted on or before September 26, 2012. Once the

public comments resulting from this notice are considered, and edits are incorporated as deemed appropriate, the ACHP will decide whether to issue the Program Comment.

Authority: 23 CFR 800.14

Issued on: August 15, 2012.

Victor M. Mendez,

Administrator.

Text of the proposed Program Comment

The following is the text of the proposed Program Comment:

Program Comment for Common Post-1945 Concrete and Steel Bridges

I. Introduction

Every year, the Federal Highway Administration (FHWA) funds the rehabilitation and replacement of hundreds of bridges under the Federal-aid program administered across the U.S. by State departments of transportation (DOT) and the Federal Lands Highway program. Other Federal agencies are also involved with projects affecting bridges through Federal assistance, approvals, or permits. Many of the bridges affected by these programs are of common types constructed by State transportation agencies after 1945, using reinforced concrete or steel beams and designs that quickly became standardized. These common bridge types are generally undistinguished, have little value for preservation in place and are rarely viable candidates for relocation. Yet, all federally funded or permitted projects affecting these bridges require review and consultation pursuant to Section 106 of the National Historic Preservation Act (16 USC 470f) to assess whether the bridge is eligible for inclusion in the National Register and, if so, to resolve potential effects. Regulations developed by the ACHP and codified at 36 CFR Part 800 describe the procedures Federal agencies must follow to meet this obligation.

Alternate compliance methods, provided by the Section 106 regulations allow agencies to meet these Section 106 obligations, but tailor the process to their mission and needs. Section 800.14(e) of the regulations provides that any agency may request a ''Program Comment'' from the ACHP in lieu of case-by-case review. The benefit of a Program Comment is that it allows a Federal agency to comply with Section 106 in a single action for a class of undertakings rather than addressing each undertaking as a separate action. The FHWA proposes the following Program Comment in accordance with 36 CFR 800.14(e) in order to waive case-by-case Section 106 consideration of effects on common post-1945 bridges. This Program Comment would be available for use by all Federal agencies. It would relieve Federal agencies from the need, under Section 106, to individually consider the effects of undertakings on the bridges described in Section V of this Program Comment, with the exceptions noted on Section IV, since such bridges lack distinctive treatments, are of little value for preservation in place, and are not located within or adjacent to historic districts.

II. Background

To develop this proposed Program Comment, FHWA met with individuals from the ACHP staff, the National Conference of State Historic Preservation Offices, the American Association of State Highway and Transportation Officials (AASHTO), and the National Trust for Historic Preservation. Participants in the meetings all have expertise on considering historic bridges in the Section 106 review process. At the meetings, the group members provided FHWA with individual advice and information. Members of the group identified bridge replacement projects as a category of undertakings that could be streamlined with regard to effects to common post-1945 reinforced concrete or steel bridges. Individuals within the group further recommended that of the alternatives to standard Section 106 review available, a Program Comment would be the most appropriate way to modify the review process to meet the needs of FHWA as well as other Federal agencies. To identify the types of bridges that could be addressed in a single comment from ACHP, FHWA referred to a national context for common historic bridges and the National Bridge Inventory.

In October 2005, the National Cooperative Highway Research Program published ''A Context for Common Historic Bridge Types.'' That context revealed that a great many of the structures built after 1935, and especially since 1946, are strictly utilitarian and lacking in distinctive engineering or architectural qualities. Increasing standardization associated with highway design as a result of growing Federal funding and the evolving standards of AASHTO both contributed to the uniformity of design in bridges of certain types.

Information about America's bridges, including their age and condition, is readily available in FHWA's National Bridge Inventory (NBI). The NBI is a collection of information (database) covering just under 600,000 of the Nation's bridges located on public roads, including Interstate Highways, U.S. highways, State and county roads, as well as publicly accessible bridges on Federal lands. It presents a State by State summary analysis of the number, location, and general condition of highway bridges within each State. This database contains detailed technical and engineering information about hundreds of thousands of bridges in the United States, including year built, bridge type, condition and many other fields. Some 45,000 bridges in the NBI are rated as structurally deficient, meaning that portions of the bridge may be in poor condition. Approximately 61,680 are identified as functionally obsolete, meaning that the design of the bridge does not meet current guidelines for its use, such as lack of safety shoulders or the inability to handle certain traffic volume, speed, size, or weight. Bridges in these categories are frequent candidates for replacement. This Program Comment is intended to dispense with the routine administrative burden of considering the effects of replacement on these bridges on a case-by-case basis and make delivery of these critical projects more efficient without affecting the preservation outcome for the vast majority of common post-1945 bridges.

III. Applicability

The proposed Program Comment relieves Federal agencies from the need to individually consider the effects of undertakings on the bridge types identified in Section V, except for those subject to the considerations noted on Section IV, in the course of compliance with Section 106.

Undertakings include those that involve applications from State transportation agencies or local governments for Federal permits, approvals, or assistance that will result in alteration, replacement, or demolition of one or more of the common bridges or culverts listed in Section V below (hereafter, ''common bridges''). All Federal agencies may take advantage of the streamlining provided by this Program Comment when it is adopted by the ACHP. Data from the NBI or existing State surveys may be used to support the determination that a particular bridge is eligible to be considered under the provisions of this Program Comment in terms of its age and type of construction. However, if data from the NBI is used, that information must be verified in the field by a qualified engineer or cultural resource professional to ensure that the date and type have been correctly recorded and that the bridge does not

meet any of the other considerations under Section IV that would render it ineligible for this Program Comment.

The Program Comment is intended to apply to effects on common bridges, regardless of ownership, except for those located on Indian tribal lands [1]. For undertakings affecting common bridge types identified in Section V, FHWA or another Federal agency official may follow the requirements of this Program Comment in lieu of case-by-case consultation with regard to the effects of proposed work on that bridge. This Program Comment is not a waiver from Section 106 for Federal undertakings that may affect common bridges as described in Section V. Federal agency officials must still complete Section 106 review and consider effects of the undertaking on historic properties other than the bridge itself. Such effects to other historic properties may be direct or indirect, and must be considered by the Federal agency official whether or not the Program Comment is applicable to the subject bridge. For example, bridge replacement projects may have the following types of effects to non-bridge historic properties that would need to be considered:

- disturbance to archeological sites as a result of construction-related ground disturbing activities;
- change in physical features within the setting that contribute to historic significance of a historic property, including alterations that a new bridge may have on the historic setting and feeling of an adjacent historic district;
- change in traffic patterns that may affect the setting, feel, and association of a historic district; or
- effects to other historic properties based on the need for temporary construction, detours, or right-of-way.

IV. Considerations

Prior to utilizing this Program Comment for an undertaking that may affect a common bridge, a qualified cultural resource specialist must complete a review to determine if the following considerations apply. If the Federal agency official, or a State official delegated the responsibility by statute or a Programmatic Agreement executed under the provisions of Section 106, determines that the bridge in question meets any of the following, an agency may not utilize this Program Comment with regard to that bridge:

A. The bridge is listed in or has previously been determined eligible for the National Register of Historic Places or is located adjacent to or within a National Register listed or eligible historic district, including linear historic districts such as a parkway, historic road, or canal.

B. In consultation among the Federal agency, State Historic Preservation Office (SHPO), and any applicants for assistance, the bridge is identified as a very early or particularly important example of its type in a State or the Nation, has distinctive engineering or architectural features that depart from standard designs, such as an aesthetic railing or balustrade, includes spans of exceptional length or complexity, or displays other elements that were engineered to respond to a unique environmental context. [See: *http://www.environment.fhwa.dot.gov/histpres/index.asp* for examples]

C. The bridge in question is or includes spans of the following types: arch bridges, truss bridges, movable spans, suspension bridges, or covered bridges.

States will have until December 31, 2012, to develop a list of any exceptional bridges which should be considered as meeting the considerations above. The FHWA Division shall organize a meeting of the SHPO, DOT, and other interested parties to determine which, if any, post-1945 bridges within the State meet the considerations above and therefore would NOT fall under the terms of this Program Comment. Where States already have a current (within the last 5 years) Programmatic Agreement, inventory, or management plan for historic bridges that identifies bridges meeting any of the listed considerations, the data included in those Programmatic Agreements, inventories, or management plans may suffice to make those determinations. States with existing Programmatic Agreements may apply the terms of such agreements in lieu of this consultation to identify particularly significant examples of a common type.

The intent of this section is not to require a statewide survey or context to be developed where none exists, but to exclude readily recognizable exceptional bridges from the Program Comment much in the same way that was done for the Interstate Highway exemption. It is understood that some bridges that fall into the types specified in Section V may be eligible for the National Register under local or State significance. Consequently some may be overlooked as not being exceptional; however, it is doubtful that any of these would warrant individual consideration under Section 106 even if they were to be determined National Register eligible. Accordingly, this Program Comment would effectively waive all subsequent requirements for consideration of effects under Section 106 regarding bridges which fall into one of the common types and do not meet any of the considerations above.

V. Bridge Types for Which No Individual Consideration Under Section 106 is Required

Based on the historic bridge context, the NBI, information developed in statewide bridge inventories across the U.S., and consultation with the National Conference of SHPOs and other stakeholders, the following common bridge types are well-documented standardized designs that lack individual distinction.[2] Provided none of the considerations specified in Section IV above apply, Federal agencies do not have to consider the effects of undertakings on the bridges that fall into the following categories under Section 106:

A. Reinforced concrete slab bridges
  (i) Reinforced concrete cast-in-place slabs
  (ii) Reinforced concrete pre-cast slabs
  (iii) Pre-stressed concrete
B. Reinforced concrete beam and girder bridges
  (i) Reinforced concrete T-Beams
  (ii) Reinforced concrete channel beams
  (iii) Reinforced concrete girders
  (iv) Reinforced concrete rigid frames
  (v) Pre-stressed concrete I-Beams
  (vi) Pre-stressed concrete box beams
C. Multi-Beam or Multi-Girder bridges
  (i) Metal-rolled multi-beams
  (ii) Metal fabricated (built up) girders
  (iii) Metal rigid frames

VI. Programmatic Mitigation

A. If a suitable example from at least one State is not already included in the collection, one set of Historic American Engineering Record (HAER) documentation, including at least narrative history and photographs, for each bridge type in Section V shall be prepared and submitted by FHWA for acceptance by HAER. The FHWA will coordinate with HAER to determine which, if any, of these types are not yet represented in the HAER collection and will work with the FHWA Division offices and State DOTs to identify a candidate for each type not already represented. The FHWA will complete recordation to HAER standards of at least one example for each type not already represented in the HAER collection and will submit such documentation to HAER before December 31, 2013.

B. The FHWA will encourage States that have not done so within the last 5 years to update inventories of historic bridges in their States to better ensure that bridges meeting the considerations in Section IV above are

[1] Indian tribes wishing to use the streamlining measures in this Program Comment for common bridges on lands under their jurisdiction are encouraged to enter into program alternatives pursuant to 36 CFR 800.14.

[2] Descriptions and examples of these common bridge types can be found in A Context for Common Historic Bridge Types. NCHRP Project 25–25, task 15, October 2005 (*http://onlinepubs.trb.org/onlinepubs/archive/NotesDocs/25-25%2815%29_FR.pdf*) .

identified and considered early in the Section 106 review process.

VII. Definitions

If not specifically addressed below, terms used within this Program Comment shall be defined consistent with the definitions provided in 36 CFR part 800.

Common Bridge is, for purposes of this Program Comment, a common post-1945 bridge or culvert of a type identified in Section V.

Program Comment is an alternative to Section 106 review that allows a Federal agency to request the ACHP to comment on a category of undertakings in lieu of conducting individual reviews under Sections 800.4 through 800.6 of the regulations (36 CFR Part 800).

Qualified cultural resource specialist means an individual meeting the Secretary of the Interior's professional qualifications for historian or architectural historian by virtue of education and experience to carry out historic preservation work.

[FR Doc. 2012–21699 Filed 9–4–12; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. FD 35654]

Genesee & Wyoming Inc.—Control—RailAmerica, Inc., et al.

AGENCY: Surface Transportation Board.

ACTION: Decision No. 2 in Docket No. FD 35654; Notice of acceptance of application; issuance of procedural schedule.

SUMMARY: The Surface Transportation Board (Board) is accepting for consideration the application filed August 6, 2012, by Genesee and Wyoming Inc. (GWI) and RailAmerica, Inc. (RailAmerica). The application seeks Board approval under 49 U.S.C. 11323–11325 of the acquisition of control of RailAmerica, a noncarrier holding company, by GWI, a noncarrier holding company. This proposal is referred to as the Transaction, and GWI and RailAmerica are referred to collectively as Applicants.

The Board finds that the application is complete and that the Transaction is a minor transaction upon the preliminary determination that the Transaction clearly will not have any anticompetitive effects. 49 CFR 1180.2(b)(1), (c). The Board makes this determination based solely on the evidence presented in the application. The Board stresses that this is not a final determination, and its finding may be rebutted by filings and evidence submitted into the record for this proceeding. The Board will give careful consideration to any claims that the Transaction would have anticompetitive effects that are not apparent from the application itself.

DATES: The effective date of this decision is September 5, 2012. Any person who wishes to participate in this proceeding as a party of record (POR) must file, no later than September 19, 2012, a notice of intent to participate. All comments, protests, requests for conditions, and any other evidence and argument in opposition to the primary application and related filings, including filings by the U.S. Department of Justice (DOJ) and the U.S. Department of Transportation (DOT), must be filed by October 5, 2012. Responses to comments, protests, requests for conditions, and other opposition, and rebuttal in support of the primary application or related filings must be filed by October 26, 2012, see the Appendix A (Procedural Schedule). Further procedural orders, if any, will be issued by the Board as necessary.

ADDRESSES: Any filing submitted in this proceeding must be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions found on the Board's Web site at ''*www.stb.dot.gov*'' at the ''E-FILING'' link. Any person submitting a filing in the traditional paper format should send an original and 10 paper copies of the filing (and also an electronic version) to: Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each filing in this proceeding must be sent (and may be sent by email only if service by email is acceptable to the recipient) to each of the following: (1) Secretary of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590; (2) Attorney General of the United States, c/o Assistant Attorney General, Antitrust Division, Room 3109, Department of Justice, Washington, DC 20530; (3) Terence M. Hynes (representing RailAmerica), Sidley Austin LLP, 1501 K Street NW., Washington, DC 20005; (4) David H. Coburn (representing GWI), Steptoe & Johnson LLP, 1330 Connecticut Ave. NW., Washington, DC 20036; and (5) any other person designated as a POR on the service list notice (as explained below, the service list notice will be issued as soon after September 19, 2012, as practicable).

FOR FURTHER INFORMATION CONTACT: Jonathon Binet, (202) 245–0368. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: GWI is a publicly traded, noncarrier holding company. RailAmerica is a publicly traded, noncarrier holding company. See Appendix B for a complete list of each company's relevant holdings.

Applicants state that, pursuant to an agreement and plan of merger (Agreement), Jaguar Acquisition Sub, Inc., a newly formed, wholly owned noncarrier subsidiary of GWI, would acquire control of RailAmerica and its railroad subsidiaries. RailAmerica's shareholders would receive $27.50 per share of RailAmerica common stock.

According to GWI, all shares of common stock of RailAmerica will be placed into an independent voting trust.[1] Applicants state that, on or after the effective date of the Board's decision authorizing the Transaction, the voting trust would be terminated, RailAmerica's shares would be transferred to GWI, and RailAmerica would become a wholly owned subsidiary of GWI.

Applicants state four primary purposes for pursuing the Transaction. First, Applicants state that expanding GWI's safe and efficient rail operation of regional and shortline railroads would improve customer service for GWI and RailAmerica customers, as well as the Class I railroads with which they connect. Second, Applicants anticipate an increased likelihood of industrial and manufacturing development opportunities in the communities they serve. Third, they seek to enhance operational efficiencies by combining the best practices of each company. Lastly, Applicants assert that the Transaction would create stability for employees and customers.

Financial Arrangements. Under the Agreement, the purchase price would be paid in cash. RailAmerica would not issue any new railroad securities in connection with the Transaction although, following approval by the Board, it may guarantee debt obligations incurred by GWI. GWI would incur approximately $2 billion of debt obligations and would issue up to $800 million of equity and/or equity-linked securities in connection with the Transaction.

[1] *See GWI Voting Trust—Control Exemption—RailAmerica, Inc.,* FD 35660 (STB served Aug. 17, 2012).

Passenger Service Impacts. Applicants state that the Transaction would not affect passenger rail service.

Discontinuances/Abandonments. Applicants state that there would not be any Transaction-related line abandonments.

Public Interest Considerations. Applicants state that the Transaction would benefit the public by providing safe, reliable, and efficient rail service and by allowing GWI to focus on local economic development. Applicants point to GWI's history in the industry and its commitment to providing continuously improved customer service as additional public benefits.

Applicants assert that the Transaction would have a negligible effect on shippers and the railroad industry and, therefore, has a limited possibility of creating any adverse competitive effects. According to Applicants, the Transaction would not create a monopoly and would not result in any restraint of trade. Applicants note that GWI and RailAmerica currently serve the same customer in only one locality—Linden, Alabama—but they state that no customer there would experience a reduction in service alternatives because the routes of these two carriers have completely opposite orientations and serve distinctly different destinations. In other words, at Linden, a shipper wishing to ship traffic east or west has one option and the same shipper wishing to ship traffic north or south has a different option.

Applicants assert that there would be no ''2-to-1 shippers'' (i.e., shippers served by two carriers before the Transaction that would be served by one after it) as a result of the Transaction. Applicants state that GWI and RailAmerica railroads interconnect or interchange in only four localities and are in close proximity (five miles or less) in two localities and that the combination would not affect competition at any of those locations. According to Applicants, the Transaction would have no effect on geographic competition. Lastly, Applicants state that the Transaction would not have a detrimental impact on non-affiliated shortlines that connect to GWI and RailAmerica railroads or on any transportation in a transportation corridor.

Applicants assert that, even if the Transaction had any adverse impacts on competition, those effects would be *de minimis* due to the limited connections between Applicants' railroad subsidiaries and, in any event, would be outweighed by the public benefits of the Transaction. As all of the railroads involved in the Transaction are shortlines, Applicants contend that they have little ability to influence rail transportation at the regional or national level. Also, because they believe the Transaction would result in safer, more reliable rail and customer service as well as local economic development, Applicants assert that these public interest considerations outweigh any *de minimis* effects on competition.

Time Schedule for Consummation. Applicants intend to consummate control of RailAmerica as soon as possible after the effective date of the final order, should the Board authorize the proposed Transaction. Applicants will place all shares of RailAmerica common stock into a voting trust. On or after the effective date of the Board's final order (assuming the Board authorizes the Transaction), the voting trust would be terminated and the shares of RailAmerica would be transferred to GWI.

Environmental Impacts. Applicants contend that, because the Transaction relates only to the change in corporate control and ownership of RailAmerica, no environmental impacts are anticipated and that the thresholds established in 49 CFR 1105.7(e)(4) and (5) would not be triggered.

Historic Preservation Impacts. Applicants contend that there is no need for historic review under Section 106 of the National Historic Preservation Act, 16 U.S.C. 470, because the Transaction involves only a corporate change in control of RailAmerica and would not substantially change the levels of operations over, or maintenance of, rail lines of any of the GWI railroads or the RailAmerica railroads.

Labor Impacts. Applicants state that no employees of the subsidiary railroads would be adversely affected. Applicants further acknowledge that the Transaction would be subject to labor protective requirements and other procedures of 49 U.S.C. 11326(b) and *Wisconsin Central—Acquisition Exemption—Lines of Union Pacific Railroad,* 2 S.T.B. 218 (1997).

Application Accepted. The Transaction has characteristics that suggest it might be classified as ''significant'' under 49 CFR 1180.2(b), given that it involves the merger of two large holding companies that own railroads transacting business in 37 states. The size of the Transaction alone, however, is insufficient to classify it as significant. As provided for under 49 CFR 1180.2, rather than meeting a size threshold, to be significant a transaction has to have the potential for anticompetitive effects. Nothing in the record thus far suggests that the Transaction would have any anticompetitive effects, and any such effects that might result from the Transaction would appear to be outweighed by its contribution to the public in meeting significant transportation needs. A transaction that does not involve the control or merger of two or more Class I railroads is not of regional or national transportation significance and, therefore, is classified as minor if: (1) The transaction clearly will not have any anticompetitive effects, or (2) any anticompetitive effects will clearly be outweighed by the anticipated contribution to the public interest in meeting significant transportation needs. *See* 49 CFR 1180.2(b), (c). Therefore, based on the information provided in the Application, the Board finds the proposed Transaction to be a minor transaction under 49 CFR 1180.2(c).[2] Such a categorization does not mean that the proposed Transaction is insignificant or not of importance. Indeed, the Board will carefully review the proposed Transaction to make certain that it does not substantially lessen competition, create a monopoly, or restrain trade and that any anticompetitive effects are outweighed by the public interest. *See* 49 U.S.C. 11324(d)(1)–(2).

On August 9, 2012, Napa Valley Railroad Company (NVRR) and Yreka Western Railroad Company (YW) filed replies in opposition to Applicants' Motion To Establish a Procedural Schedule. On August 16, 2012, similar replies were filed by Samuel J. Nasca, for and on behalf of United Transportation Union-New York State Legislative Board (UTU–NY), and jointly by Winamac Southern Railway Company (WSRY) and US Rail Corporation (URC). Opposing parties argue that the Board should treat the Transaction as a significant transaction, pursuant to the applicable statutes and regulations. For example, NVRR and YW argue that, in terms of competition among holding companies, GWI's acquisition of RailAmerica is of national transportation significance. WSRY and URC infer from the numbers (e.g., post-merger GWI would control more than 100 rail carriers, manage in excess of 15,000 miles of track, and handle 1.835 million carloads per year) that this is a matter of regional and national transportation significance. UTU–NY claims that the Transaction would result in a reduction in competition among

[2] Because the Transaction proposed in the application is a minor transaction, no responsive applications will be permitted. *See* 49 CFR 1180.4(d)(1).

Class I rail carriers. Applicants filed a response to the replies on August 28, 2012.

The Board finds the proposed Transaction to be a minor transaction, because, as we have noted, on the face of the application there does not appear to be a likelihood of any anticompetitive effects resulting from the Transaction, if approved. Applicants state that the combined GWI and RailAmerica railroads would handle only 2.8% of the carloads handled by freight railroads in the United States and would earn only 1.1% of the total gross freight revenue earned by those railroads. The Transaction involves the common ownership of individual shortlines, each limited in its geographic scope and operating in different areas of the United States. The Transaction, if approved, would alter matters at the administrative level, but Applicants indicate that the existing operating plans governing each railroad would continue unchanged. Thus, those railroads would continue to operate and compete in their own local markets.

Our analysis of the effect on competition appropriately examines not how many railroad holding companies there are, or how many miles they operate, but rather whether the combination would have an adverse effect on shippers and communities. We perform that analysis by looking at the individual serving rail carriers (here, shortline carriers that are not interconnected, with few exceptions), rather than just the holding companies. Based on a review of the application and the careful description of the interchange points, it does not appear that any shipper would have fewer competitive rail alternatives as a result of the Transaction, even in the four localities where GWI interconnects or interchanges with RailAmerica because, as addressed in the application and supporting materials, the relevant lines either run in different directions or the affected shippers are served by multiple railroads.[3] Lastly, the public would clearly benefit from GWI's demonstrated commitment to safety and customer service.

The Board reiterates, however, that its findings regarding anticompetitive impacts are preliminary. The Board will give careful consideration to any claims that the Transaction would have anticompetitive effects that are not apparent from the application itself. The Board can also condition the Transaction to mitigate or eliminate any deleterious effects on regional or national transportation.

The Board accepts the application for consideration because it is in substantial compliance with the applicable regulations governing minor transactions. *See* 49 U.S.C. 11321–26; 49 CFR pt. 1180. The Board reserves the right to require the filing of supplemental information as necessary to complete the record.

Procedural Schedule. The Board has considered Applicants' request (filed August 6, 2012) for an expedited procedural schedule under which the Board would issue its final decision before the statutory deadline of 180 days after the filing of the application. In the interest of allowing time for the record to develop fully, the Board will not at this time set a particular target date for its decision. Rather, after reviewing the record developed, we will decide whether an expedited procedural schedule is appropriate. For further information respecting dates, see the Appendix A (Procedural Schedule).

Notice of Intent To Participate. Any person who wishes to participate in this proceeding as a POR must file with the Board, no later than September 19, 2012, a notice of intent to participate, accompanied by a certificate of service indicating that the notice has been properly served on the Secretary of Transportation, the Attorney General of the United States, and Messrs. Hynes and Coburn.

If a request is made in the notice of intent to participate to have more than one name added to the service list as a POR representing a particular entity, the extra name will be added to the service list as a ''Non-Party.'' The list will reflect the Board's policy of allowing only one official representative per party to be placed on the service list, as specified in Press Release No. 97–68 dated August 18, 1997, announcing the implementation of the Board's ''One Party-One Representative'' policy for service lists. Any person designated as a Non-Party will receive copies of Board decisions, orders, and notices but not copies of official filings. Persons seeking to change their status must accompany that request with a written certification that he or she has complied with the service requirements set forth at 49 CFR 1180.4, and any other requirements set forth in this decision.

Service List Notice. The Board will serve, as soon after September 19, 2012, as practicable, a notice containing the official service list (the service-list notice). Each POR will be required to serve upon all other PORs, within 10 days of the service date of the service-list notice, copies of all filings previously submitted by that party (to the extent such filings have not previously been served upon such other parties). Each POR also will be required to file with the Board, within 10 days of the service date of the service-list notice, a certificate of service indicating that the service required by the preceding sentence has been accomplished. Every filing made by a POR after the service date of the service-list notice must have its own certificate of service indicating that all PORs on the service list have been served with a copy of the filing. Members of the United States Congress (MOCs) and Governors (GOVs) are not parties of record and need not be served with copies of filings, unless any Member or Governor has requested to be, and is designated as, a POR.

Service of Decisions, Orders, and Notices. The Board will serve copies of its decisions, orders, and notices only on those persons who are designated on the official service list as either POR, MOC, GOV, or Non-Party. All other interested persons are encouraged to secure copies of decisions, orders, and notices via the Board's Web site at ''*www.stb.dot.gov*'' under ''E-LIBRARY/Decisions & Notices.''

Access to Filings. Under the Board's rules, any document filed with the Board (including applications, pleadings, etc.) shall be promptly furnished to interested persons on request, unless subject to a protective order. 49 CFR 1180.4(a)(3). The application and other filings in this proceeding are available for inspection in the library (Room 131) at the offices of the Surface Transportation Board, 395 E Street SW., in Washington, DC, and will also be available on the Board's Web site at ''*www.stb.dot.gov*'' under ''E-LIBRARY/Filings.'' In addition, the application may be obtained from Messrs. Hynes and Coburn at the addresses indicated above.

[3] *See e.g.,* App., V.S. of Kevin Neels 11–13 (stating that common ownership of the Tazewell and Peoria Railroad and the Toledo, Peoria and Western Railway (TPW) in Peoria, Illinois would not have an anticompetitive effect because the affected customers are also served by Union Pacific and a barge terminal); *id.* 13–15 (stating that although the Illinois and Midland Railroad and TPW ''can theoretically interchange traffic at Sommer[, Illinois], no traffic has been interchanged between the railroads at that location in 15 years or more''); *id.* 19–20 (stating that the common ownership of the Meridian and Bigbee Railroad and the Alabama and Gulf Coast Railway would not negatively affect competition because one line runs north-south and the other east-west); *id.* 22–23 (stating that the railroads that would fall under common ownership in Columbus, Mississippi, not only have multiple interchange partners, but multiple Class I interchange partners); *id.* 27–28 (stating that there is no overlap in territory currently served by the RailAmerica line in Eugene, Oregon and territory currently served by the two GWI lines in Eugene, Oregon.)

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

It is ordered:

1. The application in FD 35654 is accepted for consideration.

2. The parties to this proceeding must comply with the procedural schedule adopted by the Board in this proceeding as shown in Appendix A.

3. The parties to this proceeding must comply with the procedural requirements described in this decision.

4. This decision is effective on September 5, 2012.

Decided: August 30, 2012.

By the Board, Chairman Elliott, and Commissioner Begeman. Vice Chairman Mulvey dissented with a separate expression.

Vice Chairman Mulvey, dissenting:

Congress directed the Board to ensure that certain procedural safeguards are followed when the Board reviews a rail transaction (not involving at least two Class I railroads) that is of ''regional or national transportation significance.'' 49 U.S.C. 11325(c). Presently before the Board is a request to consolidate GWI and RailAmerica, the two largest shortline holding companies in the country. If approved, more than 100 shortline railroads, operating in 37 states, would be consolidated under a single corporate umbrella. I believe that a transaction of this magnitude is of regional or national transportation significance and, accordingly, should have been classified by the Board as ''significant'' rather than ''minor.'' A ''significant'' classification would have given interested parties and the Board more information and opportunity to examine any concerns regarding the transaction.

While I do not believe that every large transaction merits a significant classification, the proposed transaction would greatly change the ownership structure of the short line industry. In the past, this agency has been criticized by some for allowing, over time and many individual transactions, significant consolidation of the Class I railroad industry. Although there remain many other shortline railroads today, the present transaction would consolidate nearly 20% of the shortlines in the country under a single owner.

This agency has only once found a transaction to be significant.[4] Yet some purportedly ''minor'' transactions have resulted in significant opposition and required significant agency resources.[5] This disconnect is a result of the Board's current and restrictive rules for classifying mergers, which base the determination solely on competitive impact even though such a limitation is nowhere to be found in 11325(c).[6] Competitive issues are, without a doubt, the Board's primary concern in merger review and I agree with the Board's preliminary determination with regard to the likely competitive impact of this merger. But because the Board's review of minor and significant mergers is not limited to just competitive issues, we should not so severely limit the analysis we employ to determine a merger's significance. *See Village of Barrington et al.* v. *Surface Transportation Board,* 636 F.3d 650 (D.C. Cir. 2011) (Board has the authority to condition minor mergers on environmental grounds); 49 CFR 1180.6 (requiring minor and significant merger applicants to submit information regarding environmental issues, total fixed charges, impacts on commuter/passenger rail transportation, *etc.*).

Although I would have classified the merger as being of regional or national transportation significance, based on the current record, I do not see an issue that would have prevented the Board from completing its review in less time than allotted for significant mergers.

Derrick A. Gardner,

Clearance Clerk.

Procedural Schedule

August 6, 2012 Motion for Protective Order filed. Application and Motion to Establish Procedural Schedule filed.

September 5, 2012 Board notice of acceptance of application published in the **Federal Register**.

September 19, 2012 Notices of intent to participate in this proceeding due.

October 5, 2012 All comments, protests, requests for conditions, and any other evidence and argument in opposition to the application, including filings of DOJ and DOT, due.

October 26, 2012 Responses to comments, protests, requests for conditions, and other opposition due. Rebuttal in support of the application due.

TBD A public hearing or oral argument may be held.

TBD Close of evidentiary proceeding.

TBD Date by which a final decision will be served.

TBD Date by which a final decision will become effective.

Holdings

According to GWI, it controls, within the United States, one Class II rail carrier, Buffalo & Pittsburgh Railroad, Inc., and 59 Class III rail carriers:

- Allegheny and Eastern Railroad, LLC;
- The Aliquippa and Ohio River Railroad Co.;
- AN Railway, LLC;
- Arizona Eastern Railway Company;
- Arkansas Louisiana & Mississippi Railroad Co.;
- Atlantic and Western Railway, LP;
- The Bay Line Railroad, LLC;
- Chattahoochee Bay Railroad, Inc.;
- Chattahoochee Industrial Railroad;
- Chattooga and Chickamauga Railway Co.;
- Columbus & Chattahoochee Railroad, Inc.;
- Columbus and Greenville Railway Co.;
- The Columbus and Ohio River Rail Road Co.;
- Commonwealth Railway, Inc.;
- Corpus Christi Termini Railroad, Inc.;
- The Dansville and Mount Morris Railroad Co.;
- East Tennessee Railway, LP;
- First Coast Railroad Inc.;
- Fordyce and Princeton RR Co.;
- Galveston Railroad, LP;
- Genesee and Wyoming Railroad Co.;
- Georgia Central Railway, LP;
- Georgia Southwestern Railroad, Inc.;
- Golden Isles Terminal Railroad, Inc.;
- Hilton & Albany Railroad, Inc.;
- Illinois & Midland Railroad, Inc.;
- KWT Railway, Inc.;
- Little Rock & Western Railway, LP;
- Louisiana and Delta Railroad, Inc.;
- Luxapalila Valley Railroad, Inc.;
- The Mahoning Valley Railway Co.;
- Maryland and Pennsylvania Railroad, LLC;
- Maryland Midland Railway, Inc.;
- Meridian & Bigbee Railroad, LLC;
- Ohio and Pennsylvania Railroad Co.;
- Ohio Central Railroad, Inc.;
- Ohio Southern Railroad, Inc.;
- Pittsburg & Shawmut Railroad, LLC;
- The Pittsburgh & Ohio Central Railroad Co.;

[4] *Canadian Pacific Ry.—Control—Dakota, Minnesota & Eastern R.R.,* FD 35081 (STB served Dec. 27, 2007).

[5] In *Canadian National Ry.—Control—EJ&E West Co.,* FD 35087 (STB served Nov. 26, 2007) (Cmr. Mulvey, dissenting), the Board classified the transaction as minor, but subsequently acknowledged that the high level of public participation in the merger review was ''unprecedented.'' *Canadian National,* slip op. at 3 (STB served Dec. 24, 2008).

[6] Section 11325(c) provides that certain procedures are to be followed ''[i]f the application involves a transaction other than the merger or control of at least two Class I railroads, as defined by the Board, which the Board has determined to be of regional or national transportation significance * * *''.

- Portland & Western Railroad, Inc.;
- Riceboro Southern Railway, LLC;
- Rochester & Southern Railroad, Inc.;
- Salt Lake City Southern Railroad Co., Inc.;
- Savannah Port Terminal Railroad Inc.;
- South Buffalo Railway Co.;
- St. Lawrence & Atlantic Railroad Co.;
- Talleyrand Terminal Railroad Co., Inc.;
- Tazewell & Peoria Railroad, Inc.;
- Tomahawk Railway, LP;
- Utah Railway Co.;
- Valdosta Railway, LP;
- The Warren & Trumbull Railroad Co.;
- Western Kentucky Railway, LLC;
- Willamette & Pacific Railroad, Inc.;
- Wilmington Terminal Railroad, LP;
- York Railway Co.;
- Yorkrail, LLC;
- The Youngstown & Austintown Railroad, Inc.; and
- Youngstown Belt Railroad Co.

GWI explains that Allegheny & Eastern Railroad, LLC and Pittsburg & Shawmut Railroad, LLC are non-operating carriers that own rail lines operated by Buffalo Pittsburgh Railroad, Inc.; and, Maryland and Pennsylvania Railroad, LLC and Yorkrail, LLC are also non-operating carriers that own rail lines operated by York Railway Company. The Board recently granted Western Kentucky Railway, LLC authority to abandon all of its remaining rail lines that have been inactive since prior to 2005.

According to RailAmerica, it operates the following Class III railroads:

- Alabama & Gulf Coast Railway LLC;
- Arizona & California Railroad Co.;
- Bauxite & Northern Railway Co.;
- California Northern Railroad Co.;
- Carolina Piedmont Division;
- Cascade and Columbia River Railroad Co.;
- Central Oregon & Pacific Railroad, Inc.;
- The Central Railroad Company of Indiana;
- Central Railroad Company of Indianapolis;
- Chesapeake & Albemarle Railroad Co., Inc.;
- Chicago, Ft. Wayne & Eastern;
- Conecuh Valley Railway;
- Connecticut Southern Railroad, Inc.;
- Dallas, Garland & Northeastern Railroad, Inc.;
- Eastern Alabama Railway, LLC;
- Grand Rapids Eastern Railroad Inc.;
- Huron & Eastern Railway Company, Inc.;
- Indiana & Ohio Railway Company;
- Indiana Southern Railroad, LLC;
- Kiamichi Railroad Co., LLC;
- Kyle Railroad Co.;
- Marquette Rail, LLC;
- The Massena Terminal Railroad Co.;
- Mid-Michigan Railroad, Inc.;
- Michigan Shore Railroad, Inc.;
- Missouri & Northern Arkansas Railroad Co., Inc.;
- New England Central Railroad, Inc.;
- North Carolina & Virginia Railroad Co., LLC;
- Otter Tail Valley Railroad Co., Inc.;
- Point Comfort & Northern Railway Co.;
- Puget Sound & Pacific Railroad; Rockdale,
- Sandow & Southern Railroad Co.;
- San Diego & Imperial Valley Railroad Co., Inc.;
- San Joaquin Valley Railroad Co.;
- South Carolina Central Railroad Co., LLC;
- Texas Northeastern Railroad;
- Three Notch Railway, LLC;
- Toledo, Peoria & Western Railway Corp.;
- Ventura County Railroad Corp.;
- Wellsboro & Corning Railroad, LLC; and
- Wiregrass Central Railway, LLC.

RR Acquisition Holding, LLC, a noncarrier affiliate of Fortress Investment Group, currently owns approximately 60% of RailAmerica's publicly traded shares.

[FR Doc. 2012–21846 Filed 9–4–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. EP 670 (Sub-No. 1)]

Notice of Rail Energy Transportation Advisory Committee Meeting

AGENCY: Surface Transportation Board, Department of Transportation.

ACTION: Notice of Rail Energy Transportation Advisory Committee meeting.

SUMMARY: Notice is hereby given of a meeting of the Rail Energy Transportation Advisory Committee (RETAC), pursuant to section 10(a)(2) of the Federal Advisory Committee Act, as amended.

DATES: The meeting will be held on Thursday, September 20, 2012, at 9 a.m., E.D.T.

ADDRESSES: The meeting will be held in the Hearing Room on the first floor of the Board's headquarters at 395 E Street SW., Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Scott M. Zimmerman (202) 245–0386. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at: (800) 877–8339].

SUPPLEMENTARY INFORMATION: RETAC arose from a proceeding instituted by the Board, in *Establishment of a Rail Energy Transportation Advisory Committee,* STB Docket No. EP 670. RETAC was formed to provide advice and guidance to the Board, and to serve as a forum for discussion of emerging issues regarding the transportation by rail of energy resources, particularly, but not necessarily limited to, coal, ethanol, and other biofuels. The purpose of this meeting is to continue discussions regarding issues such as rail performance, capacity constraints, infrastructure planning and development, and effective coordination among suppliers, carriers, and users of energy resources. Potential agenda items include presentations by the Energy Information Administration on its latest projections on coal supply and short- and long-term oil production; a discussion of tank car supply and demand issues; industry segment reports by RETAC members; and a roundtable discussion.

The meeting, which is open to the public, will be conducted pursuant to RETAC's charter and Board procedures. Further communications about this meeting may be announced through the Board's Web site at *WWW.STB.DOT.GOV.*

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Authority: 49 U.S.C. 721, 49 U.S.C. 11101; 49 U.S.C. 11121.

Decided: August 29, 2012.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2012–21801 Filed 9–4–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

United States Mint

Price for the 2012 Annual Uncirculated Dollar Coin Set

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is announcing a price of $54.95 for the 2012 Annual Uncirculated Dollar Coin Set. This set contains the following

uncirculated coins: four Presidential $1 Coins, one Native American $1 Coin, and one American Eagle Silver Coin.

FOR FURTHER INFORMATION CONTACT: B. B. Craig, Associate Director for Sales and Marketing; United States Mint; 801 9th Street, NW; Washington, DC 20220; or call 202–354–7500.

Authority: 31 U.S.C. 5111, 5112 & 9701.

Dated: August 28, 2012.

Richard A. Peterson,

Deputy Director, United States Mint.

[FR Doc. 2012–21739 Filed 9–4–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of a New System of Records.

SUMMARY: The Privacy Act of 1974 (5 U.S.C. 552(a)(e)) requires all agencies to publish in the **Federal Register** a notice of the existence and character of their systems of records. Notice is hereby given that the Department of Veterans Affairs (VA) is establishing a new system of records entitled ''VA Child Care Subsidy Program Records-VA'' (165VA05CCSP).

DATES: Comments on this new system of records must be received no later than October 5, 2012 If no public comment is received during the period allowed for comment, or unless otherwise published in the **Federal Register** by the VA, the new system will become effective October 5, 2012.

ADDRESSES: Written comments concerning the proposed new system of records may be submitted by: mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; fax to (202) 273–9026; or email to *http://www.Regulations.gov.* All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 (this is not a toll-free number) for an appointment.

FOR FURTHER INFORMATION CONTACT: The Office of Human Resources Management, Privacy Officer, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, telephone (202) 461–7863.

SUPPLEMENTARY INFORMATION: VA proposes to establish this new system of records, entitled ''Child Care Subsidy Program-VA'' (165VA05CCSP). This system will contain personal information submitted by lower-income employees who apply for VA child care subsidy benefits. This information will be used to establish and verify eligibility and the amount of the subsidy. The information will come from application forms and supporting documentation submitted by and on behalf of VA employees.

The notice of intent to publish and an advance copy of the system notice have been sent to the appropriate congressional committees and to the Director of the Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Approved: July 5, 2012.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

165VA05CCSP

SYSTEM NAME:

''Child Care Subsidy Program—VA''

SYSTEM LOCATION:

Applications to participate in the Department of Veterans Affairs (VA) Child Care Subsidy Program are currently submitted through the field facility Human Resources offices. The records are then shipped or submitted electronically to the VA Central Office Child Care Subsidy Program Service (05CCSP). Policy issues concerning this program should be submitted to the Work life and Benefits Service (058) at 810 Vermont Avenue NW., Washington, DC 20420.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees of the VA who voluntarily apply for child care subsidy program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Application forms for child care subsidy program contains personal information, including employee (parent) name, social security number, pay grade, telephone numbers, total family income, names of children on whose behalf the parent is applying for subsidy, children's dates of birth; information on child care providers used, including day care provider's names, addresses, provider license numbers and States where issued, and provider tax identification number; and copies of IRS Form 1040 and 1040A for verification purposes.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Law 1 06–58, Section 643 and Executive Order 9397

PURPOSE(S)

To establish and verify VA employees' eligibility for child care subsidies in order for VA to provide monetary assistance to its employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. For Law Enforcement Purposes—To disclose pertinent information to the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where VA becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

2. For Congressional Inquiry—To provide information to a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of that individual.

3. For Judicial/Administrative Proceedings—To disclose information to another Federal agency, to a court, or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency, when the Government is a party to the judicial or administrative proceeding. In those cases where the Government is not a party to the proceeding, records may be disclosed if a subpoena has been signed by a judge.

4. For National Archives and Records Administration and General Services Administration—To disclose to the National Archives and Records Administration and the General Services Administration in records management inspections conducted under authority of Title 44 of the U.S. Code.

5. Within VA for Statistical/Analytical Studies—By VA in the production of summary descriptive statistics and analytical studies in support of the function for which records are collected and maintained, or for related workforce studies. While published studies do not contain individual identifiers, in some instances the selection of elements of data included in the study may be structured in such a way as to make the data individually identifiable by inference.

6. For Litigation—To disclose information to the Department of Justice, or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when: (1) VA, or

any component thereof; or (2) Any employee of VA in his or her official capacity; or (3) Any employee of VA in his or her individual capacity where the Department of Justice or VA has agreed to represent the employee; or (4) The United States, when VA determines that litigation is likely to affect VA or any of its components; is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or VA is deemed by VA to be relevant and necessary to the litigation provided, however, that the disclosure is compatible with the purpose for which records were collected.

7. For the Merit Systems Protection Board—To disclose information to officials of the Merit Systems Protection Board or the Office of the Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of VA rules and regulations, investigations of alleged or possible prohibited personnel practices, and such other functions, e.g., as promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

8. For the Equal Employment Opportunity Commission—To disclose information to the Equal Employment Opportunity Commission when requested in connection with an investigation into alleged or possible discrimination practices in the Federal sector, compliance by Federal agencies with the Uniform Guidelines on Employee Selection Procedures or other functions vested in the Commission and to otherwise ensure compliance with the provisions of 5 U.S.C. 7201.

9. For the Federal Labor Relations Authority—To disclose information to the Federal Labor Relations Authority or its General Counsel when requested in connection with investigations of allegations of unfair labor practices or matters before the Federal Service Impasses Panel.

10. For Non-Federal Personnel—To disclose information to contractors, grantees, or volunteers performing or working on a contract, service, grant, cooperative agreement, or job for the Federal government.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information may be collected on paper or electronically and may be stored as in paper or electronic format.

RETRIEVABILITY:

By name; may also be cross-referenced to social security number or other personal identifying number.

SAFEGUARDS:

When not in use by an authorized person, paper records are stored in lockable file cabinets or secured rooms. Electronic records are protected by the use of passwords.

RETENTION AND DISPOSAL:

Disposition of records is according to the National Archives and Records Administration guidelines.

SYSTEM MANAGER(S) ADDRESS:

Director, Child Care Subsidy Program Office, Office of Human Resources Management, 810 Vermont Avenue NW., Washington, DC 20420.

NOTIFICATION PROCEDURE:

Individuals may submit a request on whether a system contains records about them to the system manager indicated. Individuals must furnish the following for their records to be located and identified:

a. Full name

b. Social Security Number

RECORD ACCESS PROCEDURE:

Individuals wishing to request access to records about them should contact the system manager indicated. Individuals must provide the following information for their records to be located and identified:

a. Full name

b. Social Security Number

Individuals requesting access must also follow the Office of Personnel Management's Privacy Act Regulations regarding verification of identity and amendment of records (5 CFR, Part 297).

CONTESTING RECORDS PROCEDURE:

Individuals wishing to request amendment of records about them should contact the system manager indicated. Individual must furnish the following information for their records to be located and identified:

a. Full name

b. Social Security Number

Individuals requesting amendment must also follow the Office of Personnel Management's Privacy Act Regulations regarding verification of identity and amendment of records (5 CFR part 297).

RECORD SOURCE CATEGORIES:

Information is provided by VA employees who apply for child care subsidy. Furnishing the information is voluntary.

[FR Doc. 2012–21792 Filed 9–4–12; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 77 Wednesday,

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

45 CFR Part 162

Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD–10–CM and ICD–10–PCS) Medical Data Code Sets; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 162

[CMS–0040–F]

RIN 0938–AQ13

Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD–10–CM and ICD–10–PCS) Medical Data Code Sets

AGENCY: Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule adopts the standard for a national unique health plan identifier (HPID) and establishes requirements for the implementation of the HPID. In addition, it adopts a data element that will serve as an other entity identifier (OEID), or an identifier for entities that are not health plans, health care providers, or individuals, but that need to be identified in standard transactions. This final rule also specifies the circumstances under which an organization covered health care provider must require certain noncovered individual health care providers who are prescribers to obtain and disclose a National Provider Identifier (NPI). Lastly, this final rule changes the compliance date for the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding, including the Official ICD–10–CM Guidelines for Coding and Reporting, and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, including the Official ICD–10–PCS Guidelines for Coding and Reporting, from October 1, 2013 to October 1, 2014.

DATES: *Effective date:* These regulations are effective on November 5, 2012. *Compliance dates:* Health plans with the exception of small health plans must obtain an HPID by November 5, 2014. Small health plans must obtain an HPID by November 5, 2015. Covered entities must use HPIDs in the standard transactions on or after November 7, 2016. An organization covered health care provider must comply with the implementation specifications in § 162.410(b) by May 6, 2013.

FOR FURTHER INFORMATION CONTACT: Kari Gaare (410) 786–8612, Matthew Albright (410) 786–2546, and Denise Buenning (410) 786–6711.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary for This Final Rule

1. Purpose

a. Need for the Regulatory Action

This rule adopts a standard unique health plan identifier (HPID) and a data element that will serve as an other entity identifier (OEID). This rule also adopts an addition to the National Provider Identifier (NPI) requirements. Finally, this rule changes the compliance date for the ICD–10–CM and ICD–10–PCS medical data code sets (hereinafter ''code sets'') from October 1, 2013 to October 1, 2014.

(1) HPID

Currently, health plans and other entities that perform health plan functions, such as third party administrators and clearinghouses, are identified in Health Insurance Portability and Affordability Act of 1996 (HIPAA) standard transactions with multiple identifiers that differ in length and format. Covered health care providers are frustrated by various problems associated with the lack of a standard identifier, such as: improper routing of transactions; rejected transactions due to insurance identification errors; difficulty in determining patient eligibility; and challenges resulting from errors in identifying the correct health plan during claims processing.

The adoption of the HPID and the OEID will increase standardization within HIPAA standard transactions and provide a platform for other regulatory and industry initiatives. Their adoption will allow for a higher level of automation for health care provider offices, particularly for provider processing of billing and insurance related tasks, eligibility responses from health plans, and remittance advice that describes health care claim payments.

(2) NPI

In the January 23, 2004 **Federal Register** (69 FR 3434), the U.S. Department of Health and Human Services (HHS) published a final rule establishing the standard for a unique health identifier for health care providers for use in the health care system and adopting the National Provider Identifier (NPI) as that standard (''2004 NPI final rule''). The rule also established the implementation specifications for obtaining and using the NPI. Since that time, pharmacies have encountered situations where they need to include the NPI of a prescribing health care provider in a pharmacy claim, but where the prescribing health care provider has been a noncovered health care provider who did not have an NPI because he or she was not required to obtain one. This situation has become particularly problematic in the Medicare Part D program. The addition to the NPI requirements addresses this issue.

(3) ICD–10–CM and ICD–10–PCS Code Sets

In the January 16, 2009 **Federal Register** (74 FR 3328), HHS published a final rule in which the Secretary of HHS (the Secretary) adopted the ICD–10–CM and ICD–10–PCS (ICD–10) code sets as the HIPAA standards to replace the previously adopted International Classification of Diseases, 9th Revision, Clinical Modification, Volumes 1 and 2 (diagnoses), and 3 (procedures) including the Official ICD–9–CM Guidelines for Coding and Reporting. The compliance date set by the final rule was October 1, 2013.

Since that time, some provider groups have expressed strong concern about their ability to meet the October 1, 2013 compliance date and the serious claims payment issues that might ensue if they do not meet the date. Some providers' concerns about being able to meet the ICD–10 compliance date are based, in part, on difficulties they had meeting the compliance deadline for the adopted Associated Standard Committee's (ASC) X12 Version 5010 standards (Version 5010) for electronic health care transactions. Compliance with Version 5010 and ICD–10 by all covered entities is essential to a smooth transition to the updated medical data code sets, as the failure of any one industry segment to achieve compliance would negatively affect all other industry segments and result in returned claims and provider payment delays. We believe the change in the compliance date for ICD–10 gives covered health care providers and other covered entities more time to prepare and fully test their systems to ensure a smooth and coordinated transition by all covered entities.

b. Legal Authority for the Regulatory Action

(1) HPID

This final rule implements section 1104(c)(1) of the Affordable Care Act and section 1173(b) of the Social

Security Act (the Act) which require the adoption of a standard unique health plan identifier.

(2) NPI

This final rule imposes an additional requirement on organization health care providers under the authority of sections 1173(b) and 1175(b) of the Act. It also accommodates the needs of certain types of health care providers in the use of the covered transactions, as required by section 1173(a)(3) of the Act.

(3) ICD–10–CM and ICD–10–PCS

This final rule sets a new compliance date for the ICD–10 code sets, in accordance with section 1175(b)(2) of the Act, under which the Secretary determines the date by which covered entities must comply with modified standards and implementation specifications.

2. Summary of the Major Provisions

a. HPID

This rule adopts the HPID as the standard unique identifier for health plans and defines the terms ''Controlling Health Plan'' (CHP) and ''Subhealth Plan'' (SHP). The definitions of these two terms differentiate health plan entities that are required to obtain an HPID, and those that are eligible, but not required, to obtain an HPID. This rule requires all covered entities to use an HPID whenever a covered entity identifies a health plan in a covered transaction. Because health plans today have many different business structures and arrangements that affect how health plans are identified in standard transactions, we established requirements for CHPs and SHPs in order to enable health plans to obtain HPIDs to reflect different business arrangements so they can be identified appropriately in standard transactions.

This rule also adopts a data element to serve as an other entity identifier. The OEID will function as an identifier for entities that are not health plans, health care providers, or individuals (as defined in 45 CFR 160.103), but that need to be identified in standard transactions (including, for example, third party administrators, transaction vendors, clearinghouses, and other payers). Under this final rule, other entities are not required to obtain an OEID, but they could obtain and use one if they need to be identified in covered transactions. Because other entities are identified in standard transactions in a similar manner as health plans, we believe that establishing an identifier for other entities will increase efficiency by facilitating the use of a uniform identifier.

b. NPI

This rule requires an organization covered health care provider to require certain noncovered individual health care providers who are prescribers to: (1) obtain NPIs; and (2) to the extent the prescribers write prescriptions while acting within the scope of the prescribers' relationship with the organization, disclose them to any entity that needs the NPIs to identify the prescribers in standard transactions. This addition to the NPI requirements would address the issue that pharmacies are encountering when the NPI of a prescribing health care provider needs to be included on a pharmacy claim, but the prescribing health care provider does not have, or has not disclosed, an NPI.

c. ICD–10–CM and ICD–10–PCS

This rule changes the compliance date for ICD–10–CM and ICD–10–PCS from October 1, 2013 to October 1, 2014. We believe this change will give covered entities the additional time needed to synchronize system and business process preparation and changeover to the updated medical data code sets.

3. Summary of Costs and Benefits

a. HPID

The HPID is expected to yield the most benefit for providers, while health plans will bear most of the costs. Costs to all commercial and government health plans together (Medicare, Medicaid programs, Indian Health Service (IHS), and Veterans Health Administration (VHA)) are estimated to be $650 million to $1.3 billion. However, commercial and government health plans are expected to make up those costs in savings. Further, it is our understanding that the industry will not find the HPID requirements to be overly burdensome. Many entities have indicated that they have delayed regular system updates and maintenance, as well as the issuance of new health plan identification cards, in order to accommodate the adoption of the HPID.

Health care providers can expect savings from two indirect consequences of HPID implementation: (1) The cost avoidance of decreased administrative time spent by providers interacting with health plans; and (2) a material cost savings through automation of processes for every transaction that moves from manual to electronic implementation. HPID's anticipated 10-year return on investment for the entire health care industry is expected to be between $1.3 billion to $6 billion. (This estimate includes savings resulting from the ongoing effects of adopting the HPID rather than the immediate and direct budgetary effects.)

b. NPI

The addition to the requirements for the NPI will have little impact on health care providers and on the health industry at large because few health care providers do not already have an NPI. In addition, covered organization health care providers may comply by various means. For example, a covered organization could use a simple verbal directive to prescribers whom they employ or contract with to meet the requirements. Alternately, a covered organization could update employment or contracting agreements with the prescribers. For these reasons, we believe the additional NPI requirements do not impose spending costs on State government or the private sector in any 1 year of $136 million or more, the threshold specified in the Unfunded Mandates Reform Act (UMRA).

c. Change of Compliance Date of ICD–10

According to a recent survey conducted by the Centers for Medicare & Medicaid Services (CMS), up to one quarter of health care providers believe they will not be ready for an October 1, 2013 compliance date.[1] While the survey found no significant differences among practice settings regarding the likelihood of achieving compliance before the deadline, based on recent industry feedback we believe that larger health care plans and providers generally are more prepared than smaller entities. The uncertainty about provider readiness is confirmed in another recent readiness survey in which nearly 50 percent of the 2,140 provider respondents did not know when they would complete their impact assessment of the ICD–10 transition.[2]

By delaying the compliance date of ICD–10 from October 1, 2013 to October 1, 2014, we are allowing more time for covered entities to prepare for the transition to ICD–10 and to conduct

[1] Version 5010 and ICD–10 Readiness Assessment: Conducted among health Care providers, payers and Vendors for the Centers for Medicare & Medicaid Services (CMS), December 2011 (OMB Approval No: 09938–1149). The assessment surveyed 404 providers, 101 payers, and 90 vendors, which represents 0.1% of all physician practices, 3% of hospitals, and 5% of health plans.

[2] An impact assessment for ICD–10 is performed by a covered entity to determine business areas, policies, processes and systems, and trading partners that will be affected by the transition to ICD–10. An impact assessment is a tool to aid in planning for implementation. ''Survey: ICD–10 Brief Progress,'' February 2012, conducted by the Workgroup for Electronic Data Interchange (WEDI).

thorough testing. By allowing more time to prepare, covered entities may be able to avoid costly obstacles that would otherwise emerge while in production.

Savings will come from the avoidance of costs that would occur as a consequence of significant numbers of providers being unprepared for the transition to ICD–10. In the Regulatory Impact Analysis (RIA) of this final rule, we estimate that there would be a cost avoidance of approximately $3.6 billion to nearly $8 billion in this regard. This range of estimates reflects the avoidance of two costly consequences that could occur should the compliance date remain October 1, 2013: (1) both health care providers and health plans could have to process health care claims manually in order for claims to be paid; and (2) small health care providers could have to take out loans or apply for lines of credit in order to continue to provide health care in the face of delayed payments.

In terms of costs, commercial health plans, medium and large hospitals, and large physician practices are far along in their ICD–10 implementation planning, and therefore have devoted funds, resources, and staff to the effort. According to our estimates, a 1-year delay of the ICD–10 compliance date would add 10 to 30 percent to the total cost that these entities have already spent or budgeted for the transition—an additional cost to commercial entities of approximately $1 billion to $6.4 billion. Medicare and State Medicaid Agencies have also reported estimates of costs of a change in the compliance date in recent informal polls. Accordingly, the calculations in the RIA in this final rule demonstrate that a 1-year delay in the compliance date of ICD–10 would cost the entire health care industry approximately $1 billion to $6.6 billion.

We assume that the costs and cost avoidance calculated in the RIA will be incurred roughly over a 6- to 12-month period, from October 1, 2013 to October 1, 2014. For simplicity sake, however, both the costs and the cost avoidance that result from a change in the compliance date of ICD–10 are calculated over the calendar year, 2014.

We solicited comments on our assumptions and conclusions in the RIA.

B. Background

1. Legislative and Regulatory Overview

In the April 17, 2012 **Federal Register** (77 FR 22950), we published a proposed rule titled ''Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD–10–CM and ICD–10–PCS Medical Data Code Sets'' (hereinafter referred to as the April 2012 proposed rule). The April 2012 proposed rule provides an overview of the statutory provisions and regulations that are relevant for purposes of the April 2012 proposed rule (77 FR 22952 through 22954) and this final rule. We refer readers to that discussion.

C. The Unique Health Plan Identifier (HPID) and the Affordable Care Act

Section 1104(c)(1) of the Affordable Care Act directs the Secretary to promulgate a final rule establishing a unique health plan identifier that is based on the input of a Federal advisory committee, the National Committee on Vital and Health Statistics (NCVHS). Congress created the NCVHS to serve as an advisory body to the Secretary on health data, statistics, and national health information policy. Section 1104 of the Affordable Care Act authorizes the Secretary to promulgate the rule on an interim final basis and indicates that such rule shall be effective not later than October 1, 2012.

Health plans are currently identified for different purposes using different identifiers that have different sources, formats, and meaning. A health plan may have multiple identifiers, each assigned by a different organization for a different purpose. The following discussion focuses on the types of identifiers that currently may be used to identify health plans in standard transactions. State regulators, for instance, use the National Association of Insurance Commissioners' (NAIC) Company code to identify health plans when a health plan is licensed to sell or offer health insurance in a particular State. The U.S. Department of Labor (DOL) and the Internal Revenue Service (IRS) use the 9-digit Employer Identification Number (EIN) and a 1-digit alphabetic or a 3-digit plan number to identify health plans. Employers, sole proprietorships, corporations, partnerships, non-profit associations, trusts, estates of decedents, government agencies, certain individuals, and other business entities, use EINs to identify health plans for a host of purposes and transactions. The IRS uses the EIN to identify taxpayers that are required to file various business tax returns. Health care clearinghouses assign proprietary identifiers to health plans for use in standard transactions. Multiple clearinghouses may identify the same health plan using different proprietary identifiers in different covered transactions. Health plans may use other identifiers, such as a tax identification number (TIN) or an EIN, to identify themselves in the standard transactions, to more easily integrate into existing proprietary systems, or for use on health insurance cards that they issue to health plan enrollees.

Not only are health plans identified using a variety of identifiers, but these identifiers have different formats. For instance, some identifiers are alphanumeric while other identifiers are only numeric. Identifiers also differ in length; for example, NAIC codes are typically five digits while an EIN is nine digits.

The current versions of the adopted standards (ASC X12N and NCPDP) allow health plans to use these and other identifiers in standard transactions. Therefore, for the covered transactions there is currently no requirement for consistency in the use of identifiers for health plans. The transaction standards implementation guides, though, do provide for the use of the HPID once its use is mandated and during a phase-in period. Prior to this rule, health care providers, health plans, and health care clearinghouses consequently could use EINs, TINs, NAIC numbers, or health care clearinghouse or health plan-assigned proprietary numbers to identify health plans in standard transactions. Industry stakeholders, especially health care providers, have indicated that the lack of a standard unique health plan identifier has resulted in increased costs and inefficiencies in the health care system. Health care providers are frustrated by problems with: the routing of transactions; rejected transactions due to insurance identification errors; difficulty determining patient eligibility; and challenges resolving errors identifying the health plan during claims processing.

The Affordable Care Act specifically calls for the establishment of a unique identifier for health plans. There are however, other entities that are not health plans but that perform certain health plan functions and are currently identified in the standard transactions in the same fields using the same types of identifiers as health plans. For example, health care clearinghouses, third party administrators (TPAs), and repricers often contract with insurance companies, self-funded group health plans, and provider- or hospital-run health plans to perform claims administration, premium collection, enrollment, and other administrative functions. As explained later in this final rule, we are adopting a data element—an other entity identifier—to

serve as an identifier for these other entities.

D. The National Committee on Vital and Health Statistics (NCVHS)

The NCVHS has been assigned a significant role in the Secretary's adoption of all standards, code sets, and operating rules under HIPAA, including the unique health plan identifier. In section 1104(c)(1) of the Affordable Care Act, the Secretary is directed to conduct rulemaking to establish a unique health plan identifier based on input of the NCVHS.

The NCVHS Subcommittee on Standards fulfilled these duties by conducting public hearings on the health plan identifier on July 19 through 21, 2010. Industry stakeholders, including representatives from health plans, health care provider organizations, health care clearinghouses, pharmacy industry representatives, standards developers, professional associations, representatives of Federal and State public programs, the Workgroup on Electronic Data Interchange (WEDI), the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), and individuals with health plan identifier proposals provided in-person and written testimony. Stakeholder testimony at the hearings focused on the use and need for an HPID to: facilitate the appropriate routing of transactions; reduce the cost of managing financial and administrative information; improve the accuracy and timeliness of claims payment; and reduce dissatisfaction among health care providers and patients/members by improving communications with health plans and their intermediaries. Stakeholders provided suggestions on the types of entities that need to be identified in standard transactions, those that should be eligible to obtain an HPID, and the level of enumeration for each plan (for example, the legal entity, product, benefit package etc.).

For a full discussion of the key topics and recommendations from the July 19 through 21, 2010 NCVHS hearings, we refer the reader to the April 2012 proposed rule (77 FR 22950). For the complete text of the NCVHS' observations and recommendations, go to *http://www.ncvhs.hhs.gov/100930lt1.pdf.*

E. Definition of Health Plan

The regulatory definition of health plan at 45 CFR 160.103 was initially adopted in the August 17, 2000 Standards for Electronic Transactions final rule (65 FR 50312) (hereafter Transactions and Code Sets final rule). The basis for the additions to, and clarifications of, the definition of health plan is further discussed in the preamble to the December 28, 2000 final rule (65 FR 82478 and 82576) titled ''Standards for Privacy of Individually Identifiable Health Information'' (hereinafter referred to as the Privacy Rule). For additional information on the definition of health plan, we refer readers to these rules.

F. The April 2012 Proposed Rule and Analysis of and Responses to Public Comments

In the April 2012 proposed rule, we proposed the following:

- The adoption of the standard for a national unique HPID for use in all transactions for which the Secretary has adopted a standard (hereinafter referred to as standard transactions).
- An OEID for use by entities that do not meet the definition of a health plan, but that need to be identified in the standard transactions.
- Requirements and provisions for the implementation of both the HPID and OEID.
- Additions to the NPI requirements mandating that covered health care providers require certain noncovered individual health care providers who are prescribers to obtain NPIs.
- To change the compliance date for ICD–10 code sets from October 1, 2013 to October 1, 2014.

In the April 2012 proposed rule, we solicited public comments on a number of proposals. In response to our solicitation, we received approximately 536 timely pieces of correspondence. Summaries of the public comments that are within the scope of the proposed rule and our responses to those comments are set forth in the various sections of this final rule under the corresponding headings.

II. Adopting a Standard for a Unique Health Plan Identifier (HPID)

A. The Health Plan Identifier

We proposed HPID as the standard unique identifier for health plans. We also proposed: (1) Instructions and guidance concerning how health plans may obtain an HPID; (2) the requirements that covered entities will have to meet to use the HPID in standard transactions; and (3) provisions for the HPID in a new subpart (subpart E) at 45 CFR part 162.

1. Definition of ''Controlling Health Plan'' and ''Subhealth Plan''

Health plans today have many different business structures and arrangements that affect how health plans are identified in standard transactions. There is often a ''parent'' corporation that meets the definition of health plan, which may be controlled by entities, such as holding companies, that do not meet the definition of health plan. This ''parent'' health plan may own and operate several other entities and organizations, which may also meet the definition of a health plan. While these individual health plans that are owned by the same ''parent'' corporation may have their own EIN or NAIC number, they may all use a single identifier in covered transactions because of data processing arrangements. In these situations, some health plans may not need to be identified separately in covered transactions, and may not need their own health plan identifier. To differentiate between health plan entities that would be required to obtain an HPID, and those that would be eligible, but not required, to obtain an HPID, we proposed and are adopting in this final rule, to categorize health plans as controlling health plans (CHPs) and subhealth plans (SHPs).

The definitions of CHPs and SHPs are established in 45 CFR 162.103 as follows:

a. Controlling Health Plan (CHP)

A CHP means a health plan that—(1) controls its own business activities, actions, or policies; or (2)(i) is controlled by an entity that is not a health plan; and (ii) if it has a subhealth plan(s), exercises sufficient control over the subhealth plan(s) to direct its/their business activities, actions, or policies.

We suggested that the following considerations may be helpful in determining if an entity is a CHP:

- Does the entity itself meet the definition of health plan at 45 CFR 160.103?
- Does either the entity itself or a non health plan organization control the business activities, actions, or policies of the entity?

If the answer to both questions is ''yes,'' then the entity would meet the definition of CHP. We proposed that an entity that meets the definition of CHP would be required to obtain a health plan identifier.

b. Subhealth Plan (SHP)

We proposed that a SHP means a health plan whose business activities, actions, or policies are directed by a controlling health plan.

We suggested that the following considerations may be helpful in determining whether an entity is a SHP:

• Does the entity meet the definition of health plan at § 160.103?

• Does a CHP direct the business activities, actions, or policies of the health plan entity?

If the answer to both questions is ''yes,'' then the entity meets the definition of SHP. We proposed that a SHP would not be required to obtain an HPID, but may choose to obtain an HPID, or its CHP may obtain an HPID on its behalf.

Comment: We received a few comments on the proposed definitions of CHP and SHP. Some commenters liked the proposed definitions, believing they would aid health plans in determining the appropriate enumeration level. A few commenters suggested alternatives to either broaden or narrow the definition of CHP. Commenters that requested a broader definition were generally concerned that the definition was not sufficiently broad to encompass the legal structures utilized by various third party payors. As a result, ambiguity in the standard transactions occurs because of the numerous different ways in which health plans functions are performed by different entities and the numerous ways the term ''health plan'' is interpreted. These commenters suggested that HHS expand the definition of CHP to encompass any and all potential legal relationships between holding companies and their subsidiaries that hold health insurance licenses. These commenters also requested that after HHS broadens the definition of CHP, that the CHP be required to obtain a separate HPID for each of the health plans' subsidiaries involved in the healthcare delivery system, specifically for the entities that are involved as fiduciaries with legal responsibilities for paying claims, any administrator responsible for administering any aspect of the benefits, and any holder of the participation contract with the physicians or other health care providers. These commenters suggested that HHS revisit the definition of health plan at 45 CFR 160.103 to include each of the intermediaries involved in the multitude of transactions that occur in administering payment.

Response: HHS was tasked with creating a unique health plan identifier. The term ''health plan'' is defined in section 1171(5) of the Act and at 45 CFR 160.103 of the regulations. We do not believe Congress intended to include in the definition of health plan entities that solely perform the functions of third party administrators or repricers. In addition, while we recognize that health plans and other entities that perform health plan functions may be identified in similar fields in the standard transactions, they are distinctly different organizations with different purposes. Furthermore, we proposed the adoption of a data element that will serve as the OEID discussed in section II.B. of this final rule to meet industry's need for a standard identifier for entities that do not meet the definition of health plan, but that perform related functions.

Comment: A commenter suggested that HHS narrow the definition of a CHP so that it means ''a health plan that—(1) controls its own business activities, actions, *and* policies; or (2) (i) is controlled by an entity that is not a health plan; and (ii) if it has a subhealth plan(s) (as defined in this section), exercises sufficient control over the subhealth plan(s) to direct its/their business activities, actions, *and* policies.''

Response: We believe that a narrow definition of CHP would not capture all of the ''parent'' organizations that should be required to obtain HPIDs for themselves and be authorized to obtain HPIDs for their subhealth plans, to accomplish the goals at this stage of standardization. We distinguish between CHPs and SHPs because health plans have different business structures and arrangements that determine how they are identified in the standard transactions. We recognize that different organizations may divide business responsibilities in various ways. For example, a ''parent'' organization that meets the definition of health plan may dictate some business activities, actions, or policies, but may not control all business activities, actions, or policies of entities that they own or operate that also meet the definition of health plan. Given the variations in structures and relationships, we used the word ''or'' rather than ''and'' to provide more flexibility to health plans and ensure that ''parent'' organizations are classified as CHPs and are required to obtain HPIDs.

After consideration of the public comments received, we are finalizing the definitions of CHP and SHP without modification.

2. Use of the HPID

In 45 CFR 162.510, we proposed that all covered entities would be required to use an HPID where a covered entity identifies a health plan in a covered transaction. We proposed further that, if a covered entity uses a business associate to conduct standard transactions on its behalf, the covered entity must require its business associate to use an HPID to identify a health plan where the business associate identifies a health plan in all covered transactions.

We proposed in § 162.506 that the HPID could also be used for any other lawful purpose, and provided some examples of permitted uses including the following:

• Health plans may use HPIDs in their internal files to facilitate processing of health care transactions.

• A health plan may use an HPID on a health insurance card.

• The HPID may be used as a cross-reference in health care fraud and abuse files and other program integrity files.

• Health care clearinghouses may use HPIDs in their internal files to create and process standard and nonstandard transactions and in communications with health plans and health care providers.

• HPIDs may be used in patient medical records to help specify patients' health care benefit package(s).

• HPIDs may be used to identify health plans in electronic health records (EHRs).

• HPIDs may be used to identify health plans in Health Information Exchanges (HIEs).

• HPIDs may be used to identify health plans in Federal and State health insurance exchanges.

• HPIDs may be used to identify health plans for public health data reporting purposes.

Comment: Many commenters requested further clarification of the purpose, intent, and use of the HPID, specifically if and how the HPID should be used in the standard transactions. For instance, they suggested more guidance on if and where the HPID should be used in the standard transactions and on the ISA envelope.

Response: We direct these commenters to the adopted transaction standards, the relevant implementation guides, and as appropriate, adopted operating rules, for direction on if and when to use the HPID. We note that the only required use of the HPID is that a covered entity must use an HPID to identify a health plan that has an HPID in the standard transactions where the covered entity is identifying a health plan in the standard transaction. This final rule does not require that health plans now be identified in the standard transactions if they were not identified before this rule. For instance, if a covered entity is currently identifying a health plan as the information source in the eligibility response transaction (271), Loop 2100A, Segment NM1—information source name, the covered entity will be required to use an HPID to identify that health plan as the information source once the HPID is

required. If a covered entity is currently identifying a third party administrator as the information source, the covered entity can continue to identify that third party administrator as the information source using whatever identifier the third party administrator uses after the adoption of the HPID. We anticipate we will provide additional examples of how the HPID can be used in the standard transactions outside of this final rule.

In their request for clarification, some of these commenters appeared confused regarding the affirmative obligation in 45 CFR 162.510 for covered entities to use an HPID to identify a health plan in standard transactions, when a SHP may not have its own HPID. In those cases, covered entities would use the HPID that the SHP indicates should be used to identify that SHP, which may be the HPID of its controlling health plan. If an entity has in good faith sought to identify the HPID that should be used for a SHP that has no HPID and has been unsuccessful, then it obviously cannot use an HPID to identify that SHP. However, we would anticipate that those circumstances would be rare. Nevertheless, consistent with these commenters' request to clarify the requirement, we have inserted ''that has an HPID'' immediately after ''health plan'' in § 162.510(a) and (b). We consider a health plan as ''having an HPID'' if that health plan communicates with its trading partners that it consistently uses a particular HPID, even if the HPID it uses is associated with another health plan, such as its controlling health plan.

Comment: A few commenters stated that they saw the primary purpose of the HPID as a way to eliminate the ambiguity that currently exists in the covered transactions. They note that various nonhealth plans perform certain administrative functions currently performed by health plans.

Response: These comments imply that the Department should expand the definition of ''health plan'' to include entities that are not health plans as defined by statute and regulation. Previously, we addressed why this rule does not expand the definition of health plan, and further, why we take an incremental approach in the adoption of the HPID and OEID. We seek to allow the industry time and flexibility for implementing these unique identifiers. We created the other entity identifier to provide standardization for these entities that do not meet the definition of health plan, for instance. While the use of the OEID is voluntary, its use can facilitate the standardization of electronic administrative and financial transactions.

Comment: Some commenters expressed concern that the HPID requirements and provisions are not clearly defined for industry implementation. Commenters recommended that pilot testing occur prior to the adoption of the HPID, to ensure proper and consistent implementation. Some commenters suggested that the Department work with the NCVHS to determine if operating rules for the use of HPID are necessary to clarify any implementation issues that arise following HPID implementation.

Response: We anticipate this rule serving as a first step in standardizing the way health plans are identified in the standard transactions. We note that the only required use of the HPID is to identify a health plan that has an HPID where a health plan is identified in the standard transactions. Health plans, except small health plans, have until 2 years after the effective date of this rule to obtain HPIDs. Small health plans have until 3 years after the effective date of this rule to obtain HPIDs. Covered entities are not required to use HPIDs in the standard transactions until 4 years after the effective date of this rule. (For further discussion of the HPID compliance date see section II.E. of this final rule.) The rule provides ample time for covered entities to develop their own implementation timelines, which we suggest could include pilot testing, and milestones to ensure they meet the compliance dates.

As we explained in the April 2012 proposed rule, a health plan may need to be identified in different fields in the transactions and these fields may not always require the use of a health plan identifier. For instance, the information source, in the eligibility response transaction (271), Loop 2100A, Segment NM1, may be a health plan, or an other entity that performs health plan functions, like a third party administrator. So after the applicable compliance date of the HPID, if a covered entity is identifying a health plan as the information source in the eligibility response transaction (271), Loop 2100A, Segment NM1, then the covered entity will be required to use an HPID to identify that health plan in the standard transactions. However, if after the adoption of the HPID, the covered entity is identifying a third party administrator as the information source in the eligibility response transaction (271), Loop 2100A, Segment NM1, the covered entity can use whatever identifier it was using previously or an OEID to identify that third party administrator. This final rule does not impose any new requirement for when to identify a health plan that has an HPID in standard transactions. It merely requires the use of the HPID where the health plan is identified. We did provide an example of a use of the HPID in transaction standards in the April 2012 proposed rule (77 FR 22961).

Comment: Some commenters question what the HPID will actually accomplish.

Response: The establishment of the HPID and the requirement to use it in the standard transactions to identify health plans is another step towards standardization. In standard transactions, the HPID will replace proprietary identifiers for health plans which have different lengths and formats. In addition, it will provide public access to information necessary to accurately identify health plans. This will save providers time when verifying a health plan's identity. Standardization of the health plan identifier is also expected to ameliorate some electronic transaction routing problems. The HPID and OEID will add consistency to identifiers, may provide for a higher level of automation, particularly for provider processing of the X12 271 (eligibility response) and X12 835 (remittance advice). In the case of the X12 835, the HPID and OEID may allow reconciliation of claims with the claim payments to be automated at a higher level. While the implementation of HPID, in and of itself, may not immediately provide significant monetary savings for covered entities, it is expected to provide significant time savings by immediately resolving certain transaction routing problems.

Comment: Commenters raised issues about whether the early use of the HPID in the standard transactions could result in denied or misrouted claims with the potential to cause privacy or security breaches.

Response: We believe the HPID will reduce denied and misrouted claims once fully implemented, given that all HPIDs and information related to HPIDs will be available in one database. While we recognize that there is the potential for misrouted or denied claims during the transition to the HPID, we believe that privacy or security breaches can be avoided, particularly with prior implementation planning. We believe there is more than adequate time between the compliance date for when health plans obtain HPIDs and when covered entities are required to use HPIDs in the standard transactions, which will allow industry ample opportunity to make system changes and perform extensive testing with trading partners. This additional time

and phased-in approach to compliance should reduce denied or misrouted claims during the early use of the HPID.

Comment: Some commenters requested more specific guidance about how the HPID should be used in business models, for instance in situations where one health plan may be adjudicating the claim and a separate health plan may hold the actual contract with the provider.

Response: The implementation of the HPID does not require a change to health plans' business models. Changing a health plan's current identifiers to an HPID does not change the structural organization and/or its contractual relationships with other entities, or whether it is identified in the standard transactions. For example, if the health plan that adjudicates the claim needs to be identified in a standard transaction, then the HPID of that health plan should be used. If the health plan that holds the actual contract with the provider needs to be identified in a standard transaction, then the HPID of that health plan should be used.

Comment: Several commenters raised concerns about the use of the HPID on health plan members' ID cards. Commenters were split between making the use of the HPID on member ID cards mandatory or optional. Others raised concerns that the cost of re-issuing all member ID cards far outweighs any benefit.

Response: In this rule, we only require the use of the HPID in the standard transactions. The HPID is permitted to be used for any other lawful purpose and inclusion of the HPID on health plan members' ID cards is just one example of an optional use of the HPID. While health plans are permitted to put the HPID on member ID cards, we do not require it, so the determination of whether to reissue cards, and the associated costs, lie with the health plans.

Comment: Other commenters recommended that health plans be required to comply with the health plan ID card standards set forth in the Workgroup for Electronic Data Interchange (WEDI) Health ID Card Implementation Guide, Version 1.0 (November 30, 2007).

Response: We did not address or propose the adoption of a standard format for a health plan identification card. The goal of this rule was to adopt a standard health plan identifier for use in the standard transactions. While the use of the HPID on a health plan ID card is a permitted use, we did not require it in this rule because further analysis and industry feedback is needed on standard identification cards after the implementation of the HPID.

After consideration of the public comments, we are finalizing the required and permitted uses of the HPID with the minor clarifying modifications to § 162.510(a) and (b), adding ''that has an HPID'' immediately after ''health plan.''

3. Health Plan Identifier Requirements

a. Requirements and Options for Obtaining an HPID

This final rule discusses how CHPs and SHPs will obtain an HPID from the Enumeration System. In 45 CFR 162.512, we proposed to require a CHP to obtain an HPID for itself from the Enumeration System. In addition, we proposed that a CHP may obtain an HPID from the Enumeration System for its SHP, or direct a SHP to obtain an HPID from the Enumeration System. We proposed that any SHP would be able to obtain an HPID regardless of whether or not its CHP directed it to obtain an HPID. While a CHP could only obtain one HPID for itself, a CHP could use the HPID of its SHPs for any lawful purpose.

While a CHP would be required to obtain an HPID, there would be different options available for the enumeration of SHPs based on a CHP's organizational structure and business needs. The CHP would analyze its organizational structure to determine if and which of its SHPs need an HPID based on whether the SHP needs to be identified in covered transactions. We encouraged CHPs and SHPs to coordinate their HPID applications to prevent duplication and possible confusion. See Table 1 for a comparison of requirements for obtaining an HPID.

TABLE 1—ENUMERATION REQUIREMENTS AND OPTIONS FOR CHPS AND SHPS

Entity	Enumeration requirements	Enumeration options
CHPs	Must obtain an HPID for itself	May obtain an HPID(s) for its SHP(s). May direct its SHP(s) to obtain an HPID(s).
SHPs	Not required to obtain an HPID	May obtain an HPID at the direction of its CHP. May obtain an HPID on its own initiative.

For further illustrations and examples of enumeration options to demonstrate the ways a CHP could choose to enumerate itself and its SHPs, see the April 2012 proposed rule (77 FR 22957 through 22962).

In the proposed rule, we clarified that self-insured group health plans are included in the definition of health plan in § 160.103 and therefore will need to obtain a health plan identifier if they meet the definition of a CHP. We specifically mentioned self-insured group health plans as there was industry discussion about whether these health plans should be required to obtain HPIDs because they do not often need to be identified in the standard transactions. Some industry stakeholders noted that many self-insured group health plans contract with third party administrators or other entities to perform health plan functions on their behalf and those entities, not the self-insured group health plans, may be identified in the standard transactions. Therefore, many in the industry suggested not requiring self-insured group health plans to obtain HPIDs, while others recommended requiring these plans to obtain HPIDs because they are typically the financially responsible party. Given that self-insured group health plans are included in the definition of health plan and potentially need to be identified in the standard transactions, we proposed that they be required to obtain an HPID if they meet the definition of a CHP. We solicited comments on this issue.

b. Options for Enumeration of Health Plans

As discussed previously in this final rule, stakeholders at the NCVHS hearings expressed differing viewpoints on the appropriate level of health plan enumeration. Some industry stakeholders encouraged health plan enumeration at a very high level (for example, at the level of the health plan's legal entity), while other stakeholders supported enumeration at the benefit package level. We analyzed and considered these viewpoints when we developed the policies associated with HPID adoption and implementation.

In the April 2012 proposed rule, we considered multiple uses for the HPID. We determined that the primary purpose of the HPID was for use in standard transactions in order to identify health plans in the appropriate loops and segments and to provide a consistent standard identifier for covered entities to use when identifying health plans in standard transactions. We analyzed the transaction standards to determine the existing segments and loops where a health plan may need to be identified, what identifiers are currently used in those loops and segments to identify health plans, and what information a loop or segment conveys when a health plan is being identified. We also carefully considered the information that industry stakeholders reported was missing in covered transactions, such as information related to patient financial responsibility.

We determined that much of the information testifiers wanted to obtain from the HPID might already be available in other parts of the transaction standards and associated operating rules. To illustrate this point, in the proposed rule, we discussed the CAQH CORE 154 Eligibility and Benefits 270/271 Data Content Rule, which we adopted through an interim final rule with comment period in the July 8, 2011 **Federal Register** (76 FR 40458). That operating rule is to be used with the ASC X12 Version 5010 Standard for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271) (hereinafter referred to as the Version 5010 270/271 eligibility inquiry/response standard. The operating rule requires certain additional information to be included in the Version 5010 270/271 eligibility inquiry/response transaction standard, including information about a patient's health plan name, coinsurance, copayment, and deductibles including in-network and out-of-network, as well as remaining deductible amounts. Moreover, we believe that the transaction standards themselves could more appropriately address many of the other issues raised by stakeholders about the appropriate level of enumeration. Therefore, HPID does not need to provide the level of detail that some testifiers suggested.

We discussed in the April 2012 proposed rule how requiring health plans to enumerate at a more granular level may prove burdensome to the industry as benefit package information and offerings change frequently and would require constant updates by health plans. For example, health care providers would need to update their software and systems frequently to ensure the accuracy of information. A failure of either health care providers or health plans to ensure that the HPIDs and the corresponding health plan information is up-to-date could result in increased time spent by health plan and health care provider staff to ensure the most accurate information is being used for eligibility determinations and claim payments.

As discussed in the April 2012 proposed rule, we developed the policies associated with HPID adoption and implementation after considering stakeholder testimony, analyzing transaction standards' loops and segments where the health plan identifier will be used, and taking into account newer versions of the transaction standards and the adoption of associated operating rules.

We received many comments on the enumeration requirements for CHPs and SHPs.

Comment: Some commenters generally supported our proposal that a CHP be required to obtain an HPID, while a SHP would be eligible but not required to obtain one. These commenters supported the flexibility this approach provided to a health plan to determine the appropriate level of enumeration for its organization and enumerate itself in a way that supports its business needs.

Response: We thank commenters for their support.

Comment: Some commenters emphasized that it is critical that the approach in the proposed rule be finalized so that health plans have the flexibility to determine how the health plan chooses to enumerate itself for use in the standard transaction. For instance, whether it chooses to have one HPID for its entire organization or whether it chooses to obtain separate HPIDs for its subhealth plans. While these commenters supported the proposed enumeration requirements and required uses of the HPID, they expressed concerns that future rulemaking could result in requiring divisions within health plans to be enumerated.

Response: While we appreciate the commenters' support for our proposed approach to establishing an HPID, we find the concerns expressed about future rulemaking to be outside the scope of this rule. Nevertheless, we anticipate that future changes in the requirements or prohibitions will be aligned with industry business needs and experience.

Comment: A commenter expressed concern about limiting a health plan to a single HPID. This commenter was concerned that a single HPID may present issues from a routing perspective because a single health plan may use multiple processing systems or administrators. The commenter also noted that if a health plan were limited to being enumerated with a single HPID, there would need to be intelligence associated with the HPID, such as a data element to redirect incoming transactions from the single receiving site to the multiple processing sites. This commenter further suggested that a health plan be able to obtain and use subordinate identifiers for routing purposes.

Response: This final rule limits CHPs to obtaining one HPID for themselves. Permitting a CHP to obtain multiple HPIDs would lead to unnecessary complexity and potential confusion for no discernible benefit. Any additional information necessary for the transaction should be included within the transaction standard, implementation specifications, or associated operating rule. However, we note that we do allow CHPs to obtain HPIDs for their subhealth plans based on their business needs and arrangements and allow CHPs to use the HPID of their SHPs in the standard transactions.

Comment: Some commenters supported not enumerating at a more granular level of enumeration because certain information about patient eligibility or financial information can be provided in other data fields in the transactions. They stressed that a more granular approach would add significant administrative costs to the implementation of the HPID and would require the creation of a clearinghouse to maintain the various separate identifiers and this would not benefit vendors, health care providers or health plans.

Response: We agree with these commenters that a greater level of granularity has the potential to be unnecessarily burdensome and expensive for all segments of industry. If the industry determines that additional information is needed for certain electronic transactions, changes to the transaction standards would likely be more appropriate.

Comment: Commenters recommended that HHS work with the Operating Rules Authoring Entity for the applicable transactions if additional information is needed in the future.

Response: The Affordable Care Act authorized the Secretary to establish a review committee to conduct hearings to evaluate and review the adopted standards and operating rules. The

review committee will provide recommendations for updating and improving such standards and operating rules. We believe that the industry will have sufficient opportunities to provide information about developing needs and ways to address those needs with possible changes to standards and operating rules.

Comment: Some commenters suggested that HHS provide additional guidance on enumeration to support health plans in making informed decisions on the most appropriate approach for enumeration. These commenters cautioned that, without more guidance, the proposed enumeration approach would result in health plans enumerating their organizations in different ways and this lack of consistency across health plans would impact the industry.

Response: We do not believe additional guidance on enumeration is needed at this time. This final rule seeks in large part to substitute the use of proprietary and other non-standard identifiers with a unique standard health plan identifier in HIPAA standard transactions. Covered entities nevertheless retain certain flexibility to use identifiers in ways that best serve their own business needs, even within standard transactions. As health plans are enumerated, HHS will monitor the industry and assess whether any clarification or guidance is necessary. More likely, the industry will quickly identify best practices for health plan enumeration and HHS will seek to facilitate the dissemination of this information.

Comment: Commenters urged HHS to require a greater level of health plan enumeration granularity. For example, some commenters suggested that a patient-specific benefit plan ID is needed. They stated that an identifier should include this information because from the perspective of patients, physicians, and other health care providers, the patient-specific benefit plan information is routinely necessary prior to the patient encounter. They also stated that while the current set of adopted operating rules will ensure additional information is available, they will not provide all the information associated with the patient-specific benefit plan the commenters believe is needed. They suggested that the need for a patient-specific benefit plan ID will only increase as the number of people purchasing coverage directly from Exchanges grows. According to these commenters, this information is needed at the point of service, on the eligibility response, and on the electronic remittance advice (ERA). Currently this information is only required to be provided on the ERA in text, which makes automation difficult. These commenters suggested that having specific benefit plan information associated with the HPID would improve automation.

Response: Given our gradual approach to standardization, a patient-specific benefit plan identifier is a more specific requirement than we believe would be appropriate to impose at this early stage. As other commenters have suggested, a more granular level of enumeration has the potential to cause ongoing administrative burden and would need to be continually updated by both the health plans and the providers to ensure accuracy. We understand that this first step of standardization for the identification of health plans is not going to achieve as much transparency initially as some commenters state is needed in the transactions. After experience with the implementation and use of the HPID, we will work with industry to explore next steps of enumeration that may include patient-specific benefit plan information. We also want to caution that we do not believe a standard identifier alone will be the final solution to all of the transparency challenges in standard transactions. The health plan identifier is foundational and will allow the gradual move towards greater utility.

Comment: Some commenters emphasized the need to enumerate each SHP because there are situations where the specific benefit package of that health plan under which services were performed needs to be identified, such as with coordination of benefit transactions or laboratory services.

Response: For this phase of implementation of HPID, we determined that it would not be necessary to require each SHP to obtain an HPID because health plans are essentially transitioning their multiple proprietary identifiers to HPIDs. We are not changing what is required to be identified in the standard transaction so if there are situations where the SHP may need to be identified, such as with laboratory services or coordination of benefit transactions, it will be up to the CHP within the limitations of this rule to determine how that SHP is identified in the standard transaction to ensure continuous flow of the transactions. We believe that at this stage of transition, it is wise to allow CHPs to make these decisions based on their business needs and structures.

In a previous response, we provided clarification about the affirmative obligation in 45 CFR 162.510 for covered entities to use an HPID to identify a health plan in standard transactions, when a SHP may not have its own HPID, and we believe the discussion is applicable to this comment. As we explained previously, in those cases, covered entities would use the HPID that the SHP indicates should be used to identify that SHP, which may be the HPID of its controlling health plan. If an entity has in good faith sought to identify the HPID that should be used for a SHP that has no HPID and has been unsuccessful, then it obviously cannot use an HPID to identify that SHP. While we anticipate those circumstances would be rare, we have inserted ''that has an HPID'' immediately after ''health plan'' in § 162.510(a) and (b). We consider a health plan as ''having an HPID'' if that health plan communicates with its trading partners that it consistently uses a particular HPID, even if the HPID it uses is associated with another health plan, such as its controlling health plan.

Comment: It was also suggested by commenters that there be a national standard fee schedule identifier that is separate from the HPID. A payer-assigned fee schedule identifier and a mandate that each entity that serves as a contracting agent issue a unique fee schedule identifier in conformance with that standard for each separate fee schedule would allow physicians and other health care providers to automatically post and reconcile claims payments from multiple payers for multiple products.

Response: For this rule, we decided to take a gradual approach towards standardization of the health plan identifier and not attempt to address all information needs that industry wants from the standard transactions with a health plan identifier. We understand that other types of identifiers, such as a payer-assigned fee schedule identifier may be useful in the future to move towards a system where health care providers can automatically post and reconcile payments. For some of the suggested identifiers, we may not have the necessary legal authority to adopt them, and regardless, we believe this final rule provides a foundation that can be built upon in the future.

Comment: We received numerous comments on enumeration of self-insured group health plans. Some commenters supported the requirement because self-insured group health plans may need to be identified as the financially responsible entity in the standard transactions. A majority of commenters recommended that only self-insured group health plans that are conducting the standard transactions directly should be required to be

enumerated since few self-insured group health plans directly conduct transactions. These commenters recommended that if business needs are identified that require the identification of a self-insured group health plan, changes to the standards or operating rules should be considered to address these issues.

Response: The definition of health plan at 45 CFR 160.103 specifically includes the self-insured group health plans. While self-insured group health plans will be required to obtain an HPID to the extent they meet the definition of a CHP, the HPID of a self-insured group health plan will *only need to be used* by covered entities *if* that self-insured group health plan is identified in the standard transactions. While many commenters recommended that a self-insured group health plan only be required to obtain an HPID if it needs to be identified in the standard transactions, we believe it is important that the requirement to obtain an HPID extend to any entity that meets the definition of CHP. Therefore, we require self-insured group health plans to obtain an HPID to the extent they meet the definition of CHP.

Comment: Some commenters also discussed operational challenges that health plans functioning as TPAs would encounter because of the requirement that self-insured group health plans obtain an HPID. These commenters stated that self-insured group health plans would need to enumerate on behalf of their plan sponsors so that they can be identified in the standard transactions.

Response: We are not requiring that the HPID of the self-insured group health plan be used to identify that self-insured group health plan, if the transaction standard does not require it. For example, if a covered entity is identifying the self-insured group health plan in the standard transaction, then the covered entity must use the HPID of the self-insured group health plan. If, however, the covered entity *was not* identifying the self-insured group health plan prior to this final rule, because, for example, it was identifying either another health plan or an entity such as a TPA, then the covered entity *would not* be required to identify a self-insured group health plan. This rule *does not* require that a self-insured group health plan be identified in the standard transactions.

Comment: Commenters also requested clarification about what identifier a health plan should use in the standard transaction if it is functioning as a third party administrator.

Response: The primary purposes of this rule include adopting a unique health plan identifier and establishing the enumeration system for the HPID. While we recognize that health plans have various business structures and arrangements, health plans need to be identified with a unique identifier using a standardized format. HPIDs will therefore need to be used in standard transactions to identify health plans in accordance with the requirements of the implementation guides for the relevant transaction standards. We would also note that because health plans are eligible to obtain an HPID, they are ineligible to receive an OEID.

Comment: A number of commenters requested additional guidance on enumeration for various business arrangements. A commenter specifically requested additional guidance on situations where the holding companies/controlling entities for multiple affiliated health plans do not meet the definition of health plan and consider allowing affiliated CHPs to share a single HPID in certain clearly defined circumstances.

Response: While each CHP is required to obtain an HPID, these comments suggest it may be helpful and more efficient for affiliated CHPs to share an HPID in limited circumstances in the standard transactions based on their unique organizational structures and business arrangements. We appreciate these comments and will provide further guidance in the near future. We would note that the regulation text broadly states that a covered entity must use an HPID to identify a health plan that has an HPID.

Under this latter requirement, we envision that a health plan would be considered to ''have an HPID'' if it communicates to its trading partners that it should be identified with a particular HPID of an entity with which it is associated, such as its CHP. A CHP for instance could direct its SHPs to use its own HPID for all HIPAA covered transactions. Presuming that the SHPs have communicated with their trading partners that they use their CHP's HPID, the SHPs would be considered to ''have an HPID'' which the trading partners must use to identify the SHPs.

Comment: A few commenters stated that they already have health plan identifiers that are identical in format and are consistent with ISO 7812, like the HPID and OEID. These identifiers had been assigned by a private firm. These commenters recommended that these existing identifiers be incorporated in the Enumeration System so they do not have to reissue health insurance cards.

Response: We regret that entities may have already obtained identifiers from other parties that were not issued through the Enumeration System. However, this final rule requires that HPIDs only be obtained from the Enumeration System. This requirement ensures that HHS oversees the issuance of all HPIDs, that the HPIDs meet the requirements in this rule, and that necessary information about the health plan is available in the Enumeration System database. To grandfather in existing numbers could cause confusion among industry, a lack of integrity in the database, and disproportionate burden on health plans that do not have a current number that can be grandfathered in. While health plans are permitted to put the HPID on health insurance cards, we do not require it so the determination to reissue cards lies with the health plans.

Comment: One commenter requested that expatriate health plans, which they defined as plans whose principal purpose is covering those lives outside their country of citizenship and their dependents, be exempted from complying with the HPID requirements. This commenter alleged that compliance would be an added burden on U.S.-based insurers of expatriate plans and would competitively disadvantage them vis-à-vis their non-U.S. competitors.

Response: As discussed previously, this rule adopts the HPID as the standard unique health plan identifier for all health plans covered by HIPAA. Section 162.504 provides that all health plans that are not small health plans have until 2 years after the effective date of this rule and small health plans have until 3 years after the effective date of this rule to obtain an HPID and comply with the other provisions of § 162.512. To fully implement the HPID, all covered entities have until 4 years after the effective date of this rule to use an HPID to identify a health plan that has an HPID in standard transactions and comply with the other provisions of § 162.510. (For more information regarding the HPID compliance dates, see section II.E. of this final rule.) We believe that these dates provide covered entities, including ''expatriate plans'' that are health plans covered by HIPAA, sufficient time to meet the requirements of this rule. Moreover, we note that if a category of health plans were exempted from obtaining an HPID, other covered entities needing to identify those health plans would be adversely affected when attempting to conduct standard transactions with such exempted entities. Furthermore, neither HIPAA nor the Affordable Care Act authorizes

HHS to exempt health plans from complying with these adopted regulations simply because those health plans also conduct certain financial and administrative transactions electronically outside of the United States or are also covering individuals that are not U.S. citizens.

c. Changes to a Health Plan's HPID in the Enumeration System

In the April 2012 proposed rule, we proposed to require each health plan to disclose its HPID, upon request, to any entity that needs the HPID to identify that health plan in a standard transaction. We proposed to require each health plan to communicate changes (updates, corrections, etc.) to its own data to the Enumeration System within 30 days of the date of the change. We proposed that a SHP would ultimately be responsible for submitting updates for its own data in the Enumeration System regardless of whether it obtained its HPID independently or the CHP obtained the HPID on its behalf.

Comment: We received comments about CHP and SHP responsibilities for obtaining HPIDs and maintaining information related to the HPID in the Enumeration System. Some commenters suggested that HHS should clarify the respective obligations of CHPs and SHPs and that there should be a clear and defined responsible party for both the HPID application process and the HPID maintenance process to avoid the need for coordination. For instance, these commenters suggested that a CHP have responsibility for application and maintenance of HPIDs for itself and its SHPs. These commenters believe this would prevent duplicate numbers that could cause confusion and costly manual intervention in the claims process. Some commenters recommended that rather than have the SHP be responsible for updating its own information in the Enumeration System, the responsibility for updating information associated with an HPID should be left to the CHP and SHP to determine based on their business practices.

Response: We allow a CHP or SHP to obtain the HPID for a SHP because we recognize there are different arrangements that impact what entity may control the business actions, activities, or policies of an organization. For example, a CHP may dictate or manage the data and information systems for all of its SHPs and choose to obtain HPIDs on behalf of their SHPs to ensure coordination. On the other hand, a CHP may instruct its SHPs to obtain HPIDs. While we wanted to ensure flexibility during the application process, we also wanted to be sure that the responsibility to update the information rested with one entity and was clearly delineated. We believe that the simplest way to ensure the integrity of the data is that each entity be responsible for updating the information linked to its HPID. We anticipate that entities may delegate the update responsibility to other entities, although the health plan identified by an HPID still retains the responsibility to update its required data elements in the Enumeration System.

Comment: A few commenters recommended that changes to information associated with an identifier should be required within 5 days of the change, rather than the proposed 30 days. Another commenter recommended that an enumerated entity provide a minimum of 60 days' notice *prior* to the effective date of any change that would impact the HPID and OEID under which that entity is enumerated, which would be sufficient time to allow providers and their vendors or clearinghouses to make adjustments in their systems to avoid transaction rejections or failures.

Response: We have considered the comments about notification of changes and believe that entities should be given up to 30 days to make changes during this initial implementation stage. We recognize the operational challenges often associated with organizational changes or restructuring, and believe that 30 days strikes a good balance between the need to update the information in the Enumeration System and the entity's competing operational responsibilities. With that said, we encourage entities to make any necessary changes in a shorter timeframe when possible.

After consideration of the public comments, we are finalizing the policy regarding health plan requirements without modification.

4. HPID Standard Format

a. Introduction

Per the NCVHS recommendations, which were based on stakeholder testimony from a wide range of potential HPID users, in the April 2012 proposed rule, we proposed to adopt an HPID that is a 10-digit, all-numeric identifier with a Luhn check-digit as the 10th digit. The Luhn check-digit is an algorithm used most often on credit cards as a check sum to validate that the card number issued is correct. We sought public and stakeholder comments on the feasibility and utility of this format for the HPID.

b. The International Organization for Standardization (ISO) Standard

The International Organization for Standardization (ISO) is the world's largest developer and publisher of international standards. National standards institutes from 160 nations comprise the ISO. The ISO has published more than 16,500 standards for numerous industries such as agriculture, electrical engineering, and other information technology industries. For more information on the ISO, refer to the Web site at *http://www.iso.org.* Based on stakeholder testimony, the NCVHS recommendations, and our review, we proposed that the ISO 7812 standard format, ISO/IEC 7812–1:2006 and ISO/IEC 7812–2:2007, which consists of a 10-digit, all-numeric identifier with a Luhn check-digit as the 10th digit, be adopted as the standard for the HPID. We proposed that the HPID format will essentially be an intelligence-free identifier, except that the start digit of the identifier would signal that the identifier is assigned to a health plan, as opposed to an ''other entity'' or a health care provider, which each have a different start digit. In the proposed rule, we explained that the number of digits of the HPID will not exceed the number permitted for identifiers in the relevant data fields of the standard transactions.

Comment: We received many comments regarding the proposed HPID format. The majority of the commenters supported the proposed format. A few commenters offered additional suggestions and questions, many of which were technical. One commenter responded to the following language in the proposed rule: ''that if additional capacity for HPIDs were needed in the future, the relevant data fields would permit additional numeric digits to be added at that time.'' (77 FR 22962). The commenter suggested that HHS adopt a format that would exceed capacity but was concerned that HHS would then expand the number of digits in the format identifier past 10 digits to increase capacity. Increasing the number of digits in the identifier though would not meet the Luhn check digit. This commenter emphasized that HHS should adopt a format with ample capacity in order to avoid the need to perform additional programming and testing of systems in the future.

Response: In the proposed rule, we did not intend to suggest that we would be increasing the length of the identifier when we stated we would add additional numeric digits. Instead, we meant that we would increase capacity by introducing a new start digit that still

met the Luhn check digit logic; therefore, we believe that this commenter's concern has been adequately addressed.

Comment: A commenter supported the rule's proposal to adopt the ISO Standard 7812 format for the HPID and OEID, similar to the NPI. The commenter suggested that it may be helpful to provide more information about the ISO Standard 7812. For instance, information that the full identifier number under the ISO 7812 Standard is a composite of the ISO 80840 Issuer Identification Number (IIN), a number assigned by the holder of the IIN, and the Luhn modulus −10 check digit. The commenter stated this information is clearly provided in the NPI final rule.

Response: We appreciate the comment regarding the importance of providing information about the ISO 7812 Standard. For those readers interested in more background on the ISO 7812 Standard, we recommend that they refer to the discussion in the NPI final rule (69 FR 3442).

After consideration of the public comments received, we are finalizing the policy to adopt an HPID that is a 10-digit, all-numeric identifier with a Luhn check-digit as the 10th digit without modification.

B. Adoption of the Other Entity Identifier (OEID)

In addition to proposing the adoption of an identifier for health plans, in the April 2012 proposed rule we proposed to adopt a data element that will serve as the OEID, which would be an identifier for other entities for use in standard transactions. We proposed that the OEID would be optional—other entities could choose to obtain one or not.

Health plans often use the services of other entities to conduct certain financial and administrative transactions on their behalf. Rental networks, benefit managers, third party administrators, health care clearinghouses, repricers, and other third parties often perform functions similar to, or on behalf of, health plans. In many cases, these other entities are identified in standard transactions in the same fields and using the same type of identifiers as health plans. The NCVHS recommended that HHS consider allowing these entities to obtain HPIDs as they may be the actual recipients of eligibility queries or claims on behalf of the health insurance issuer or the entity ultimately responsible for payment. The NCVHS recommended that HHS consider making these entities eligible to obtain an HPID when there is a clear case for them to be enumerated. Based on the NCVHS recommendation, we found that a clear case does exist for these other entities to be enumerated.

We proposed that the OEID would serve as an identifier for entities that are not health plans, health care providers, or individuals,[3] yet need to be identified in standard transactions. We proposed that these other entities would not be required to obtain an OEID, but that they could obtain one from the Enumeration System and use it where they need to be identified in covered transactions. We proposed that the OEID could also be used for any other lawful purpose. If they obtained an OEID, other entities would be expected to disclose it upon request to entities that need to identify the other entities in covered transactions.

Offering the OEID as an adopted data element to identify other entities that need to be identified in covered transactions should reduce costs and improve efficiency for covered entities. Because other entities are identified in the transaction standards in a similar manner as health plans, we believe that establishing a data element to serve as an identifier for these entities will increase efficiency by encouraging the use of a uniform identifier and promote compliant use of the HPID for health plans. Like the standard for HPID we proposed to adopt, the OEID would also follow ISO standard 7812, and be a 10-digit, all-numeric identifier with a Luhn check-digit as the 10th digit. Consequently, entities would not need to significantly modify their information technology systems to accommodate the OEID since they would follow the same ISO standard as the HPID.

We solicited industry and stakeholder comments on the enumeration of other entities and adoption of the OEID for use in the standard transactions.

We received many comments on our proposal to adopt the OEID for use in the standard transactions.

Comment: Commenters requested that we provide greater clarification about the definition of an OEID as it relates to the eligibility to obtain an OEID. For example, a few commenters questioned whether or not a non-individual health care provider qualifies for an OEID and whether non-covered entities, such as auto liability and workers compensation carriers, are able to obtain OEIDs. A few other commenters suggested that the definition of OEID be further limited to entities that perform functions of a health plan and should not include healthcare clearinghouses because they state the only place the health care clearinghouse could be identified independently in the existing transactions is on the ISA envelope.

Response: The intent of the proposal for an OEID is to provide a mechanism that facilitates standardization to provide greater transparency in electronic transactions. Thus, we have proposed that the definition and eligibility for the OEID include a wide variety of entities, and have provided few limits on the types of entities that can obtain OEIDs. One limit is that it cannot be an individual. Another limit is that the entity cannot be eligible to obtain either an HPID or an NPI. The reason is to avoid having multiple and differing types of identifiers for the same entity. Therefore, if the non-individual health care provider is eligible for an NPI, it would not be eligible to obtain an OEID. On the other hand, HIPAA non-covered entities, such as auto liability and workers compensation carriers, would be eligible to obtain an OEID as long as they need to be identified in a HIPAA covered transaction. They are entities that are not individuals and not eligible to obtain an HPID or NPI. We included clearinghouses as an example in the proposed rule as our goal was to keep the definition broad so that use and requirements for the OEID in the standard transactions could be further developed in the future.

Comment: A few commenters requested clarification about whether specific entities are eligible to obtain an OEID, specifically atypical providers, accountable care organizations (ACOs), and clearinghouses. Some commenters recommended that we state clearly whether atypical providers are eligible to obtain an OEID. A few of these commenters stated that if atypical providers obtained OEIDs, they should be required to disclose them and use them to identify themselves in all standard transactions. A commenter stated that the OEID should be available to any entity that performs the functions of a payer but acts as an independent third party.

Response: We appreciate the comments about atypical providers. Atypical providers are individuals or organizations that furnish atypical or nontraditional services that are indirectly health-care related, such as taxi, home, and vehicle modification, insect control, habilitation, and respite services. We encourage entities to review the definition of health care provider in § 160.103 and the discussion of atypical providers in the NPI final rule (69 FR 3437) in determining their

[3] Individual is defined at 45 CFR 160.103 as ''the person who is the subject of protected health information.''

eligibility to obtain an OEID. We decided to place few requirements on entities that obtain an OEID, because we wanted to allow industry business needs to drive industry use of the OEID, presumably through contractual arrangements.

A determination of eligibility for an OEID will be specific for each entity based on individual factors.

Comment: A commenter cautioned that if atypical providers are eligible to obtain OEIDs, the Health Care Provider Taxonomy code should not be included as a data field in the OEID application. These commenters stated that if all atypical non-individual providers qualify for an OEID and taxonomy code(s) are included in the data elements for the OEID application, it will require adding new taxonomy codes for this purpose, which will create a potential problem due to the structure of the code set.

Response: We are still developing the required data elements but do not anticipate using this taxonomy code.

Comment: A number of commenters requested that we provide clarification on the use of the OEID in the standard transactions. A commenter requested clarification on whether the OEID could be used in the provider identifier field, in some instances.

Response: We will provide further examples of potential ways the OEID can be used in the standard transactions outside of this final rule. In the meantime, we encourage those commenters and others to review the directions within the relevant implementation guides to determine the appropriateness of using an OEID in particular data fields.

Comment: Some commenters requested that the Department work with the appropriate standard development organizations to determine where the OEID should be included in the standard transactions. They emphasized that it is important to specify that the OEID should be used in all places in the standard transactions where the HPID can be used to avoid confusion and inconsistency. Other commenters suggested that there should be a pilot test of the OEID to determine if and what changes are needed to the standard transactions and the operating rules to clarify OEID use and requirements.

Response: We appreciate the commenters' interest in the development and use of the OEID. Our intent was to create a standard identifier and allow business needs and efficiencies to drive its adoption and uses. At this initial stage of implementation, we do not believe it is necessary yet to work with standards organizations to address this question or conduct independent pilot tests.

Comment: We received many comments regarding our proposal that the OEID be voluntary. Some commenters supported that the OEID be voluntary, while others advocated that the OEID should be mandatory. Supporters of a voluntary OEID believed that business needs will drive the use of the OEID and industry can refine OEID requirements as experience with the OEID is gained. In addition, some commenters believed that if the OEID were required it may result in entities that have no current business need to use an OEID nevertheless obtaining an OEID. Those commenters in support of the OEID being mandated advocated that the OEID requirements match the HPID requirements to limit system requirement variability. They believed that this approach promotes administrative simplification and encourages a greater return on investment. They suggested that a voluntary OEID would result in additional changes to existing connections as some entities replace their current identifiers and thus would introduce another level of complexity. They added that a voluntary enumeration system would add just another identifier option for other entities to use in the standard transactions and would not necessarily lead to standardization. One commenter even suggested that the Tax Identification Number be required rather than create a new identifier.

Response: We created the OEID based on industry input and NCVHS recommendations that it would be helpful to have a standard identifier for entities that need to be identified in the standard transactions but that do not meet the definition of a health plan. The value of the OEID would be to create greater standardization in the transaction so that all parties that needed to be identified in the transactions would have a standard identifier that would be listed in a publicly available searchable database. Because of the diversity of entity types that may need an OEID and potential new uses for the OEID, we believe it would be helpful to begin with a voluntary approach that allows for gradual implementation and improvised use based on industry needs and practices. We recognize this approach may have certain risks associated with it, but we believe the risk of harm to the industry is relatively low and the potential benefit quite high.

Comment: A commenter suggested that the Secretary should require all covered entities to require any trading partner that would qualify for an OEID to be enumerated by contract, trading partner agreement, or business associate agreement to require that the identifier be used according to the transaction standards.

Response: We reiterate that covered entities could require their trading partners and business associates to obtain and use an OEID, and we believe that entities will take advantage of that approach if it is appropriate for them.

Comment: A few commenters suggested that other entities be able to obtain more than a single OEID for use in the standard transactions.

Response: At this point, we believe this proposed approach has the potential to lead to significant confusion while undermining the goal of having one unique number tied to each entity.

After consideration of the public comments received, we are finalizing the OEID requirements without modification.

C. Assignment of the HPID and OEID—The Enumeration System

We proposed in 45 CFR 162.508, that the Enumeration System would assign unique HPIDs and OEIDs to eligible health plans and eligible other entities, respectively. Once operational, the Enumeration System will be a comprehensive system for uniquely identifying and enumerating all eligible health plans and other entities. It will collect and maintain certain identifying and administrative information about CHPs, SHPs, and other entities. The Enumeration System will also disseminate information through a publicly available searchable database or through downloadable files.

HPIDs and OEIDs will be assigned by the Enumeration System through an online application process. A health plan or other entity, when applying online for an HPID or OEID, will be required to provide certain identifying and administrative information for verification and eligibility determinations during the application process. For assistance, a help desk or other applicant assistance functions will be available to assist with and troubleshoot the online application process.

We proposed that the Enumeration System would also be able to deactivate or reactivate an HPID or OEID based on receipt of sufficient information to justify deactivation or reactivation. Deactivation of an HPID may occur in the event of fraudulent or unlawful use of the HPID by the health plan itself or another entity, the change of ownership of a health plan, or the restructuring of

a health plan's data processing systems such that the SHP determines that its HPID would no longer be needed. Deactivation of an OEID may also occur for the fraudulent or unlawful use of an OEID by itself or another entity, the change of ownership of the other entity, or if the other entity no longer exists. Reactivation of an HPID or OEID could occur, for example, if there were a change of ownership of a health plan or other entity, or for health plans if there were a restructuring of a health plan's data processing systems and a SHP determines that it again needs its HPID.

With that said, upon further reviewing the proposed regulation text in the April 2012 proposed rule, we noticed that while we had discussed having the Enumeration System be able to reactivate a deactivated OEID or HPID in the preamble of the April 2012 proposed rule, we unintentionally omitted ''or OEID'' in the proposed § 162.508(c) that would have enabled the Enumeration System to deactivate an OEID, as it would an HPID. Because this reflects a technical drafting error that was obviously inconsistent with the preamble discussion at (77 FR 22963), and further, § 162.508(d) clearly presupposes that the Enumeration System would have that authority, we are finalizing § 162.508(c) with ''or OEID'' inserted.

We solicited stakeholder comment on our proposals regarding the enumeration system and process.

Comment: We received numerous comments on the type of information to be collected in the Enumeration System. Some commenters recommended that HHS collect only ''minimally necessary'' information that does not include confidential business information in order to decrease burden. These commenters recommended collecting data elements, such, as name of health plan, tax identification number, address, EDI contact phone number, email address, other legacy identifiers, and the BIN/IIN or PCN number associated with that health plan. Other commenters suggested collecting a robust amount of information in the Enumeration System. These commenters suggested collecting routing and demographic information. For example, all demographic information related to that health plan and all information necessary to enroll with the health plan to send and receive standard transactions as well as transmit standard transactions to the correct destination. In addition, they recommended that the database include information to identify the health plan type, the health plan's relationship with any other entity serving in a health plan role, and if the health plan utilizes a different network of physicians through a rental network of the physician network by region. These commenters also suggested that specific routing information for each standard transaction for each mode of transaction (that is, nearly real-time batch) be included in the database. Many commenters stated they could not provide detailed feedback on the design and information collected in the Enumeration System because they were not in the proposed rule and they would like the opportunity to review and comment on this information.

Response: We appreciate commenters' suggestions regarding the type of information to be collected in the Enumeration System. The purpose of the Enumeration System is to provide an identifier and collect only that amount of information that is necessary to uniquely identify a health plan and ensure that a link exists between a CHP and its SHPs. We have not at this point developed the data fields or identified the specific information we will need to collect to achieve the purpose of the Enumeration System. At this point, we believe that only minimally necessary information will be collected in the Enumeration System, based on the current limited purpose of the Enumeration System. When we develop the data fields, we will take into consideration the comments offered to the proposed rule and further consult industry. In the future, if and when the purpose and use of the Enumeration System expands, we will work with industry to identify other data elements that will need to be collected.

Comment: A commenter requested specific guidance that would clarify when an HPID that has been issued for a health plan can continue to be used after that health plan has undergone a business merger or acquisition.

Response: If a health plan wants to retain its HPID after a merger or acquisition, it should update its health-plan related data in the Enumeration System. If the health plan does not want to retain its HPID, it should deactivate its HPID. We anticipate that there will be more guidance available on operational questions, such as these, as the Enumeration System is implemented.

Comment: Some commenters stressed the importance of the Enumeration System having both a look-up capability, similar to that for the NPI, and downloadable files to easily disseminate information about HPIDs and OEIDs.

Response: We anticipate that both a look-up function and downloadable files will be available in the future.

Comment: Some commenters asked when entities could apply for identifiers from the Enumeration System.

Response: While we anticipate entities may access the system and learn more about the application process and Enumeration System on October 1, 2012, we anticipate providing additional information about the Enumeration System in the near future.

Comment: A few commenters provided other suggestions about system design and specific system features. For instance, a commenter stated that all user activity should be conducted through an ''account'' and a user is granted access to the system by a system administrator. Through the establishment of an ''account'' in the system, the user would have the ability to apply for identifiers, maintain information associated with identifiers, download reports, establish users who could access or perform activities related to the account, transfer control over an identifier to another account, and upload batch files. The benefit of this ''account'' approach is that it would enable an administrator to access and manage all identifiers for itself and subordinate plans and other entities. It would also enable the Enumeration System administrator to deal with fewer entities, reduce phone calls, and increase accuracy and efficiency. Another commenter suggested that the Enumeration System have a listserv function so entities could be notified of any changes in identifier information. Another commenter suggested that the database have the capability to provide near real-time updates and the ability to electronically ping databases from a practice management system or other provider administrative systems based on selected search criteria.

Response: We are still in the process of collecting information and developing the Enumeration System and will take these comments into consideration in the process.

After consideration of the public comments received, we are finalizing the Enumeration System policies without modification with the one minor exception of inserting ''or OEID'' in § 162.508(c).

D. Other Considerations

1. Pharmacy Transactions

In the April 2012 proposed rule, we noted that currently, the pharmacy industry utilizes two unique identifiers to identify entities responsible for administering claims in retail pharmacy

transactions, the Bank Identification Number/Issue Identification Number (BIN/IIN) and the Processor Control Number (PCN). These identifiers are programmed into the pharmacy's software and identify the route for processing the transaction from the pharmacy to the entity responsible for administering the claim, which could be the health plan or the pharmacy benefit manager. A pharmacy benefit manager is a third party administrator for prescription drug programs and is responsible for processing and paying claims on behalf of the health plan or drug plan sponsor. The BIN/IIN is a 6-digit number, requested by the pharmacies from either the American National Standards Institute (ANSI) or the National Council for Prescription Drug Programs (NCPDP), for use by retail pharmacies to route prescription drug claims to the entity responsible for processing the transaction, usually the pharmacy benefit manager. The PCN is an identifier of up to 10 characters that is assigned by pharmacy benefit claim processors if there is a need to further define benefits and routing. For instance, the Medicare Part D prescription drug benefit plan Coordination of Benefits (COB) contractor has unique requirements for processing Medicare Part D claims. To accommodate those requirements, many administrators or processors have created PCNs to further differentiate the Medicare Part D prescription drug plan benefit COB business from their other (commercial or Medicaid) COB business.

The BIN/IIN and PCN identifiers are included in information from pharmacy benefit managers and/or health plans that are distributed to pharmacies to provide details on who will be processing the transaction, where to route the transaction and what rules are expected to be applied during transaction processing. We took note of the NCPDP's testimony from the July 20120 NCVHS Subcommittee on Standards meeting that the use of these two identifiers has been very effective in ensuring efficient, timely prescription claim processing.

We also considered testimony from the July 2010 NCVHS meeting that the HPID, BIN/IIN and PCN identifiers convey different information and serve different purposes. The BIN/IIN and PCN identifiers cannot provide the information needed about the health plan, nor can the information in the HPID provide the information inherent in the BIN/IIN and PCN identifiers. We considered the claims that if the health plan identifier were required to replace the BIN/IIN and/or PCN, such a change would be extremely costly to the retail pharmacy industry and cards would need to be re-issued with the HPID, with no direct patient or pharmacy benefit.

There was also testimony that an HPID-only requirement would require a substantive change to the NCPDP D.0. In Version D.0, the Plan ID field is either not used or its use is optional, meaning its use was intentionally not defined in the standard. However, the use of the BIN and PCN fields is mandatory.

We reviewed the September 30, 2010 NCVHS recommendation letter to the Secretary, where the NCVHS observed that retail pharmacy transactions utilize the BIN/IIN and/or PCN identifier to facilitate their transaction processing, and that changing to another identifier would significantly affect existing data flows in the retail pharmacy industry that currently work effectively. As such, the pharmacy industry requested an exemption from the requirement to use only HPID in retail pharmacy transactions because of the current success with the BIN/IIN and PCN identifiers for routing purposes.

We further considered the NCVHS recommendation that use of the HPID in place of the existing BIN/IIN and PCN identifier in retail pharmacy business transactions not be required, but that the use of HPID be required on the HIPAA-named standard transactions for retail pharmacy.

In the April 2012 proposed rule, we did not propose any changes to the NCPDP Version D.0 standard. So where the D.0 calls for the BIN/IIN and PCN to be used, this final rule has no impact or effect because health plans are not being identified in those fields. We clarified that we do not believe that the HPID should be required in place of the existing BIN/IIN and PCN identifier in retail pharmacy transactions.

We received a few comments regarding the use of the HPID in pharmacy transactions.

Comment: Several commenters did not believe the HPID should be used in place of the BIN/IIN and PCN in pharmacy transactions, but that the HPID be required on the HIPAA-named standard transactions for retail pharmacy.

Response: We thank commenters for their comments.

After consideration of the public comments received, we are finalizing the policy regarding the use of the HPID in pharmacy transactions without modification.

2. Definition of Covered Health Care Provider

We proposed to move the definition of ''covered health care provider'' from 45 CFR 162.402 to 45 CFR 162.103 because the term has a broader application beyond just Subpart D. We did not receive any comments on the proposal to move the definition of ''covered health care provider'' from 45 CFR 162.402 to 45 CFR 162.103, and therefore, we are finalizing this change as proposed.

E. Effective Date and Compliance Requirements for the HPID

In section 1104(c)(1) of the Affordable Care Act, Congress specified that ''the Secretary shall establish a standard for a unique health plan identifier based on the input of the National Committee on Vital and Health Statistics.'' Congress further provided that the rule shall be ''effective'' not later than October 1, 2012. The effective date would mark the beginning of the implementation period for the HPID, which we indicated in the proposed rule is the day we expect would be the first day health plans could apply to obtain an HPID and the first day an entity could apply to obtain an OEID from the Enumeration System. We would like to clarify that entities will not be able to obtain identifiers on that date, but that they may begin to access the Enumeration System and learn more about the application process. We proposed that the compliance date for all covered entities, except small health plans, to use the HPID in standard transactions be 2 years after the effective date of the final rule which, if the effective date is October 1, 2012 as we proposed, would be October 1, 2014. The compliance date for small health plans would be October 1, 2015. Neither small health plans nor other covered entities would be prohibited from using HPIDs in their transactions at any time before their respective compliance dates.

In line with our previous interpretations, we have interpreted the ''effective date'' of this rule to mean the date the Secretary adopts the HPID as the unique health plan identifier. In the NPI final rule, for instance, the effective date of the rule was the date the Secretary adopted a standard unique health identifier for health care providers, and the compliance date marked the date by which an entity had to obtain and use an NPI in the standard transactions. We consequently interpreted section of the 1104(c)(1) of the Affordable Care Act as specifying October 1, 2012 as the effective date of the final rule, the date on which the policies take effect and the implementation period for the HPID begins.

We solicited comment on the effective and compliance dates for the HPID.

Comment: We received extensive comments on the compliance dates and implementation requirements of HPID. The majority of commenters emphasized the need for additional time to test and implement HPID, and requested that we establish a date by which health plans should obtain their HPIDs in advance of the date by which covered entities are required to use the HPID in standard transactions. These commenters emphasized that health plans must obtain their identifiers and communicate them to all covered entities well in advance of the required use of the HPID in the standard transactions. This additional time would allow for internal system changes to accommodate the HPID and for extensive testing among trading partners. Commenters explained that ample time to perform system changes and testing is critical to the successful implementation of the HPID by all covered entities. Implied in many of these comments was that because covered transactions virtually always involve multiple parties, a single ''go-live'' date by which all covered entities must use the HPID should be established.

Response: We have considered the significant operational challenges described by commenters that occur as a result of a single compliance date for both the health plans to obtain HPIDs and covered entities to use the HPIDs to identify health plans in the standard transactions. We agree that the successful implementation of HPID could be jeopardized. Therefore, in this final rule we are changing the approach to compliance with new implementation requirements shown in Chart 1.

Comment: Commenters warned that if ICD–10 and the HPID have the same compliance date of October 1, 2014, it will be financially and administratively burdensome. In addition, commenters suggested that it would be difficult to determine the cause of any claim delays or problems with implementation.

Response: We agree that implementation of these two initiatives at the same time could impose technical and operational problems, which would be difficult to diagnose and address.

Comment: Some commenters suggested that there be a dual use period for implementation of HPID, during which time both legacy health plan identifiers and the new health plan ID is permitted in the transactions. These commenters suggested that the dual use period would assist industry during simultaneous compliance for both ICD–10 and HPID. A dual use period was allowed in the transition to NPI and this provided the ability to validate crosswalks and resolve any implementation issues prior to full transition. Finally, these commenters stated that a dual use period would allow CMS to monitor the rate of adoption and readiness of the industry through metric reporting.

Response: While we believe that a period of dual usage would be helpful, we do not believe it necessary to mandate such a dual use period. The new HPID compliance dates will address many of the concerns raised by these commenters. The compliance date for HPID to be used in the standard transaction, which we are now referring to as the full implementation date, is no longer the same date as for ICD–10. In addition, in contrast to the single compliance date for NPI, the new phased-in approach for HPIDs, where there is lag time between when health plans are required to obtain an HPID and when covered entities are required to begin using HPIDs in the standard transactions, will allow the opportunity for dual use and sufficient time for a successful transition. The additional time will allow industry the opportunity to perform extensive testing of the HPID prior to full implementation.

Comment: Commenters recommended that large and small health plans have the same full implementation date by which all covered entities must use the HPID should be established.

Response: Based on the comments above regarding the compliance dates for HPID, the following changes have been made to the implementation requirements to ensure a smooth transition to the HPID. The effective date of this final rule is 60 days after the publication date of this rule. Compliance with the implementation specifications for obtaining the HPID will be 2 years after the effective date of this rule, except for small health plans, which will have 3 years after the effective date of this rule. Full implementation of the HPID—or the date by which all covered entities must use HPIDs to identify health plans that have an HPID—will be 4 years after the effective date of this rule. To reflect our intention of having a single date by which all covered entities must have fully implemented the HPID, we are referring to 4 years after the effective date of this rule) as the full implementation date for the HPID. We determined that 2 years after the time health plans (other than small health plans) are required to have obtained their HPIDs and 1 year after the time when small health plans are required to have obtained their HPIDs provides more than sufficient time for all covered entities to make any necessary system changes prior to the full implementation date of 4 years after the effective date of this rule. In Chart 1, we provide the actual HPID compliance and implementations dates based on the timeframes discussed in this section of the final rule. These dates are also reflected in the **DATES** section of this final rule.

CHART 1—HPID IMPLEMENTATION

Entity type	Compliance date for obtaining HPID	Full implementation date—for using HPID in standard transactions
Health Plans, except small health plans	November 5, 2014	November 7, 2016.
Small Health Plans	November 5, 2015	November 7, 2016.
Healthcare Clearinghouses	N/A	November 7, 2016.
Healthcare Providers	N/A	November 7, 2016.

After consideration of the public comments received, we are modifying the compliance requirements of the HPID and have made changes to the regulation text to reflect these new dates. We have revised § 162.504(a) to reflect the new policy that all covered entities are required to use HPIDs in the standard transaction by 4 years after the effective date of this rule and removed references to compliance dates for covered health care providers and health care clearinghouses that are no longer necessary.

III. Addition to the National Provider Identifier Requirements

A. Background

As discussed in section I of this final rule, the final rule adopting the NPI as the standard unique health identifier for health care providers was published on January 23, 2004 (69 FR 3434) (''2004 NPI final rule''). While the 2004 NPI final rule requires covered health care providers to obtain NPIs for themselves and certain subparts and use them in standard transactions, it does not require a health care provider who is not a covered entity to obtain an NPI. Even if a noncovered health care provider chooses to obtain an NPI, the provider is not required to comply with certain NPI requirements, which means the provider does not have to disclose its NPI to entities who may need it for standard transactions. When a noncovered health care provider does not obtain an NPI or does not disclose it, certain problems arise for entities that need to identify that noncovered health care provider in standard transactions. We proposed an addition to the requirements in the NPI regulations to address such problems.

The 2004 NPI final rule (69 FR 3445) recognized that, ''[s]ituations exist in which a standard transaction must identify a health care provider that is not a covered entity * * *. A noncovered health care provider may or may not have applied for and received an NPI. In the latter case, * * * an NPI would not be available for use in the standard transaction. We encourage every health care provider to apply for an NPI, and encourage all health care providers to disclose their NPIs to any entity that needs that health care provider's NPI for use in a standard transaction. Obtaining NPIs and disclosing them to entities so they can be used by those entities in standard transactions will greatly enhance the efficiency of health care transactions throughout the health care industry * * *. The absence of NPIs when required in * * * claims by the implementation specifications may delay preparation or processing of those claims, or both. Therefore, we strongly encourage health care providers that need to be identified in standard transactions to obtain NPIs and make them available to entities that need to use them in those transactions.''

The 2004 NPI final rule (69 FR 3445) provided the following example of a situation when a health care provider is not a covered entity but its NPI is needed for a standard transaction: ''A pharmacy claim that is a standard transaction must include the identifier (which, as of the compliance date, would be the NPI) of the prescriber. Therefore, the pharmacy needs to know the NPI of the prescriber in order to submit the pharmacy claim. The prescriber may be a physician or other practitioner who does not conduct standard transactions. The prescriber is encouraged to obtain an NPI so it can be furnished to the pharmacy for the pharmacy to use on the standard pharmacy claim.''

Within just a few months after implementation of the 2004 NPI final rule, this issue had been raised so frequently to HHS that, on September 23, 2008, it published a Frequently Asked Question to address questions about pharmacy claims rejected by payers for lack of an individual prescriber NPI (Answer ID 9419) (*https://questions.cms.hhs.gov/app/answers/detail/a_id/9419/~/does-the-national-provider-identifier-(npi)-final-rule-require-individual*).

Due to recurring issues, we believe this scenario described in the 2004 NPI final rule needs to be addressed. Pharmacies are encountering situations where the NPI of a prescribing health care provider needs to be included in the pharmacy claim, but the prescribing health care provider does not have an NPI or has not disclosed it. This situation has become particularly problematic in the Medicare Part D program, as we explain more fully later in this final rule.

By way of background, every prescriber has at least one identifier that may be submitted on a pharmacy claim. These identifiers include the NPI, Drug Enforcement Administration (DEA) number, uniform provider identification number (UPIN), or State license number. The Medicare Part D program is an optional prescription drug benefit for all Medicare beneficiaries. Medicare Part D contracts with private companies, called plan sponsors, to administer the benefit through Part D drug plans. In the Medicare Part D program, plan sponsors must submit a prescription drug event (PDE) record to Medicare Part D every time a beneficiary's prescription is filled under the program. Plan sponsors use information from the claim generated by the pharmacy to complete the PDE record, which contains summary information. These PDE records, which currently must contain a prescriber identifier, are necessary to support accurate payments to plan sponsors by Medicare Part D.

The use of multiple and invalid prescriber identifiers in the Medicare Part D program has been identified as a concern. In a June 2010 report titled, ''Invalid Prescriber Identifiers on Medicare Part D Drug Claims'' (''June 2010 report''), the HHS Office of the Inspector General (OIG) reported the findings of its review of prescriber identifiers on 2007 Part D PDE records. The OIG reported finding 18.4 million PDE records that contained 527,749 invalid identifiers, including invalid NPIs, DEA registration numbers, and UPINs. Payments by Part D drug plans and enrollees for prescriptions associated with these PDE records totaled $1.2 billion. Prescriber identifiers are valuable Part D program safeguards. These identifiers are the only data on Part D drug claims to represent that licensed practitioners have written prescriptions for Medicare enrollees. Although invalid prescriber identifiers are not an automatic indication of erroneous or fraudulent prescriptions or pharmacy claims, the lack of valid prescriber identifiers on Part D drug claims hampers Medicare's program integrity efforts.

To address these concerns raised by the June 2010 report, in the ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' final rule (which was published in the April 12, 2012 **Federal Register** (77 FR 22072) and is hereinafter referred to as the April 2012 final rule), CMS requires Part D sponsors to include an active and valid prescriber NPI on prescription drug event records (PDEs) that they submit to CMS beginning January 1, 2013. This change will assist the Federal government in fighting possible fraudulent activity in the Part D program, because prescribers will be consistently and uniformly identified. This policy will not interfere with beneficiary access to needed medications because Part D sponsors must validate the NPI at point of sale, and if this is not possible, permit the prescription to be dispensed by paying the claim and obtaining the valid NPI afterwards (77 FR 22075).

Pharmacies that contract with Part D sponsors may be involved in obtaining a prescriber's NPI depending on the agreement between the pharmacies and Part D sponsors. However, Part D sponsors and pharmacies generally have no regulatory leverage or other recourse over prescribers who do not have NPIs or do not disclose them. In the latter case, the sponsors and pharmacies must resort to using provider information databases to determine if a prescriber has an NPI, or contact the prescriber if known. If a Part D sponsor or network pharmacy is unable to obtain a prescriber NPI for use on the claim and PDE, the reimbursement from Medicare

Part D to the sponsor (or alternatively, from the sponsor to the pharmacy depending on the agreement between the parties), could be negatively affected. This final rule addresses the problems that are presented by prescribers who do not have NPIs or do not disclose them, by proposing an additional requirement in the NPI regulations.

B. Provisions for a Requirement To Obtain and Use NPIs

We proposed an additional requirement for organization covered health care providers that have as a member, employ, or contract with, an individual health care provider who is not a covered entity and is a prescriber. Organization health care providers are health care providers that are not individuals. Our proposal would require an organization to require such a prescriber to: (1) Obtain an NPI; and (2) to the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

Organization covered health care providers would be required to implement the requirement within 180 days after the effective date of the final rule, which we proposed would be reflected in 45 CFR 162.404(a)(2) with regulation text stating that an organization covered health care provider must comply with the implementation specifications in 45 CFR 162.410(b). For example, if the final rule was effective on October 1, 2012, covered organization health care providers would have to meet the requirement by April 7, 2013.

We proposed that the requirement would be reflected in the regulation text in 45 CFR 162.410(b) by adding the following new language. ''An organization covered health care provider that has as a member, employs, or contracts with an individual health care provider who is not a covered entity and is a prescriber, must require such health care provider to: (1) Obtain an NPI from the National Plan and Provider Enumeration System (NPPES) and (2) to the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.''

This requirement represents a narrow exception to the position we took in the 2004 NPI final rule. In the 2004 NPI final rule (69 FR 3440), we stated ''[w]e do not consider individuals who are health care providers * * * and who are members or employees of an organization health care provider to be ''subparts'' of those organization health care providers, as described earlier in this section. Individuals who are health care providers are legal entities in their own right. The eligibility for an ''Entity type code 1'' NPI of an individual who is a health care provider and a member or an employee of an organization health care provider is not dependent on a decision by the organization health care provider as to whether or not an NPI should be obtained for, or by, that individual. The eligibility for an ''Entity type code 1'' NPI of a health care provider who is an individual is separate and apart from that individual's membership or employment by an organization health care provider.''

We still do not consider noncovered health care providers that are prescribers to be subparts of organization health care providers, and we did not propose that they would not be legal entities in their own right. This final rule closes a gap in the NPI rule by virtue of the types of relationships that covered organization health care providers have with noncovered individual health care providers.

The providers we intend to reach are prescribers who are not required to obtain and disclose an individual NPI under the current NPI regulations. To the best of our understanding, these prescribers are largely hospital-based providers who staff clinics and emergency departments, or otherwise provide on-site medical services, such as medical residents and interns, as well as prescribers in group practices, whose services are billed under a group, or ''Entity type code 2'', NPI regardless of whether they have obtained an individual, or ''Entity type code 1,'' NPI. These prescribers are using the ''Entity type code 2'' to identify themselves on prescriptions, which does not identify them as individuals, or are using no identifier.

We believe this final rule describes the various relationships that organization health care providers have with such prescribers, and that the relationship is one in which organizations can exercise control over these prescribers and require them to do something. For instance, a physician or dentist who prescribes may be a member of a group practice. As noted in the 2004 NPI final rule (69 FR 3439 and 3440), ''group health care providers are entities composed of one or more individuals (members), generally created to provide coverage of patients' needs in terms of office hours, professional backup and support, or range of services resulting in specific billing or payment arrangements. For purposes of this rule, we consider group health care providers to be organization health care providers.'' By virtue of the contractual or other relationship between a group and a member, a group can require the member to do certain things, such as work certain on-call hours. Likewise, a resident or nurse practitioner who performs medical services at a hospital can be required to do certain things, such as to abide by medical staff by-laws and hospital policies and procedures, as a hospital employee or contractor.

This final rule does not specify how organization covered health care providers should impose the requirement to obtain an NPI and disclose it on prescribers. Organization covered health care providers may have a number of alternatives by which they may accomplish this, for example, through a written agreement, an employment contract, or a directive to abide by the organization health care provider's policies and procedures.

We proposed that the requirement for a prescriber to disclose his or her NPI would apply for prescriptions written pursuant to the prescriber's relationship with the covered health care organization provider. For example, if a physician works for two group practices, A and B, group practice A would have to require the physician to disclose his or her NPI for pharmacy claims that are for prescriptions written by the prescriber for a patient of group practice A, and group practice B would be required to do the same for pharmacy claims for prescriptions written by the prescriber for a patient of that group practice.

We considered expanding our proposal to organization covered health care providers that grant clinical privileges to individual health care providers who are not covered entities and are prescribers, so that we would be certain to encompass hospital residents and interns under our proposal (to the extent they are not otherwise required to obtain Type 1 NPIs). However, it is our belief such prescribers will be encompassed under this final rule, as we believe it encompass virtually all prescribers who are not currently required to obtain and disclose an individual NPI. Very limited exceptions may include, by way of example, a self-employed physician who does not bill insurance plans and does not have a member, employee or contractual relationship with an organization covered health care provider (or has one

with a noncovered organization health care provider), such as a psychiatrist or plastic surgeon who only accepts cash-paying patients. Even with respect to these prescribers, we hope this final rule highlights the importance of voluntarily obtaining NPIs to facilitate their patients' access to prescribed items.

We believe this final rule furthers several goals and purposes identified in the Act. First, the statutory purpose of the Administrative Simplification provisions of HIPAA (see section 261 of the Act (42 U.S.C. 1320d note)) is to improve the Medicare program under title XVIII of the Act, the Medicaid program under title XIX of such Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of uniform standards and requirements for the electronic transmission of certain health information and to reduce the clerical burden on patients, health care providers, and health plans. In accord with this statutory purpose, this final rule will improve the Medicare program by virtually ensuring the availability of an NPI as a prescriber identifier on pharmacy claims in the Part D program, because virtually all prescribers would have to obtain an NPI and disclose it to entities that need it for use in standard transactions. This, in turn, would support program integrity efforts described in the April 2012 final rule which requires Part D sponsors to submit PDEs that contain only individual NPIs as prescriber identifiers, effective January 1, 2013.

As noted in the April 2012 final rule, ''[w]hen multiple prescriber identifiers, not to mention dummy or invalid identifiers, are used, authorities must take an additional step in their data analysis before even achieving a refined data set to use for further analysis to identify possible fraud. For example, having to cross-reference multiple databases that update on different schedules to be certain of the precise prescribers involved when multiple identifiers were used, would necessitate several additional steps of data pre-analysis and also would introduce potential errors in correctly matching prescribers among databases.'' Invalid identifiers are generally those that do not appear as current in any prescriber identifier registry. Dummy or default identifiers have never appeared in any prescriber identifier registry but have been used successfully on pharmacy claims in place of valid prescriber identifiers (for instance, when the prescriber's NPI was not available), because they met the length and format requirements of a prescriber identifier. Dummy and default identifiers present additional challenges to authorities, since the actual prescription must be researched to identify the prescriber.

Valid prescriber identifiers are essential to conducting claims analyses to identify aberrant claims prescribing patterns that may indicate fraudulent activity, such as drug diversion schemes or billing for prescription drugs not provided, which includes circumstances with active prescriber participation and those involving forged prescriptions. Improving the accuracy and dependability of the prescriber identifier on Part D claims and PDEs, improves the ability to identify fraud and, in turn, protects and improves the Medicare program.

This final rule further improves the Medicare program by nearly eliminating the instances in which Part D sponsors' reimbursement (or possibly their network pharmacies' reimbursement, depending on the contractual relationship between the sponsors and the pharmacies) would be negatively impacted due to the actions of prescribers with whom they may have no business relationship. Part D sponsors would be expected to price any measurable expectation of financial risk, if any, due to nonreimbursement by CMS into their Part D bids, thus possibly increasing premiums and subsidies paid under the program. This final rule makes such action by Part D sponsors unnecessary by virtually ensuring the availability of prescriber NPIs for PDEs.

This final rule also accords with the purpose of HIPAA as amended by the Affordable Care Act. Section 1104(a)(2) of the Affordable Care Act revised the statutory purpose of HIPAA Administrative Simplification by adding, at the end, that its purpose is to ''reduce the clerical burden on patients, health care providers, and health plans.'' To the extent pharmacies only have to accept one identifier—the NPI—rather than four possible identifiers from prescribers for the majority of their claims, the administrative burden on all parties involved in the processing and payment of these claims is lessened. Pharmacies and payers should no longer have to cross-check provider identifier databases to determine if the prescriber has an NPI when an alternate identifier was used, or contact the prescriber. Moreover, pharmacies and prescribers should no longer have to respond to inquiries from payers regarding the existence of an NPI because an alternate prescriber identifier is used.

The final rule is also supported by section 1173(a)(3) of the Act, which requires the transaction standards adopted by the Secretary to accommodate the needs of different types of health care providers. This final rule accommodates the needs of pharmacies, a type of health care provider, by ensuring that a prescriber NPI is available to them when needed for their claims and reducing the instances in which they must cross-reference provider information databases or research a prescription. Similarly, section 1173(b)(1) of the Act states that,

> [t]he Secretary shall adopt standards providing for a standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system. In carrying out [this requirement] for each health plan and health care provider, the Secretary shall take into account multiple uses for identifiers and multiple locations and specialty classifications for health care providers.

This final rule takes into account the particular needs of pharmacies for an NPI.

While some prescribers will have to apply to obtain an NPI under this requirement, the NPI is free of charge and requires only the completion of a three-page application form that primarily seeks identifying and location information. Thus, we believe the reduction in administrative burden that will be achieved by this final rule outweighs the minimal burden placed on prescribers who will have to obtain NPIs.

The 2004 NPI final rule, as noted previously, foretold the issues that could arise if noncovered health care providers did not obtain NPIs, and therefore encouraged them to do so. The preamble of the 2004 NPI final rule stated that disclosing NPIs to entities for use in standard transactions will greatly enhance the efficiency of health care transactions throughout the health care industry, and that the absence of NPIs when required in those claims by the implementation specifications may delay preparation or processing of those claims, or both. Health care providers responded by obtaining NPIs in large numbers, even when not required to, and we believe the vast majority of prescribers already have NPIs. CMS data shows that approximately 90 percent of Medicare Part D claims as reported in PDEs submitted through January 2012 contained valid prescriber NPIs even though alternate prescriber IDs are currently permitted. Less than 1 percent of PDEs were submitted without a valid identifier. Nevertheless, while the vast majority of Medicare Part D claims contain individual NPIs, 10 percent do not. We note that this submission rate increased incrementally through the

latter months of 2011, likely due to the issuance of the CY 2012 Part D final call letter on April 4, 2011, signaling that CMS was considering only accepting individual prescriber NPIs on PDEs for CY2013, the subsequent CMS outreach to sponsors and pharmacies, and the CMS April 12, 2012 final rule requiring individual prescriber NPIs be submitted with PDEs. This final rule, coupled with the CMS April 12, 2012 final rule, will help ensure this last 10 percent is addressed.

After discussions with representatives of the provider data industry in the fall of 2011, we estimated at that time that there were approximately 1.4 million active prescribers in the United States, of which approximately 160,000 did not have an NPI. It is these prescribers who will have to obtain an NPI under this final rule.

Comment: A national and a state hospital association, several health care provider associations, a standards organization and a company offering connectivity solutions to health care providers, supported our proposal. The state hospital association stated that it was aware of patients being unable to fill pharmacy prescriptions because the prescriber NPIs were not available and had already encouraged its members to obtain NPIs for interns, residents and other prescribers. One provider association specifically acknowledged that our proposal would improve coordination of patient care, increase anti-fraud detection capabilities, and is in line with the goal of modernizing and reforming the health system at large. The company agreed with our statement that, because there are few health care providers who do not already have an individual NPI, our proposal would have little impact on health care providers and the industry at large.

Response: We appreciate and agree with these comments. We are concerned about any pharmacy claims being denied for lack of a prescriber NPI, for instance, because the payer requires an individual NPI to be submitted on the pharmacy claim, especially when the payer is not required to pay the claim and obtain the NPI later. We believe this final rule will address this issue.

Comment: Two prescription health plans/pharmacy benefit managers supported the proposal, but encouraged us to go further and require all prescribers to obtain and disclose individual NPIs. Another commenter, a hospital association, echoed the idea that all prescribers be required to obtain and disclose individual NPIs. A third commenter recommended expanding the requirement to all individual referring, ordering, and rendering providers. In the alternative, one of the commenters expressed the hope that our rule would highlight the importance of health care providers voluntarily obtaining individual NPIs to facilitate their patients' access to prescribed items.

Response: We appreciate the support for our proposal and also hope that all health care providers who do not currently have an individual NPI will voluntarily obtain them and not wait to be directed to do so by an organization covered health care provider of whom they are a member, are employed by, or with whom they have a contractual relationship. We note that HIPAA does not give us direct authority over health care providers who are not covered entities.

In addition, our proposal was intended to address specific problems that are presented by prescribers who do not have NPIs or do not disclose them. Therefore, our proposal was designed in consideration of our authority under HIPAA and narrowly tailored to address these specific problems.

Comment: A commenter, expressed concern about the compliance burden placed on hospitals, stating that significant staff time would be required to mandate, track and disclose NPIs for all prescribers who are a member, employee, or contract with a hospital, because it would necessitate the maintenance of a central database that would have to provide 24-hour staffing to disclose these NPIs to retail pharmacies. Another commenter, urged us not to underestimate the impact of this final rule on software vendors and their customers, especially those in the hospital systems market, without providing any specific details about the concerns. However, another commenter agreed with our statement that organization covered health care providers may have several alternatives for compliance.

Response: The proposed rule did not specify how organization covered health care providers should impose the requirement on individual health care providers who are prescribers. We tried to be very clear in the preamble of the proposed rule that organization health care providers may have a number of alternatives for doing so, for example through a written agreement, an employment contract, or a directive to abide by the organization health care provider's policies and procedures. Organization covered health care providers may choose a proactive approach to ensure the requirement it imposes upon individual prescribers is followed by the prescribers. Other organizations may choose to take action upon any inquiries or complaints that a prescriber does not have an NPI or has not disclosed it on prescriptions, for instance. With respect to the latter, organization covered health care providers may want to also voluntarily impose an additional requirement on prescribers to proactively disclose their individual NPIs, so the organization covered health care provider receives as few inquiries or complaints as possible. In addition, we note that pharmacies and payers have access to prescriber NPI databases which are routinely consulted at point-of-sale, to which the additional NPIs that must be obtained under this final rule will be added. In this regard, we fully expect that prescribers will abide by an organization covered health care provider's requirement to obtain an NPI, if they have not already done so voluntarily. We do not expect hospitals to respond to NPI inquiries on a 24-hour basis, but rather, to respond in a reasonable timeframe to what we believe will be infrequent inquiries about prescriber NPIs, or virtually no inquiries, if the prescribers proactively disclose them on the prescriptions they write. We note that such action by prescribers will assist their patients in obtaining the medications they have prescribed for them.

With respect to hospital computer updates, we note that individual NPIs are already obtained by prescribers, who are members of, employed by, or contracted with, hospitals, and disclosed to pharmacies. Our proposal merely marginally expands the pool of prescribers who will be required, by virtue of certain relationships with organization covered health care providers, to obtain individual NPIs and disclose them. While some hospitals may desire to implement computer updates to prevent the use of an alternate prescriber identifier on a prescription, it is not required by this final rule. Thus, we do not believe compliance with this new requirement will necessarily be burdensome.

Comment: A commenter responded to our specific request for comments on whether our proposal would reach residents and interns by stating that it would. Another commenter expressed concerns about our proposal's applicability to residents, interns and medical students, stating that residents and interns are not in full control of what is ordered and are typically acting upon an attending physician's directive, and that medical students would not order or prescribe without counter signature. This commenter suggested that residents obtain an NPI for use during their training tenure and later, a different one for actual practice. A third

commenter requested that we require residents, medical students, and prescribers coming from abroad to obtain their NPIs before they leave training/school and before they enter the United States, respectively.

Response: With respect to the concerns expressed about the applicability of our proposal to resident, interns, and medical students, and what their authority is to prescribe, our proposal applies to all health care providers who are prescribers. Thus, to the extent a resident, for example, is a prescriber under applicable state law, and is reached by this new NPI requirement by virtue of his or her relationship with an organization covered health care provider, such resident will have to obtain and disclose his or her individual NPI. While there is currently no NPI type that identifies a person as being in his or her residency, for purposes of data analysis, a physician can identify the period of time during which they are/were a resident with certainty in any outlier analysis. In addition, the NPI is intended to be a lasting identifier for the health care provider to which or whom it has been assigned. In the 2004 NPI final rule (69 FR 3441), we stated that, ''[f]or health care providers with an 'Entity type code' of 1, the NPI will be a permanent identifier, assigned for life, unless circumstances justify deactivation.'' Residents and other health care providers en route to this country should be reached by this final rule by virtue of their relationships with the organization covered health care providers pursuant to which they are prescribers. If they are not prescribers, they will not be reached by this final rule.

Comment: A commenter suggested that we replace ''NPI'' in the regulation text with ''Type 1 NPI.'' The commenter also suggested that, in order to be more precise as to our intent, we add the word ''proactively'' before ''disclose'' in § 162.410(b)(2) so that the regulation would read ''To the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, proactively disclose the NPI * * *''

Response: We disagree with the commenter about the suggestion to add ''Type 1'' to the regulations text. Only individuals may obtain a Type 1 NPI, so adding ''Type 1'' to the regulation text as the commenter suggested would be redundant. With respect to the comment that urges us to add the term ''proactively'' to the regulation, we do not require other covered health care providers to proactively disclose their NPIs, and we do not believe it would be appropriate to single out individual prescriber health care providers to do so. We did not propose such a change, but we do encourage organization covered health care providers to require prescribers who are members, employees, or with whom they have a contractual relationship, to proactively disclose their Type 1 NPIs on the prescriptions they write, so the pharmacy has it for the claim and there will be no need for additional follow-up by the pharmacy or payer.

Comment: A commenter stated that there appears to be a loophole in the regulation text, when a provider who is not contracted (for example, out of network), but who bills a health plan, would not need to obtain an individual NPI.

Response: We believe the commenter misunderstands the applicability of our proposal. Our proposal applies to organization covered health care providers. Health plans are not organization covered health care providers. In addition, to the extent a health care provider bills a health plan, such health care provider, if a covered health care provider, would be required to obtain an NPI under HIPAA. If the prescriber is not a covered health care provider but is, for example, a member of a group practice that does bill health plans, this final rule will reach that prescriber by virtue of his or her relationship with the group practice.

Comment: A few commenters made a number of suggestions concerning data enhancements to the NPPES data base and NPI registry.

Response: Our proposal was very limited. We consider these comments, suggesting the creation of new types of NPI numbers and data base enhancements, to be beyond the scope of our proposal, although we appreciate suggestions for future improvements.

After consideration of the public comments received, we are finalizing these provisions as proposed

C. Effective and Compliance Dates

We proposed that the date by which an organization covered health care provider must comply is 180 days after the effective date of the final rule. In other words, if the final rule is effective 60 days after the date of publication; then 180 days after the effective date, organization covered health care providers that have a prescriber as a member, employ, or contract with a prescriber who is not a covered entity must require him or her to: (1) obtain an NPI and; (2) to the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

Comment: A commenter stated that the NPI implementation date of October 1, 2013 is not attainable. Other commenters requested that the compliance deadline be delayed until 1 year after the publication of the final rule so that organization covered health care providers have sufficient time to implement the requirement.

Response: We are not certain why the other commenter is referring to a compliance date of October 1, 2013. We proposed that the compliance date for the modification to the NPI rule would be 180 days after the effective date of the final rule. This final rule is effective on 60 days after the date of publication, which means that the compliance date is 180 days after the effective date of this final rule. In other words, by 180 days after the effective date of this final rule, a organization covered health care provider that has a member, employs, or contracts with, an individual health care provider who is not a covered entity and is a prescriber, must require such health care provider to obtain an NPI from NPPES and, to the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

Comment: A few commenters requested that CMS align the compliance date of this NPI requirement with the compliance date in the Medicare Part D program requirement that PDEs be submitted with individual NPIs beginning January 1, 2013.

Response: The Medicare Part D Program PDE requirement that PDEs must include a valid and active NPI is effective on January 1, 2013. In order to align the compliance date of the Part D requirement with the NPI requirement adopted in this final rule, CMS would have to delay the new requirement for PDEs or we would have to provide a compliance date for the NPI requirement that is substantially shorter than 180 days. We are not willing to shorten the 180-day compliance date in order to give covered organization health care providers sufficient time to comply with this final rule. Further, the CMS Medicare Part D program requirement is not within the scope of this regulation. Therefore, we cannot accept the commenter's suggestion.

After consideration of the public comments received, we are finalizing these provisions as proposed.

IV. Change to the Compliance Date for ICD–10–CM and ICD–10–PCS

A. Background

As discussed in section I. of this final rule, the final rule adopting ICD–10–CM and ICD–10–PCS (collectively, ''ICD–10'') as HIPAA standard medical data code sets was published in the **Federal Register** on January 16, 2009 (74 FR 3328) (the ''2009 ICD–10 final rule''). The 2009 ICD–10 final rule requires covered entities to use ICD–10 beginning October 1, 2013.

In late 2011 and early 2012, three issues emerged that led the Secretary to reconsider the compliance date for ICD–10: (1) The industry transition to Version 5010 did not proceed as effectively as expected; (2) providers expressed concern that other statutory initiatives are stretching their resources; and (3) surveys and polls indicated a lack of readiness for the ICD–10 transition.

1. The Transition to Version 5010 and Its Effect on ICD–10 Readiness

Concurrent with the publication of the 2009 ICD–10 final rule, HHS published in the **Federal Register** the Modifications final rule which set January 1, 2012 as the compliance date for Version 5010 (74 FR 3296). As the industry approached the January 1, 2012 Version 5010 compliance date, a number of implementation problems emerged, some of which were unexpected. These included—

- Trading partners were not ready to test the Version 5010 standards due to vendor delays in delivering and installing Version 5010-compliant software to their provider clients;
- Version 5010 errata were issued to correct typographical mistakes and other maintenance issues were discovered as the industry began its internal testing of the standards, which delayed vendor delivery of compliant products and external testing;
- Differences between address requirements in the ''provider billing address'' and ''pay to'' address fields adversely affected crossover claims processing;
- Inconsistent payer interpretation of standard requirements at the front ends of systems resulted in rejection of claims, as well as other technical and standard misinterpretation issues;
- Edits made in test mode were later changed when claims went into production without adequate notice of the change to claim submitters; and
- Insufficient end to end testing with the full scope of edits and business rules in place to ensure a smooth transition to full production.

Given concerns that industry would not be compliant with the Version 5010 standards by the January 1, 2012 compliance date, we announced on November 17, 2011 that we would not initiate any enforcement action against any covered entity that was not in compliance with Version 5010 until March 31, 2012, to enable industry adequate time to complete its testing and software installation activities. On March 15, 2012, this date was extended an additional 3 months, until June 30, 2012.

The 2009 ICD–10 final rule set October 1, 2013 as the compliance date, citing industry testimony presented to NCVHS and many of the over 3,000 industry comments received on the 2009 ICD–10 final rule. The analysis in the 2009 ICD–10 final rule with regard to setting a compliance date emphasized the interdependency between implementation of ICD–10 and Version 5010, and the need to balance the benefits of ICD–10 with the need to ensure adequate time for preparation and testing before implementation. As noted in the 2009 ICD–10 final rule (74 FR 3334), ''[w]e cannot consider a compliance date for ICD–10 without considering the dependencies between implementing Version 5010 and ICD–10. We recognize that any delay in attaining compliance with Version 5010 would negatively impact ICD–10 implementation and compliance.'' Based on NCVHS recommendations and industry feedback received on the 2009 ICD–10 final rule (74 FR 3334), we determined that ''24 months (2 years) is the minimum amount of time that the industry needs to achieve compliance with ICD–10 once Version 5010 has moved into external (Level 2) testing.'' In the 2009 ICD–10 final rule, we concluded that the October 2013 date provided the industry adequate time to change and test systems given the 5010 compliance date of January 1, 2012.

As implementation of ICD–10 is predicated on the successful transition of industry to Version 5010, we are concerned that the delays encountered in the implementation of Version 5010 have affected ICD–10 planning and transition timelines.

2. Providers' Concerns That Other Statutory Initiatives Are Stretching Their Resources

Since publication of the 2009 ICD–10 and Modifications final rules, a number of other statutory initiatives were enacted, requiring health care provider compliance and reporting. Providers are concerned about their ability to expend limited resources to implement and participate in the following initiatives that all have similar compliance timeframes.

The EHR Incentive Program was established under the Health Information Technology for Economic and Clinical Health (HITECH) Act, a part of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5). Medicare and Medicaid incentive payments are available to eligible professionals and hospitals for adopting EHR technology and demonstrating meaningful use of such technology. Eligible professionals and hospitals that fail to meaningfully use EHR technology could be subject to Medicare payment adjustments beginning in FY 2015. The Physician Quality Reporting System (PQRS) is currently a voluntary reporting program that provides incentive payments to eligible professionals and group practices that satisfactorily report data on quality measures for covered Physician Fee Schedule services furnished to Medicare Part B fee-for-service beneficiaries. However, eligible professionals and group practices who do not meet the reporting requirements will start receiving penalties in 2015. The Electronic Prescribing (eRx) Incentive Program is a reporting program that uses a combination of incentive payments and payment adjustments to encourage electronic prescribing by eligible professionals. Beginning in 2012 through 2014, eligible professionals who are not successful electronic prescribers are subject to a payment adjustment. Finally, section 1104 of the Affordable Care Act imposes additional HIPAA Administrative Simplification requirements on covered entities, shown in Chart 2.

CHART 2—HIPAA COMPLIANCE DATES FROM THE AFFORDABLE CARE ACT

Covered entity compliance date	HIPAA Requirements from the Affordable Care Act
January 1, 2013	• Operating rules for eligibility for a health plan and health care claim status transactions.
December 31, 2013	• Health plan compliance certification requirements for health care electronic funds transfers (EFT) and remittance advice, eligibility for a health plan, and health care claim status transactions.
January 1, 2014	• Standards and operating rules for health care electronic funds transfers (EFT) and remittance advice transactions.
December 31, 2015	• Health plan compliance certification requirements for health care claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, health care claims attachments, and referral certification and authorization transactions.
January 1, 2016	• Standard for health care claims attachments. • Operating rules for health care claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, referral certification and authorization transactions.
4 years from effective date of this rule (For more information see section II.E. of this final rule.).	• Unique health plan identifier.

3. Current State of Industry Readiness for ICD–10

It is crucial that all segments of the health care industry transition to ICD–10 at the same time because the failure of any one industry segment to successfully implement ICD–10 has the potential to affect all other industry segments. Ultimately, such failure could result in returned claims and provider payment delays that disrupt provider operations and negatively impact patient access to care.

In early 2012, it became evident that sectors of the health care industry would not be prepared for the October 1, 2013 ICD–10 compliance date. Providers in particular voiced concerns about their ability to meet the ICD–10 compliance date as a result of a number of factors, including obstacles they experienced in transitioning to Version 5010 and the other initiatives that stretch their resources. A CMS survey conducted in November and December 2011 (hereinafter referred to as the CMS readiness survey) found that 26 percent of providers surveyed indicated that they are at risk for not meeting the October 1, 2013 compliance date.[4]

In February 2012, the Workgroup for Electronic Data Interchange (WEDI) conducted a survey on ICD–10 readiness, hereinafter referred to as the WEDI readiness survey.[5] WEDI received responses from more than 2,600 providers, health plans, and vendors showing that the industry is uncertain about its ability to meet ICD–10 compliance milestones. Data from the WEDI survey indicated that nearly 50 percent of the provider respondents did not know when they would complete their impact assessment.[6] In addition, the survey found that approximately 33 percent of providers did not expect to begin external testing in 2013, while approximately 50 percent of providers did not know when testing would occur.[7]

Other segments of the industry, such as health plans and software vendors, also reported that they would benefit from additional time for implementation. While the CMS ICD–10 Implementation Guide recommends that payers begin external testing in the fall of 2012, the WEDI readiness survey found that most health plans do not expect to begin external testing until 2013. In addition, about 50 percent of vendors are not yet halfway through development of ICD–10 products. Vendor delays in product development can result in provider and payer delays in implementing ICD–10.

Given the evidence that segments of the health care industry will likely not meet the October 1, 2013 compliance date, the reasons for that likelihood, and the likelihood that a compliance date delay would significantly improve the successful and concurrent implementation of ICD–10 across the health care industry, we proposed to extend the compliance date for ICD–10.

B. Public Comments on the 1-Year Delay of ICD–10

Faced with growing evidence that a group of providers would not be ready to transition to ICD–10 on October 1, 2013, and the possibility that payment for millions of health care claims would be delayed, we considered the following options before proposing a 1-year delay of the compliance date in the April 2012 proposed rule:

Option 1: Maintain October 1, 2013 deadline

Option 2: Maintain the October 1, 2013 compliance date for ICD–10–PCS (procedure codes) and only delay the compliance date for ICD–10–CM (diagnosis codes)

Option 3: Forgo ICD–10 and wait for ICD–11

Option 4: Mandate a uniform delay of the compliance date for ICD–10

We proposed Option 4, mandate a uniform delay for 1 year of the ICD–10 compliance date, because we believed it would be the most effective way to mitigate the significant systemic disruptions and payment delays that could result if a large percentage of providers are not ready to implement ICD–10 on October 1, 2013. In addition, as the Regulatory Impact Analysis (RIA) in this final rule indicates, Option 4 is most likely to minimize the costs of delay and to maximize the benefits to providers who need more time to implement.

Of the more than 500 public comments submitted, there was some support for each of the options considered. The compliance date of October 1, 2014, as proposed in the April 2012 proposed rule, was supported by the highest number of public comments in comparison to the other options. We summarize the

[4] ''Version 5010 and ICD–10 Readiness Assessment: Conducted among Health Care Providers, payers, and Vendors for the Centers for Medicare & Medicaid Services (CMS),'' December, 2011, Prepared by CMS. Survey responses received from 404 health care providers, 101 payers, and 90 vendors.

[5] ''Survey: ICD–10 Brief Progress,'' February 2012, conducted by the Workgroup for Electronic Data Interchange (WEDI).

[6] An impact assessment for ICD–10 is performed by a covered entity to determine business areas, policies, processes and systems, and trading partners that will be affected by the transition to ICD–10. An impact assessment is a tool to aid in planning for implementation.

[7] For providers, the CMS ICD–10 Implementation Guide recommends that they complete their impact assessments by Winter 2012 and begin external testing in the Fall of 2012. CMS provides implementation guides for providers, payers, and vendors to assist with the transition from ICD–9 to ICD–10 codes. It is a resource for covered entities providing detailed information for planning and executing the ICD–10 transition process. CMS recommends industry use the guide as a reference.

options from the April 2012 proposed rule below, present the public comments related to them, and provide our responses. We also summarize and respond to additional options and suggestions commenters presented that were not considered in the April 2012 proposed rule. Finally, we summarize some of the comments that address issues outside the scope of this regulation.

1. Option 1: Maintain October 1, 2013 Deadline

Segments of the health care industry expressed support for staying the course regarding the October 2013 compliance date. Many health plans, large hospitals, physician practices, and IT vendors have already made large investments upgrading systems, hiring personnel for the transition, and making other preparations for implementation. There is a financial and psychological momentum toward implementing ICD–10 that may be disrupted by a delay. According to the Edifecs poll, ''a potential delay of the ICD–10 compliance deadline could have far reaching—and highly negative—impact to the health care industry's effort to implement the mandate.'' [8]

Comment: Some commenters recommended maintaining the October 1, 2013 deadline. Some commenters argued that considerable expense has been expended by many entities in order to meet the October 1, 2013 deadline, and any delay will be costly. Another commenter described the investment of time and resources that has been spent on education, outreach, and policy discussions in order to meet the October 1, 2013 compliance date. Some commenters noted the costs that would be incurred by coders, students, teaching institutions, and training programs if the compliance date were delayed. Students and teaching programs have invested much in training geared toward an October 1, 2013 compliance date.

One commenter noted that, among the downsides to delaying implementation of ICD–10, if we continue to use current codes, the ability to progress population-based healthcare and improve patient care will be limited. Commenters suggested that a delay prolongs the period until industry can use the improved code sets that support the improvement of quality and outcomes data, cost-effective approaches to delivering care, and information for better research.

Another commenter urged no delay, noting that the U.S. health care industry has known for at least 15 years that ICD–10 would be adopted as a replacement for the severely outdated and broken ICD–9. The commenter stated that the industry has had 3 years to prepare, since the publication of the ICD–10 final rule, and, therefore, it does not seem likely that the provision of more time, by itself, will be sufficient to ensure those lagging in ICD–10 will be ready by a delayed compliance date.

Other commenters recommended that if a delay is necessary, that it be for less than 1 year, citing similar reasons to those already described.

One commenter suggested that maintaining the October 1, 2013 compliance date would be difficult because the ICD–10 project timelines for both physicians and vendors—on which physicians are often dependent—were affected by the obstacles associated with the implementation of Version 5010. Another commenter argued that the survey results used in the RIA that indicated that 25 percent of physicians did not think they were prepared for IC–10 may well overestimate the percentage of physicians who would be well-prepared for an October 1, 2013 compliance date, and that maintaining the October 1, 2013 date would be ill-advised.

Response: We recognize that many individual entities that were on target to meet the October 1, 2013 deadline will be financially impacted by a delay. We also recognize that there are opportunity costs associated with a delay, such as a delay in taking advantage of the improved code sets that support the improvement of quality and outcomes data, cost-effective approaches to delivering care, and information for better research. But we believe that the risk of a major disruption in physicians' reimbursements nationwide and the possible effects on patient care outweighs those costs.

As we indicated in the April 2012 proposed rule, it is clear to us that a significant number of health care entities will not be prepared to meet an October 1, 2013 compliance date. Reasons for this include that entities may not have altered their systems, thoroughly analyzed their processes, changed their forms, prepared for training their personnel, begun testing their internal systems, or are not in a financial position to begin these preparations.

While we cannot project precisely what percentage of certain sectors of the health care industry would not be prepared for an October 1, 2013 deadline, the studies we have used in the RIA of this final rule reflect that the numbers are significant enough to cause a disruption in health care claim payments. We project a number of quantifiable negative consequences of such a disruption in the RIA and believe that there may be a number of unanticipated costs as well, including possible indirect economic impacts on related industries and the economy at large.

It is also likely that health care entities have stopped or slowed their preparations for an October 1, 2013 deadline since the Secretary announced in February 2012 that a delay would be considered through rulemaking. Because of this, there may be more entities that would be unprepared for an October 1, 2013 deadline than what we predicted in the April 2012 proposed rule.

We believe a delay of the ICD–10 compliance date will increase the readiness of the industry at large, and thus avoid a large disruption in health care claim payments. Entities that were not on schedule to be ready by October 1, 2013 can use the time to become prepared, and entities that are on schedule can use the delay to conduct more thorough testing and work with their trading partners to decrease the possibility of unforeseen obstacles to implementation and increase the possibility of a smooth transition.

We recognize that the 1-year delay in compliance date does not guarantee that entities will use the time to become better prepared to meet the original compliance date of October 1, 2013. However, additional activities are planned to mitigate this risk. During the 1-year delay, we expect to increase education and outreach events and to work with industry on improvements to the overall standards implementation process.

2. Option 2: Maintain the October 2013 Compliance Date for ICD–10–PCS (Procedure Codes) and Only Delay the Compliance Date for ICD–10–CM (Diagnosis Codes)

In the April 2012 proposed rule, we considered a split implementation alternative: Maintaining the compliance date for ICD–10–PCS, which is used for inpatient hospital procedure coding, at October 1, 2013, while delaying the compliance date for ICD–10–CM, the diagnosis codes used by physicians, to some later date, for example October 1, 2015. The rationale for this option was that hospitals, with their greater access to resources, would be in a better position to move forward with ICD–10–

[8] See ''Survey: Industry Reaction to Potential Delay of ICD–10—A Delay will be Costly, but Manageable * * * Unless it's more than a Year,'' Edifecs, February 27, 2012: *http://www.edifecs.com/downloads/EdifecsSurvey-ICD10Delay.pdf.*

PCS, which would result in at least partial compliance with the October 1, 2013 date. This option would also afford small providers additional time to become compliant with the ICD–10–CM diagnosis codes.

Comment: Some commenters believed that a split implementation of the ICD–10 procedure versus diagnosis codes would be an appropriate approach. Moving first to adopt ICD–10–PCS for the inpatient setting, commenters stated, would permit HHS and the industry to evaluate the impact on a defined part of the health care system and better inform challenges and solutions before moving the broader health care industry to ICD–10–CM codes.

One commenter noted that moving to adopt ICD–10–PCS for the inpatient setting first would alleviate the issue of the lack of granular coding for inpatient procedures, a concern vocalized by both hospitals and device manufacturers.

Other commenters argued against mandating different compliance dates for procedure and diagnosis codes. One commenter stated that a split approach would result in significant increases in costs to vendors because they would have to support dual systems. These costs would then be passed on to clients. Another commenter noted that a split approach would be costly with regard to the coordination of concurrent payer rules for ICD–9 and ICD–10 as applied to adjudication, duplicate claims checking, and fraud and abuse. The same commenter stated that there would be added complexities for clearinghouses because they would be running dual systems.

Other commenters argued that splitting the compliance date could confuse certain providers because of the overlap of hospitals and ambulatory sites of services in some contexts. Another commenter argued that splitting the implementation date would have three consequences: Added cost to support dual coding systems and the analyses, coding, and testing that each of the two code sets would require before implementation; increased provider confusion because the industry is supporting both code sets; and the need for a complete rewrite of CMS' diagnostic related groups (DRGs). This would eventually have an impact on revenue neutrality, the commenter suggested. Staggered implementation would also make interpretation of data difficult, the commenter added.

Response: We agree with commenters that argue against a phased-in approach to implementation of ICD–10–PCS followed at a later date by ICD–10–CM. We believe that different compliance dates for diagnostic and procedure codes would burden the health care industry with a substantially greater cost than a uniform implementation because many sectors of the health care industry would have to run dual systems. This option would also place considerably more burden on hospitals because they would effectively have to implement ICD–10 twice: once in 2013 for ICD–10–PCS and then again at a later date for ICD–10–CM, increasing their implementation costs.

Further, there is a risk that a split implementation of procedure and diagnostic codes would render an operationally difficult implementation of the new code set even more difficult. These operational complexities would translate into added costs for all parties. Also, where a split-compliance approach contributes its own implementation challenges—that is, complexities in terms of dual processing and dual payer rules—we do not believe that HHS would easily be able to derive useful lessons that could applied to a successive implementation of ICD–10–CM.

Given that the costs of such an approach would be greater than a uniform delay of ICD–10–PCS and ICD–10–CM, and that the experience of a phased approach would yield few beneficial lessons that could be applied to implementation of ICD–10–CM for the broader industry, we do not support such an approach.

Comment: Some commenters suggested a related option of adopting ICD–10–PCS and ICD–10–CM both, but only in the inpatient setting. One commenter stated that this would mirror the approach taken by other nations, and would capture much of the nation's public health data. Commenters noted that moving to ICD–10–CM in the inpatient setting would provide data that would inform a decision whether to move to ICD–10–CM in outpatient settings.

One commenter suggested implementing a small ''subset'' of ICD–10–CM in the outpatient setting and excluding certain providers from detailed requirements. The commenter referred to Germany's approach in this regard.

Response: Both these approaches would appear to have the same costs and involve the same complexities as implementing ICD–10–PCS first and ICD–10–CM later: (1) Many entities would be required to maintain dual processing, which is costly and adds complexity; (2) there would be confusion among providers that are in settings where there is overlap between inpatient and outpatient environments or environments where ICD–9 and the small subset of ICD–10–CM would be used; and (3) concurrent sets of payer rules would have to be followed.

The suggestion that data could be garnered from using ICD–10 in the inpatient setting to inform a decision whether to move the code set to outpatient settings, implies that the decision to mandate ICD–10–CM in outpatient settings has not yet been made, but could be made based on the experience of implementing ICD–10 in the inpatient setting only. This is incorrect. The decision to require ICD–10 to be used by covered entities has already been made, and it was based on years of industry discussions, consensus building, and government rulemaking. Before publishing the proposed rule that proposed to require covered entities to implement ICD–10–CM and ICD–10–PCS, the Secretary considered recommendations of the NCVHS, as well as input from Federal and State agencies, private and professional organizations, and industry stakeholders, including organizations representing providers, health plans, clearinghouses, and vendors. For a history of the adoption of ICD–10, see the proposed rule titled ''HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS'', published on August 22, 2008 (73 FR 49796) (hereinafter referred to as the August 2008 ICD–10 proposed rule). After the August 2008 ICD–10 proposed rule was published, HHS considered over 3,000 public comments on the proposed mandate. (See the January 16, 2009 final rule titled ''HIPAA Administrative Simplification Modifications to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS'' (74 FR 3328).)

3. Option 3: Forgo ICD–10 and Wait for ICD–11

The option to forego a transition from ICD–9 to ICD–10, and instead wait for ICD–11, was another alternative that was considered. This option was eliminated from consideration because the World Health Organization (WHO), which creates the basic version of the medical data code set from which all countries create their own specialized versions, is not expected to release the basic ICD–11 medical data code set until 2015 at the earliest.

From the time of that release, subject matter experts state that the transition from ICD–9 directly to ICD–11 would be more difficult for industry and it would take anywhere from 5 to 7 years for the

United States to develop its own ICD–11–CM and ICD–11–PCS versions.[9]

Comment: A number of commenters referred to an article titled ''There are Important Reasons for Delaying Implementation of the New ICD–10 Coding System,'' published in *Health Affairs* in May 2012, using it to support their opinion that the United States should forgo ICD–10 and wait for ICD–11.[10] Commenters noted a number of highlights from the article, including the following:

- Reference to a study that found that ICD–10 codes failed to outperform ICD–9 codes in capturing clinical data.
- Reference to an analysis of ICD–10 codes that found a lower percent of codes dedicated to diseases, compared to ICD–9 codes.
- Deficiencies in the ICD–10 code set, including a lack of genomic information such as family history.
- Reasons why SNOMED–CT, on which ICD–11 is based, is a superior clinical coding language.
- Reasons why ICD–10 is nearing obsolescence.

One commenter pointed out that, if ICD–11, as scheduled for release by the WHO, should be accepted without further modifications as the reporting standard for the U.S., ICD–11 could be ready for adoption before the 2020–2022 date estimated in the April 2012 proposed rule. Another commenter argued that we should forgo ICD–10 because implementing ICD–10 in 2013 or 2014 would delay the eventual adoption of ICD–11 given the time it takes for code sets to be implemented in the U.S. This would again put us behind the rest of the world because we would be using an obsolete code set—ICD–10—for 13+ years after the WHO adopts ICD–11.

One commenter recommended moving to ICD–11 in the same timeframe as the rest of the world in order not to defeat the primary purpose of having the interoperability to exchange the most accurate health care data.

Other commenters argued against waiting for ICD–11 and argued for preceding with ICD–10 as mandated. Some of these commenters quoted an article that was published in the July 2012 *Journal of AHIMA* that rebutted the article Chute et.al. point by point. (One commenter submitted the entire article as her comment.)[11] Some commenters argued against waiting for ICD–11 because the current code set, ICD–9–CM, is not adequate to support health information and data needs. ICD–9 does not allow for clinically relevant or robust data, commenters wrote, and its continued use reduces physicians' ability to assess patient outcomes, track public health risks, and exchange meaningful data with other health care organizations and reporting entities. It could also slow the adoption of value-based purchasing and other payment reform models, according to the commenter.

Some commenters noted that the structure of ICD–10 was designed to allow for the eventual changeover to ICD–11, and that failure to have this structure in place for ICD–11 would result in retrofitting many more health care systems at catastrophic costs. One commenter noted that, while ICD–11 may hold great promise, the commenter believed that claims about ICD–11's benefits were speculative, at best, because so much of it had yet to be developed.

Another commenter noted that, despite the appeal of putting off the cost and disruption of transitioning to a new code set indefinitely, the disruption and costs of transitioning to ICD–11 are highly unlikely to be less those of transitioning to ICD–10.

Response: We recognize that there is a debate within the health care industry as to the value of ICD–10 compared to ICD–11. We do not participate in this debate in this rule, except to say that we are convinced of the benefit of ICD–10 to health care delivery in this country. One of our responsibilities is to consider costs and benefits. We can make some rough calculations as to the investment that would be lost if we were to forgo ICD–10. In the RIA, we estimate the cost of a 1-year delay to be $1 to $6.6 billion. This represents what we believe to be approximately 10 to 30 percent what has been invested or budgeted, to date, into implementation of ICD–10. Forgoing ICD–10 translates into a loss of up to $22 billion for the U.S. health care industry. This does not take into account the projected fiscal and public health benefits that would be lost every additional year that we use ICD–9.

Given the considerable financial investment made by entities in preparation for ICD–10, and the timelines and uncertainties regarding a possible adoption of ICD–11, we cannot forgo ICD–10 in the hopes that a future, more effective code set will be adopted.

Comment: One commenter recommended that October 1, 2014 remain the compliance date for ICD–10–PCS since this is the area that has run out of ICD–9 procedure codes. HHS should then set October 1, 2016 as the compliance date for ICD–11 diagnosis codes, using ICD–11 as established by the WHO without the clinical modification. This would allow the industry to spend the time prior to October 1, 2016 preparing for ICD–11.

Response: This approach appears to require the processing of three different code sets over a 2-year period: ICD–10–PCS and ICD–9–CM from October 1, 2014 to October 1, 2016; ICD–10–PCS and ICD–11 from October 1, 2016 on. It is unlikely that any version of ICD–11 would be adopted in the timeframes suggested and, as we have noted, dual processing is a more costly and complex approach than a uniform implementation. We do not believe that this is an appropriate approach.

4. Option 4: Mandate a Uniform Delay of the Compliance Date for ICD–10

The fourth option considered was a uniform delay of the compliance date for both ICD–10–CM and ICD–10–PCS. The advantage to an across-the-board delay is that it will yield a single compliance date among all industry segments. Contemplating such an option gave rise to a secondary question—what length of delay would be appropriate?

In the proposed rule, we considered a 1-year and a 2-year delay of the compliance date. We believed a 1-year delay achieves a balance between the needs of those who have already taken the initiative to plan for one-time compliance with ICD–10 and the need for other entities to have additional time to become ICD–10 compliant. While not without additional costs, a 1-year delay, to October 1, 2014, represents what we consider to be a reasonable compromise. Short of maintaining the October 1, 2013 date, delaying ICD–10–CM and ICD–10–PCS by one year does the least to disrupt existing implementation efforts, while affording the small provider community an additional year to become compliant.

a. 2-Year Delay

Comment: Some commenters suggested extending the ICD–10 compliance date 2 years, until October 1, 2015, or beyond. In general, these

[9] Rhonda Butler, ''Why we can't skip ICD–10 and go straight to ICD–11,'' Healthcare Finance News, March 29, 2012; Carl Natale, ''Why we're not ready to plan ICD–11 implementation,'' ICD10Watch, February 20, 2012, *http://www.icd10watch.com/*, ''ICD–10 Frequently Asked Questions,'' American Health Information Management Association (AHIMA), *http://www.ahima.org/ICD10/faqsall.aspx#36.*

[10] C. Chute, S. Huff, J. Ferguson, J. Walker, and J. Halamka, ''There are Important Reasons for Delaying Implementation of the New ICD–10 Coding System,'' *Health Affairs,* May 2012, Vol. 31, No. 5.

[11] R. Averill and S. Bowman, ''There are critical reasons for not further delaying the Implementation of the new ICD–10 coding system,'' *Journal of AHIMA,* vol. 83, no. 7, July 2012.

commenters stated that an additional 2 years is needed to perform system testing, staff training, further analysis, and outreach and education by both the federal government and the private sector to those entities that experience difficulty implementing ICD–10.

One commenter suggested that 2 years would be preferable in order for front line care providers to ''buy into'' the change and integrate ICD–10 into their day-to-day operations. One commenter suggested that, given the interdependency between implementing Version 5010 and implementing ICD–10, HHS should monitor the implementation of Version 5010 carefully, as an additional delay in its implementation may require a delay longer than one year for ICD–10.

One commenter noted that its state Medicaid program would incur substantial costs if the delay was 1 year instead of 2 years due to the schedule in which it Medicaid Management Information System MMIS would be updated.

Another commenter stated that the uncertainty over the compliance date had caused resource planning challenges because organizations have put on hold their partially complete planning and implementation efforts. A 2-year delay would allow organizations to more effectively re-plan their efforts. One commenter noted that a 2-year delay would better align resources and spread costs out over time.

One commenter noted that a 2-year delay is necessary because federal mandates and independent business initiatives were straining already constrained resources in health services delivery and health plan administration. The commenter's organization had committed significant resources in EHR development, Meaningful Use certification, PQRS creation and ACO design and development. Two years would also give the commenter's entity time to implement significant business model changes in 2013 to accommodate provisions of the Affordable Care Act.

One commenter argued that a 2-year delay would give worker's compensation (WC) and third party liability (TPL) insurances time to implement ICD–10 voluntarily because of industry pressure to do so. The commenter further argued that a 2-year delay would enable further study demonstrating the positive impact of ICD–10 for providers who have yet to be convinced.

Some commenters suggested that a delay longer than 2 years was necessary, citing some of the same reasons given for a 2-year delay.

Many commenters agreed with the assumption that implementation costs would increase with every year of a delay, while there were no commenters that argued otherwise. Commenters reported that a 2-year delay would increase costs to maintain implementation efforts, staff training, and systems changes. One commenter stated that a delay in ICD–10 beyond 1 year would result in higher implementation costs for insurers and ultimately for customers. They stated that a delay beyond 1 year would require costly and time-consuming work, including conducting systems inventories that will have become outdated and would need to be completely reassessed.

Some commenters noted that each year of delay prevents the industry from realizing the anticipated benefits of implementing ICD–10.

Some commenters also suggested that any delay beyond 1 year would result in the industry losing momentum in implementation efforts, which could ultimately jeopardize the implementation of ICD–10. One commenter argued that, in the case of a 2-year delay, the staffing and financial resources that were dedicated to the implementation would likely be diverted elsewhere. Some commenters expressed concern about the system implications of moving to ICD–10 the same year some may implement Stage 2 of Meaningful Use.

A commenter stated that our analysis did not include some categories of additional costs of a 2-year delay associated with the ICD–9–CM code set, including ''inaccurate diagnosis and clinical decisions, administrative inefficiencies due to manual processes, coding errors due to outdated codes, worsening imprecision of the ICD–9–CM code (due to stasis if the code freeze is not lifted), and ongoing maintenance of both ICD–9–CM and ICD–10–CM/PCS code sets.''

Response: Based upon the methodology and baseline estimates from the RIA that follows, we estimate it will cost health plans up to an additional 30 percent of their current ICD–10 implementation budgets for a 1-year delay. Therefore, we can assume that a 2-year delay would be at least double the cost.

An informal survey of State Medicaid programs also indicated that an October 1, 2015 compliance date may be problematic for some states that are undergoing IT-intensive MMIS transitions that same year.

Extending the ICD–10 compliance date to October 1, 2015 would likely result in having to lift the current code set freeze, as the industry could not wait an additional 2 years for maintenance updates to the medical data code sets. A code set freeze is a suspension of updates to code sets, in this case, the existing and outdated ICD–9 medical code set. Updates to code sets are usually necessary on an annual basis in order to encompass new diagnosis and procedure codes that capture new technologies or diseases. Lifting the code set freeze would result in the release of potentially thousands of changes to the ICD–10–CM and ICD–10–PCS code sets, all of which would have to be re-programmed into systems in order to be ready for an October 1, 2015 compliance date, at considerable industry cost. The Medicare fee-for-service health plan estimated that the cost for re-programming just one of its systems due to a code set freeze lift would result in, at minimum, $1 million in additional expense. If each of the nation's approximately 1,887 health plans incurred a similar cost, it would translate into a minimum additional expense of nearly $2 billion.

A 2-year delay in the ICD–10 compliance date could also signal a lack of HHS' commitment to ICD–10, potentially engendering industry fear that there could be another delay in, or complete abandonment of, ICD–10 implementation, with subsequent heavy financial losses attributable to ICD–10 investments already made.

We agree that a 2-year delay would provide more time for entities to coordinate implementation with other federal mandates and programs and would give the entire industry more time to conduct system testing, training, further analysis and outreach and education. However, as illustrated in the RIA and as reflected in many of the comments, every year carries considerable costs for those that have already invested resources in order to meet an October 1, 2013 deadline. As well, the entire health care industry will suffer the opportunity costs of not moving to a more effective code set. We also believe there is a risk that ICD–10 could be abandoned altogether if a 2-year delay was established. We do not believe the benefits of more time outweigh the costs and risks of a 2-year delay.

b. 1-Year Delay

Comment: Of all the options, the highest number of commenters supported the proposed 1-year delay of ICD–10. Commenters supported the proposed delay for a number of reasons. Some stated they would benefit from the additional time for implementation given that they are in the process of

implementing numerous other competing priorities during the same time frame. Some commenters believed a 1-year delay would ensure that all industry segments had ample time to transition to ICD–10 and would be ready to do so on the same date.

One commenter supported the 1-year delay because it would allow additional time for planning, testing, training, and price negotiation with vendors, the opportunity for additional business impact assessments, and implementation of appropriate workflow changes, additional time for vendor and payer readiness, and alignment with other health system-wide initiatives.

Some commenters supported the proposed 1-year delay because of the financial advantages. One commenter noted that the 1-year delay would be helpful in order to recover from the cash outlay that was made in order to transition to Version 5010. Some commenters argued in support of the 1-year delay because they believed that their organizations could not support the financial investment necessary to make the ICD–10 transition by the original compliance date.

One commenter supported a 1-year delay because the delay effectively balances the interests and current implementation status of multiple stakeholders. The commenter described the range of opinions and readiness of physicians in the commenter's state, noting that some physicians preferred a longer delay due to competing initiatives, lack of resources, and other mitigating factors, while others preferred no delay because of their early investment in staff and resources to support the effort.

Many commenters did not agree that a 1-year delay was a reasonable approach, arguing for one of the other options or arguing for options that we did not consider in the proposed rule. We have included their arguments under those options.

Response: We agree with commenters that believe a 1-year delay would be helpful operationally, financially, and in terms of planning and coordinating with other initiatives. We agree that a delay beyond one year carries costs and risks that do not outweigh the benefit of a longer delay.

5. Options Not Considered in the April 2012 Proposed Rule

Comment: Some commenters suggested a staggered approach to implementation based on covered entity type. These commenters recommended that clearinghouses and health plans should comply with ICD–10 first and then providers should comply at least 12 months later. Commenters argued that implementation by health plans must be thoroughly vetted before involving providers in the implementation. They believed this would allow providers to fully test with trading partners before their compliance date. These commenters stated that separate compliance dates would minimize the disruption to health care delivery and claims payment processes.

One commenter recommended against any dual implementation period for ICD–10. The commenter argued that such an approach would be nearly impossible to implement from an operational perspective and would cause great challenges both in the development of health plan and provider contracts as well as the implementation of quality improvement strategy reporting, which depends on ICD–10 diagnostic and procedure codes. It would also add significant costs and marketplace confusion to the implementation of ICD–10.

Response: With respect to health plans, all analysis, design and development has been done according to the initial requirement of a cutover implementation. This means health plans have not prepared for processing both ICD–9 and ICD–10 code values on initial claims with dates of service received after the cutover date, as would be expected if health plans were required to be ICD–10 compliant before providers. The strategy to require ICD–10 codes as of a specific date of service has been reinforced in industry outreach and education by HHS, and vendor contracts have been based on this strategy. Some entities have recently indicated a change in this foundational requirement would effectively require them to start over, which would cause a multiyear delay. We assume that the same would be true for many entities were we to change approaches.

A specific compliance date for health plans, followed by another date a year later for providers' compliance, is effectively a 2-year delay of the date when the health care industry as a whole ''goes live'' with ICD–10. In practice, therefore, an argument for a different compliance date for providers and health plans/clearinghouses is an argument for a 2-year delay of the compliance date. We have estimated that a 2-year delay of the compliance date of ICD–10 carries with it considerable costs. We do not believe that the benefits of a 2-year compliance delay would be worth the costs.

Comment: Some commenters made suggestions that went beyond consideration of a delay in compliance date of ICD–10 and questioned the implementation of ICD–10 in general. Commenters stated that the initiative should be abandoned completely because it represents an enormous burden on medical practices with no benefit to patients or no improvement to quality of care. Another commenter argued that ICD–10 will not enhance the process of reporting medical claims.

Response: Beyond stating the basic thesis that there is no benefit to implementing ICD–10, the commenters did not provide detail as to how they arrived at this conclusion. We respectfully disagree with these commenters' conclusion. Although the benefits of ICD–10 have been reiterated in many studies and articles, we emphasize a number of the benefits here: standardized medical data for research, accessing and interpolating global health data in any language, drug discovery for complex diseases, individualized medicine (both predictive and preventative), clinical decision support, improved patient outcomes, optimized billing, and accurate insurance administration, leading to lower health care costs. ICD–10 will allow for better monitoring of patients with chronic conditions such as asthma, diabetes, and sickle cell disease, and will permit better tracking of injuries that can lead to improved preventive and safety measures. For a comprehensive discussion of the expected benefits of ICD–10, and the reasons why we adopted it, see the ICD–10 proposed and final rules (August 22, 2008 (73 FR 49796) and January 16, 2009 (74 FR 3328), respectively.)

6. Other Suggestions From Commenters on How Best To Implement ICD–10

(a) Increased Education and Outreach

Comment: Many commenters urged increased education and outreach on ICD–10, both from the federal government and from industry resources and organizations. One commenter urged HHS to continue to engage the 30+ organizations that are working on ICD–10 education and to leverage their tools and resources. One commenter noted that industry surveys continue to show the lack of awareness of ICD–10 among providers and that education and outreach might mitigate this. Another commenter suggested that HHS educate providers on the synergies between Meaningful Use and ICD–10. The commenter suggested that private sector firms and entrepreneurs should be engaged in education and outreach tasks. One commenter suggested that HHS reach out to health care professions and trade organizations to

assist the health care industry, including local and state providers, plans, and payers—governmental and private.

One commenter suggested that HHS create an education plan and conduct education in a wide range of formats, including webinars, handouts, podcasts, frequently asked questions, and a variety of other formats.

Some commenters suggested that HHS develop and publish specific milestones or benchmarks on the implementation of ICD–10 so that industry could measure its own progress toward ICD–10 readinesss.

One commenter stated that, while large providers many not need assistance, small providers will need assistance to determine if their current documentation practices will enable the selection of an appropriate ICD–10 code.

Response: We will continue to work with industry to provide outreach and education. We will continue to engage stakeholders on a wide variety of ICD–10 implementation issues, including reduction of burden on physicians and other healthcare segments.

Comment: One commenter urged HHS to engage a national Coding Authority to provide a recognized source of accurate and timely coding information. The Coding Authority for ICD–10, such as the Cooperating Parties, would provide the needed awareness and timely answers for ICD–10 transition questions.

Response: We note that the Cooperating Parties, which includes CMS, the Centers for Disease Control and Prevention (CDC), the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA), serve as the national coding authorities on both the ICD–10 and the ICD–9–CM code sets. CMS has the lead on ICD–9–CM and ICD–10–PCS procedure code maintenance. CDC has the lead on ICD–9–CM and ICD–10–CM diagnosis maintenance. AHA has established a Central Office on ICD–9–CM coding and will continue that role with ICD–10. The AHA's Editorial Advisory Board for Coding Clinic is already addressing ICD–10 coding issues for inclusion in their publication Coding Clinic for ICD–9–CM. All of the Cooperating Parties serve on the Editorial Advisory Board. We are confident in the Cooperating Parties continuing role as the national authorities on both ICD–9–CM and ICD–10.

(b) Code Freeze

Comment: Some commenters suggested the ICD–10 code freeze be extended an additional year or until October 1, 2015. One commenter requested clarification on when the code freeze would be lifted.

Response: The issue of the partial code freeze was discussed over several meetings of the ICD–9–CM Coordination and Maintenance Committee. Based on these discussions it was decided to make the last regular update to ICD–9–CM and ICD–10 codes on October 1, 2011. Beginning on October 1, 2012, only codes for new technologies and new diseases would be considered for code updates. The committee decided that, 1 year after the initial compliance date of October 1, 2013, regular updates to ICD–10 would begin and no further updates to ICD–9–CM would occur upon the implementation of ICD–10. The Committee is the public forum for discussions on the maintenance and updates to both ICD–9–CM and ICD–10 code sets and will therefore be the source of discussion and any decisions on the implementation of any further code freeze based on the provisions of this final rule.

(c) Crosswalks

Comment: One commenter argued that, even with a delayed compliance date, the lack of a single forward crosswalk from ICD–9–CM to ICD–10–CM and a single backward crosswalk from ICD–10–CM to ICD–9–CM that is more specific than the General Equivalence Mappings (GEMs) will hamper implementation. According to the commenter, the GEMs are not actual crosswalks that are sufficiently specific to be useful for forward or backward cross-walking in automated billing systems. The commenter suggested that HHS establish true forward and backward crosswalks that eliminate the ambiguity of the GEMs for billing and reimbursement purposes while providing a single authoritative standard for the industry.

Another commenter urged that HHS not endorse a single crosswalk that enhances GEMs with one-to-one mapping forward and backward. ICD–10 creates many-to-many mappings, the commenter noted, and, in contrast to relying on national crosswalks established by HHS, health plans should build rules and medical policy and ensure their use of ICD–10 supports that policy. Another commenter urged that HHS take a lesson from the Canadian transition to ICD–10: ''don't crosswalk.''

Response: We are aware that there is not an exact one-to-one match in the forward or backward translation between ICD–9 and ICD–10. However, we believe that our General Equivalency Mapping (GEMs) is a useful tool to assist with transitioning between ICD–9 and ICD–10. Furthermore, we believe that the training materials posted to the CMS Web site, as well as the scheduled outreach and educational opportunities which are periodically provided by CMS, suffice for training and technical support.

(d) Implementation and Testing Plan and Certification

Comment: Some commenters recommended that HHS develop an implementation and testing plan that expands outreach and education, ensures adequate testing, and develops milestones/timelines to ensure the new compliance date is met. Some commenters discussed the need for HHS to apply lessons learned from Version 5010 implementation when designing a testing plan. Many commenters suggested that there was a false sense of readiness with regard to the transition to Version 5010. True readiness could only be realized through adequate testing.

One commenter suggested that a consistent testing approach be applied by all stakeholders. Another commenter suggested that an ICD–10 Pilot Test could include a representative number of covered entities that, after testing, could establish regional solution centers that would identify best practices on problem solving, obstacles to avoid, and concrete solutions in the implementation of ICD–10. The commenter also recommended standardizing the ICD–10 testing process, which should also include end-to-end testing, so that a national approach could be used for each particular category of entity.

Another commenter suggested we work with NCVHS to develop an ICD–10 testing and implementation plan. The plan should include milestones and metrics that would provide a better understanding of the state of the industry.

Another commenter suggested we tap the Workgroup for Electronic Data Interchange (WEDI), to identify and coordinate pilot participants, liaise with CMS, and work with the agency to disseminate the results to industry.

One commenter suggested that, along with certification, HHS should survey and publish the expected downstream costs that health plans, clearinghouses, Medicare Intermediaries, and Medicare Advantage contractors intend to transfer to their internal and external customers.

One commenter argued against the development of a certification program, and urged HHS to leverage and adopt existing best practice guides and schedules.

One commenter suggested HHS require the certification of all health plans and clearinghouses to be able to

accept ICD–10 codes. The commenter suggested that provider management systems (PMS) and billing systems should be certified by a private entity. Certification of these products, the commenter stated, would greatly assist physician practices in identifying the software necessary to comply with federal mandates and in taking advantage of the various administrative simplification initiatives. The commenter added that certification can also drive implementation by standardizing software requirements and leveraging market forces to ensure practices can meet federal requirements.

Response: We agree that implementation and testing plans are essential for a successful transition to ICD–10. We recognize the need for a shared, industry-wide definition and understanding of ''readiness'' based on testing. We are evaluating methods to establish that common understanding and will issue guidance and offer general assistance on timelines and testing protocols through education and outreach.

(E) PM and Billing Software Vendors

Comment: Some commenters emphasized the integral role PMS and billing software vendors play in covered entities' abilities to meet compliance dates. Commenters noted that vendors needed to provide ICD–10 products and services in a timely manner in order to achieve timely compliance and functionality for all ICD–10 processes. Some commenters therefore suggested that there be compliance tracking and testing of practice management and billing software vendors.

One commenter agreed that software vendors played an important role, but urged that vendors self-report readiness to implement ICD–10. The commenter believed that the self-reporting approach affords an organization more time than a full-blown certification process that will likely increase the cost of implementation for providers and vendors. One commenter suggested that HHS aggressively educate and monitor billing software vendors for the reasons given above.

Response: We agree with commenters that software vendor readiness impacts covered entities' ability to meet compliance dates. While certification of software vendors is not within our authority in this rule, we will issue guidance on expected deliverables and timelines for vendors, and work to establish effective communication, education and outreach for vendor support in realizing these objectives.

(f) Coordinating With Other CMS and Federal Initiatives

Comment: Some commenters emphasized the need for CMS to expedite the availability of a mainframe version of the DRG grouper.

One commenter urged CMS to provide specific guidance on how Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) should approach claim submission and medical necessity documentation, specifically when an initial claim is made in ICD–9 and subsequent claims are made in ICD–10.

One commenter recommended that CMS evaluate and alleviate the financial impact of implementation on state Medicaid programs. The short-term and long-term financial cost associated with ICD–10 will place excessive stress on safety net payer systems that are already under duress, the commenter said.

Some commenters argued that CMS should modify the Medical Loss Ratio (MLR) rule. According to the commenters, in the MLR final rule published on December 7, 2011, CMS recognized that ICD–10 conversion implementation costs are quality improvement activities, and the rule ''proposed to limit the amount of ICD–10 conversion costs to only those incurred in 2012 and 2013. The commenter suggested that the MLR final rule should adjust the 0.3 percent cap on ICD–10 costs to reflect the proposed changes' costs and extend the ability to take costs into account beyond 2013 into 2013.

One commenter requested that all references within the Meaningful Use Stage 2 regulations from both CMS and the Office of the National Coordinator (ONC) be adjusted to align with the ultimate decision on the timing of ICD–10 compliance, including the availability of and flexibility in certification to clinical quality measure specifications that reference ICD–10.

Another commenter suggested that ONC require that all certified EHRs be required to include the capabilities necessary for the use of ICD–10–CM and ICD–10–PCS in the 2014 certification requirements.

Another commenter suggested that CMS use its Quality Improvement Organizations to assist providers in the implementation and testing of ICD–10.

Another commenter brought forward a number of concerns about ICD–10 and CMS' policies regarding the payment system and classification criteria for inpatient rehabilitation units of general hospitals (IRH/Us) and access to care for the patients they serve.

One commenter suggested leveraging existing programs, such as Regional Extension Centers, to enhance provider outreach and education (ONC has implemented a set of Regional Extension Centers (RECs), which are defined as organizations that receive funding under the Health Information Technology for Economic and Clinical Health Act to assist health care providers with the selection and implementation of electronic health records). The commenter suggested that we work with ONC to create and disseminate educational and operational programs, tools, and other ICD–10 resources.

Other commenters addressed specific impacts of ICD–10 on other CMS programs and requested guidance or changes to the policies of those programs based on a delay of ICD–10 implementation.

Some commenters urged that HHS harmonize federal programs with regard to ICD–10. Lack of a coordination of multiple overlapping initiatives could threaten ICD–10 implementation, one commenter stated. Another commenter stated that it was critical that we align the ICD–10 deadline with any dependencies built into all other federal and state programs, such as those involving clinical quality measures that reference ICD–10 codes. Another commenter stated that existing federal health information technology mandates on physicians, such as meaningful use, e-prescribing and quality reporting, must be evaluated in the context of the enormous burden and cost of ICD–10.

Response: We appreciate these observations and suggestions. However, these programs, regulations, and initiatives are the purview of the CMS and other federal agencies and are, therefore, outside of the scope of this regulation. We cannot represent CMS' policy decisions or the programs of other federal agencies.

Comment: Some commenters suggested that HHS review upcoming administrative simplification deadlines and other federal deadlines to see if some of them should be adjusted. One commenter suggested that HHS work with the NCVHS to determine if the compliance dates for operating rules related to the electronic remittance advice, electronic funds transfers, and future operating rules related to enrollment, authorizations, and referrals, and claims should be adjusted. One commenter stated that the HPID compliance date being on the same date as the compliance date of ICD–10 (October 1, 2014) would create a potentially difficult situation in the industry.

Response: We appreciate these observations. We are working to

improve future regulatory alignment, timetables and scheduled deliverables within the limits of our authority. For instance, with HPID, we believe we accommodated some commenters' concerns about the timeframe for compliance by mandating in this final rule that October 1, 2016 be the date by which covered entities must use HPID in standard transactions.

Comment: One commenter recommended that the ICD–10 mandate be extended to noncovered entities, such as workman's compensation and auto insurance, to eliminate the duplicity of administrative processes and systems for health care providers. Otherwise, health care providers will have to maintain dual processes and system capabilities to perform transactions using ICD–9 and ICD–10, which will result in increased administrative burden for providers.

Response: We agree with commenters that some noncovered entities create duplicate processes for health care providers. For purposes of this rule, however, workman's compensation and auto insurance companies are not required to implement ICD–10.

Comment: Commenters urged that, once the final rule is published, HHS not introduce any further delays to ICD–10 implementation, including ''discretionary enforcement periods'' like those used after the Version 5010 compliance date. Further delays would impact other areas of health care such as the successful implementation of electronic health records and reporting that will be required as part of state based exchanges. One commenter noted that further changes in the compliance date would cause significant costs for health plans and ultimately for their customers at a time when the industry will be preparing for the implementation of health insurance exchanges and other Affordable Care Act-mandated changes. This is because systems naturally evolve for a number of reasons over time and an extended delay will require an extension of testing activities and prolonged maintenance of the testing environment.

Other commenters suggested that, as the delayed compliance date draws closer, HHS assess industry readiness and, if necessary, postpone compliance further. One commenter suggested establishing a delay, but delaying still further at a later date if the industry continues to struggle with Version 5010.

Response: We agree with commenters that further delay of the ICD–10 compliance date would be costly to the industry at large. We do not expect any further delays of the ICD–10 compliance date.

(g) Further Analysis

Comment: One commenter suggested that an analysis of the costs of ICD–10 implementation for providers should be conducted by HHS, including how those costs would contribute to the cost of total health care delivery. The commenter wanted the study to include an analysis of whether the ''costs have any benefit to the nation's health,'' and stated that, once the study was conducted, HHS should consider whether implementation of ICD–10 was still in the best interests of the country or if alternatives or an extended timetable for further study would achieve the best results.

Some commenters suggested additional studies and analysis be undertaken before HHS mandate any compliance date for providers. For one, commenters suggested that, as an interim step, HHS fully examine the current ICD–9–CM code development allocation process and make the necessary changes to permit the full utilization of the current code set and the rapid assignment of necessary codes.

Some commenters suggested an analysis be conducted that compared the costs to industry of using ICD–9 for another few years before transitioning to ICD–11 to the industry costs of using ICD–10 for those years. Commenters suggested HHS conduct a further analysis of the cost of requiring two code conversions—to ICD–10 then to ICD–11—over the next 15 years. These analyses, commenters stated, are necessary in order to make a better-informed decision (ostensibly about whether to implement ICD–10).

Some commenters urged that HHS complete a comprehensive cost-benefit analysis to determine the impact of ICD–10 implementation on each health care industry sector before mandating ICD–10. The commenters stated that this analysis should include consultations with appropriate provider organizations and HHS advisory groups, and a final report should be issued that includes the benefits to physician practices and other sectors. The commenters suggested that the analysis include costs for information system changes, rate negotiations, recalculation of reimbursement methodologies, training, and changes to forms. Further, the analysis should consider the timing of the transition, including the impact of timing options on costs and benefits, potential return on investment, and interaction with other major health information investment tasks, including participation in other CMS HIT and quality initiatives. The commenters stated that the analysis should identify immediate and future costs and benefits on physician practices and others of improved data for, but not limited to, patient safety, outcomes analysis, reimbursement, disease management, utilization review and health statistics.

Response: A common assumption of these suggestions is that, after a particular analysis, HHS would consider the merits of implementing ICD–10 and whether to mandate its use or not. In terms of this assumption, we make the following observations:

- The decision to mandate ICD–10 for covered entities has already been made, and it was based on years of industry discussions, consensus building, and government rulemaking. Before publishing the proposed rule that proposed to require covered entities to implement ICD–10–CM and ICD–10–PCS, the Secretary considered recommendations of the NCVHS as well as input from federal and state agencies, private and professional organizations, and industry stakeholders, including organizations representing providers, health plans, clearinghouses, and vendors. For a history of the adoption of ICD–10, see the ICD–10 proposed rule and final rules (August 22, 2008 (73 FR 49796) and January 16, 2009 (74 FR 3328), respectively).
- A number of studies have been conducted with regard to the costs and benefits of ICD–10. The April 2012 proposed rule listed a number of analyses in this regard. A robust analysis of the cost and benefits of ICD–10 was provided in the August 2008 ICD–10 proposed rule, and public comments on the analysis were subsequently incorporated or responded to in the January 2009 ICD–10 final rule. As well, there have been numerous other academic studies, analysis, and articles related to ICD–10. All of these studies have demonstrated costs and benefits with implementation.

Given these points, there is little evidence that another study would, itself, convince HHS to overturn years of rulemaking (or, in the likelihood of it approximately concurring with the results of previous studies, serve any use whatsoever). However, it is clear that further analysis or study means more delay and uncertainty for the health care industry. Because ICD–10 has been mandated, many entities have invested considerable resources to comply. As our RIA—and many of the comments we received—illustrate: Every day that we delay—or create uncertainty around—the implementation of what has been mandated translates to considerable cost to the health care industry.

We do not believe that further analysis of ICD–9 or ICD–10 would be a responsible use of stakeholders' and the federal government's resources.

Comment: Another commenter suggested that a 2-year delay would provide us with the time to analyze the costs and benefits of implementing ICD1–10 on physician practices. The commenter suggested that, at the same time, we should engage all stakeholders to assess whether an alternative code set approach is more appropriate than the full implementation of ICD–10. The commenter noted that other countries implemented ICD–10 with a modified version of the code set. The commenter argued that stakeholders should reach consensus on the question of costs, scope, and whether a modified version is appropriate within the 2-year delay; otherwise, the industry should not implement ICD–10.

Response: We reiterate that further analysis of the costs and benefits of ICD–10 is probably not a responsible approach given the substantial rulemaking and analysis conducted to date and the fact that a significant proportion of the health care industry has already spent resources implementing ICD–10. While we appreciate the suggestion that this analysis take place within a limited time; that is, a 2-year period, and that the analysis is narrowed only to the impact on physician practices, we do not believe the health care industry would participate in a cost/benefit analysis on the current version of ICD–10 while at the same time participating in a decision on whether to create a modified version, as the commenter suggests. This would send contradictory messages to the industry as to what is being proposed or mandated and, again, the delay and uncertainty would be costly, whatever the outcome of these discussions.

It is unclear from the commenters' comments how the concept of consensus is defined and whether consensus refers to stakeholder agreement on the costs of ICD–10 on physicians, stakeholder agreement on the decision to modify ICD–10, or stakeholder agreement on a suggested modified version itself. Regardless, it is questionable whether some defined methodology for achieving consensus would be a valid or appropriate mechanism for agreeing on cost estimates or a decision to modify ICD–10, and whether such a process could or should override years of industry input and government rulemaking that has been used to arrive at the current mandate.

Given the obstacles and uncertainties that we envision 2 years of analysis and decision-making would engender, it is unlikely that any consensus could be made with regard to costs or a proposed modification of ICD–10 within 2 years. For reasons stated earlier, however, it is clear that there would be tremendous costs for the both government and commercial entities.

7. Summary

After analysis and consideration of these comments, we are finalizing the policy to delay the ICD–10 compliance date by 1 year to October 1, 2014.

IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

- In 162.504, we have revised the term ''dates'' to read ''requirements''.
- In 162. 504(a), we have revised the term ''specifications'' to read ''requirements''.
- In 162.504(a), we have revised the term ''Covered health care providers'' to read ''Covered entities''.
- In 162.504(a), we have revised the year ''2014'' to read ''2016''.
- In 162.504(b), we have removed the reference to ''162.510''.
- In 162.504, we have deleted paragraph (c).
- In 162.508 (c), we have inserted ''or OEID'' after the phrase ''deactivate an HPID''.
- In 162.510, we have inserted the term ''Full'' before implementation and revised the term ''specifications'' to read ''requirements''.
- In 162.510(a), we have inserted ''that has an HPID'' immediately after ''health plan''.
- In 162.510(b), we inserted the phrase ''that has an HPID'' immediately after ''health plan''.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment on a collection of information requirement submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicited comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency.
- The accuracy of the agency's estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

A. Information Collection Requirements (ICRs) Regarding HPID/OEID on Health Plan and Other Entities (§ 162.512 and § 162.514)

In order to apply for an HPID or OEID, there is an initial one-time requirement for information from health plans that seek to obtain an HPID and other entities that elect to obtain an OEID. In addition, health plans and other entities may need to provide updates to information.

With respect to the collection of information requirements for the HPID, it is important to bear in mind that: (1) Systems modifications necessary to implement the HPID/OEID may overlap with the other systems modifications needed to implement other Affordable Care Act standards; (2) some modifications may be made by contractors such as practice management vendors, in a single effort for a multitude of affected entities; and (3) identifier fields are already in place and HPID/OEID will, in many instances, simply replace the multiple identifiers currently in use.

Under this final rule, a CHP, as defined in 45 CFR 162.103, will have to obtain an HPID from a centralized electronic Enumeration System. A SHP, as defined in 45 CFR 162.103, would be eligible but not required to obtain an HPID. If a SHP seeks to obtain an HPID, it would apply either directly to the Enumeration System or its CHP would apply to the Enumeration System on its behalf. Other entities may apply to obtain an OEID from the Enumeration System. Health plans that obtain an HPID would have to communicate any changes to their information to the Enumeration System within 30 days of the change. A covered entity must use an HPID to identify a health plan that has an HPID in a standard transaction.

We estimate that there will be up to 15,000 entities that will be required to, or will elect to, obtain an HPID or OEID. We based this number on the following data in Chart 3.

CHART 3—NUMBER AND TYPE OF ENTITIES THAT MAY OBTAIN AN HPID OR OEID

Type of entity	Number of entities
Self insured group health plans	* 12,000
Health insurance issuers, individuals and group health markets, HMOs, including companies offering Medicaid managed care	** 1,827
Medicare, Veterans Health Administration (VHA), Indian Health Service (IHS), TRICARE, and State Medicaid programs	60
Clearinghouses and Transaction Vendors	*** 162
Third Party Administrators	**** 750
Total	~15,000

* "Report to Congress: Annual Report on Self-Insured Group Health Plans," by Hilda L. Solis, Secretary of Labor, March 2011.
** "Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, 2011 **Federal Register** (Vol. 76), July, 2011," referencing data from *www.healthcare.gov*.
*** Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule *http://edocket.access.gpo.gov/2008/pdf/E8–19296.pdf*, based on a study by Gartner.
**** Summary of Benefits and Coverage and the Uniform Glossary; Notice of Proposed Rulemaking *http://www.gpo.gov/fdsys/pkg/FR-2011-08-22/pdf/2011-21193.pdf*.

Note that the number of health plans that will be required, or have the option, to obtain an HPID is considerably larger than the number of health plans which we used in the calculations in section V. of this final rule. This is because self-insured group health plans are required to obtain HPIDs if they meet the requirements of a CHP under this final rule. However, we assume that very few self-insured group health plans conduct standard transactions themselves; rather, they typically contract with TPAs or insurance issuers to administer the plans. Therefore, there will be significantly fewer health plans that use HPIDs in standard transactions than health plans that are required to obtain HPIDs, and only health plans that use the HPIDs in standard transactions will have direct costs and benefits.

To comply with these requirements, health plans and other entities will complete the appropriate application/update form online through the Enumeration System. This online form serves two purposes: applying for an identifier and updating information in the Enumeration System.

Most health plans and other entities will not have to furnish updates in a given year. However, lacking any available data on rate of change, we elected to base our assumptions on information in the Medicare program that approximately 12.6 percent of health care providers provide updates in a calendar year. We anticipate this figure would be on the high end for health plans and other entities. Applying this assumption, we can expect that 1,764 health plans will need to complete and submit the HPID application update form in a given year.

Applying for an HPID or OEID is a one-time burden, although we anticipate health plans will need to update any information changes in the Enumeration System. In future years, the burden to apply for HPIDs and OEIDs will impact only new health plans and other entities that choose to obtain an OEID as described in the section V of this final rule. While health plans will need to update their information in the Enumeration System, we anticipate the burden associated with this requirement will be negligible as health plans will already have access to the Enumeration System and the information collected about the health plan is minimal so little information will need to be updated on a regular basis. From 2013 to 2018, industry trends indicate that the number of health plans will remain constant, or even decrease.[12] We assume that the number of new health plans will be small, and that the costs for application and update of information in the Enumeration System will be negligible. Therefore, our calculations reflect that there will be no statistically significant growth in the number of health plans or other entities and we calculate zero growth in new applications.

We estimate it will take 30 minutes to complete the application form and use an hourly labor rate of approximately $23/hour, the average wage reported for professional and business and services sector, based on data from the Department of Labor, Bureau of Labor Statistics, June 2011, "Average hourly and weekly earnings of production and nonsupervisory employees (1) on private nonfarm payrolls." (*ftp://ftp.bls.gov/pub/suppl/empsit.ceseeb11.txt*). This represents a unit cost of $11.50 per application for both HPID and OEID.

Because our initial estimate for the number of applications for OEID is small (162 Clearinghouses and Transaction Vendors + 750 TPAs = 912) and the costs negligible, we do not include separate calculations. We have elected instead to offer the unit cost figure as a baseline if commenters demonstrate that the universe of applications for OEID is likely to expand significantly.

To further reduce burden and plan for compliance with the Government Paperwork Elimination Act, we proposed accepting electronic applications and updates over the internet. We explicitly solicited comment on how we might conduct this activity in the most efficient and effective manner, while ensuring the integrity, authenticity, privacy, and security of health plan and other entity information.

We did not receive any comments on these [requirements?] and we are finalizing these provisions as proposed.

B. ICRs Regarding Implementation Specifications: Health Care Providers (§ 162.410)

We proposed to put an additional requirement on covered organization health care providers that employ, have as members, or have contracts with individual health care providers who are not covered entities but who are prescribers. By 180 days after the effective date of the final rule, such organizations must require such health care providers: (1) To obtain, by application if necessary, an NPI from the National Plan and Provider Enumeration System (NPPES); (2) to the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose his or her NPI, upon request, to any entity that

[12] *See* Robinson, James C., "Consolidation and the Transformation of Competition in Health Insurance," Health Affairs, 23, no.6 (2004):11–24; "Private Health insurance: Research on Competition in the Insurance Industry," U.S. Government Accountability Office (GAO), July 31, 2009 (GAO–09–864R); American Medical Association, "Competition in Health Insurance: A Comprehensive Study of US Markets," 2008 and 2009.

needs the NPI to identify the prescriber in a standard transaction.

The burden associated with the addition to the requirements of § 162.410 as discussed in this final rule is the one-time application burden, and later update burden as necessary, on prescribers who do not already have an NPI, who have a relationship with a covered health care provider, and who must be identified in a standard transaction. We estimate that as of the fall of 2011 there were approximately 1.4 million prescribers in the United States, of which approximately 160,000 did not have an NPI. It is these prescribers who would have to obtain an NPI. Based on the estimations in the NPI final rule, we estimate that it will take 20 minutes to complete an application for an NPI and use an hourly labor rate of approximately $23/hour, the average wage reported for professional and business and services sector, based on data from the Department of Labor, Bureau of Labor Statistics, June 2011, ''Average hourly and weekly earnings of production and nonsupervisory employees (1) on private nonfarm payrolls.'' (*ftp://ftp.bls.gov/pub/suppl/empsit.ceseeb11.txt*). Additionally, we have calculated an increase of 3 percent for labor costs for each of the years 2013 through 2016 for an hour rate of approximately $24/hour for year 2013. Table 2 shows the estimated annualized burden for the HPID and NPI PRA in hours.

We did not receive any comments and we are finalizing these provisions as proposed.

TABLE 2—TOTAL INFORMATION COLLECTION BURDEN *

Regulation section	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden	Hourly labor cost of reporting ($)	Total labor cost	Total capital/maintenance costs ($)	Total cost ($)
§ 162.410	0938–New.	160,000	160,000	0.33	52,800	24	1,267,200	0	1,267,200
§ 160.512	0938–New.	15,000	15,000	0.50	7,500	24	180,000	0	180,000
Total	.....	175,000	175,000	.....	60,300	.....	.....	.....	1,447,200

* 2013 dollars.

To obtain copies of the supporting statement and any related forms for the paperwork collections referenced previously, access our Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326. If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this final rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–0040–F; Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

VI. Regulatory Impact Statement (or Analysis)

A. Statement of Need

1. NPI for Non-Covered Health Care Providers

The compliance date for use of the NPI by health care providers was May 23, 2007. As of the fall of 2011, we believe there were 160,000 prescribing health care providers who do not already have an NPI. For these health care providers, obtaining an NPI is not a burdensome endeavor, as it is free of charge and takes approximately 20 minutes to file an application to obtain one. However, the availability of these additional prescriber NPIs will greatly assist entities who need them for use in standard transactions, including for the Medicare Part D program, as described previously. See section V.B. of this final rule specifically for a summary of the time costs associated with obtaining an NPI. We have included the costs associated with obtaining an NPI detailed in section V.B. of this final rule and in the summary Tables 20 and 21 of the RIA.

2. HPID

As noted in section I of this final rule, health plans, and other payers are identified in a number of different ways in covered transactions by the health care industry. Health plan identifiers are currently used to facilitate routing of covered transactions or, in other words, ''to determine either where the standard electronic transactions are to be sent if the receiver is [a] health plan or from where they came from if the sender is a health plan.'' [13] The primary function of the HPID in this rule is to create a standard for covered entities to identify health plans in HIPAA covered transactions.

Different segments in each HIPAA standard transaction require an identifier to identify the payer or sender/recipient of a particular transaction. (See Table 1 in the April 2012 proposed rule for a list of HIPAA standard transactions, and Table 2 for an example of a segment that requires a payer identifier.) Currently, when a covered entity, for business reasons, inputs an identifier that identifies a health plan into a transaction segment, the identifier is proprietary or based on the NAIC code, EIN, or TIN of the health plan or other entity. Some health plans use multiple identifiers to identify themselves in transactions.

Standardization of the health plan identifier is expected to ameliorate some routing issues. It is expected to clarify, to some extent, the sender or recipient of standard transactions, when the sender or recipient is a health plan. For instance, a health plan that uses different identifiers to identify itself in covered transactions creates inefficiencies and potential confusion among its trading partners. Participating health care providers that are its trading partners, for instance, could be required to use different identifiers for different transactions, even to identify the same health plan. With the adoption of the HPID, such a health plan will likely use one identifier, thereby making it easier for the covered health care provider to

[13] J. Daley, ''Testimony before the NCVHS Subcommittee on Standards on the National Health Plan Identifier on behalf of America's Health Insurance Plans and the Blue Cross and Blue Shield Association,'' July 19, 2010, *http://www.ncvhs.hhs.gov.*

identify the health plan as the sender or recipient of the standard transaction.

By ameliorating routing issues, the HPID and OEID will add consistency to identifiers, which will provide for a higher level of automation, particularly for provider processing of the X12 271 (eligibility response) and X12 835 (remittance advice). In the case of the X12 835, the HPID and OEID will allow reconciliation of claims with the claim payments to be automated at a higher level.

However, according to testimony and industry studies, the most significant value of the HPID and the OEID is that they will serve as foundations for other regulatory and industry initiatives. The implementation of HPID, in and of itself, may not provide significant monetary savings for covered entities, with the exception of providing time savings by immediately solving certain routing issues. Instead, financial benefits are expected to be realized mostly downstream, when the HPID is used in coordination with other regulatory and industrial administrative simplification initiatives. Testimony from the July 19, 2010 NCVHS hearing reinforced this idea.

As an analogy, the standardization of the width of railroad tracks does not, in and of itself, result in monetary savings. However, such standardization has ensured connectivity between diverse railroad systems that has resulted in time and cost savings in the movement of freight across the country. In a like manner, standardization of a single data element in health care transactions does not, in and of itself, produce substantial time or cost savings. However, the diverse identifiers currently used by multiple health plans are akin to the different track widths used by various railroad systems. Like the standardization of railroad track widths, the HPID serves as a foundation for more efficient and cost effective transmission of health care information.

In an industry white paper, one health care provider association echoed the foundational importance of the HPID and stated that a standard identifier for health plans is ''viewed by many as a crucial step toward one-stop, automated billing.'' [14] In the same paper, that association stated that, in order to begin the movement toward automated billing, standard identifiers were needed for more entities with ''payer'' function than just ''health plans,'' including entities with primary financial responsibility for paying a particular claim, entities responsible for administering a claim, entities that have the direct contract with the health care provider, and secondary or tertiary payers for the claim.[15] The association went on to contend that fee schedules and plan and product types would need to be identified with this health plan identifier.

We did not propose that the HPID or the OEID contain intelligence that would include fee schedules or benefit plans or product types. However, we view the adoption of the HPID and the OEID as foundations for the ''one-stop, automated billing'' that this professional association advocated.

This impact analysis will take these foundational benefits of HPID and, for the sake of illustration, attribute some of the monetary savings from the downstream results to implementation and use of the HPID. It is important to view these estimates as an attempt to illustrate the foundational effect of the HPID rather than as a precise budgetary prediction.

3. Need for a Delay in Implementation of ICD–10, and General Impact of Implementation

The ICD–10 final rule requires covered entities to comply with ICD–10 on October 1, 2013. The provisions of this final rule changes the compliance date to October 1, 2014.

The process of transitioning from ICD–9 to ICD–10, if not carefully coordinated, poses significant risk to provider reimbursement. Should health care entities' infrastructure not be ready or thoroughly tested, providers may experience returned claims and delayed payment for the health care services they render to patients. There has been mounting evidence that a significant percentage of providers believe they do not have sufficient resources or time to be ready to meet the October 1, 2013 ICD–10 compliance deadline.

Two distinct types of issues are implicated by a transition of this magnitude, and the costs associated with both might be avoided if the ICD–10 compliance date is delayed. First, there may be entities that have not readied their systems, personnel, or processes to achieve compliance by October 1, 2013. For example, vendor practice management and/or other software must be updated to process claims with ICD–10 codes, then installed and tested internally. Likewise, staff needs to be trained and systems and forms prepared for the new code set. In a CMS survey conducted in November and December 2011 (hereinafter referred to as the CMS readiness survey), 25 percent of providers surveyed indicated that they are at risk for not meeting the October 1, 2013 compliance date.[16] In February 2012, the Workgroup for Electronic Data Interchange (WEDI) conducted a survey on ICD–10 readiness (WEDI readiness survey) that indicated that nearly 50 percent of the 2,140 provider respondents did not know when they would complete their impact assessment.[17] An illustration of what could occur if elements of industry are not prepared for the transition to ICD–10 can be seen by the January 1, 2012 transition to Version 5010, where we have heard from several provider organizations reporting that numerous practices were not paid for long periods due to the Version 5010 transition.

Second, beyond ''readiness'' and ''compliance,'' there are issues that will arise if trading partners have not thoroughly tested ICD–10. ''Readiness'' is only a self-reported indicator of the potential success of an ICD–10 transition and can be unreliable; we know this from similar industry surveys done for Version 5010 that indicated high levels of readiness only to find multiple issues once claims were submitted in production mode. The other indicator of success is the quality and robustness of testing. Clearinghouses cannot assist in the ICD–10 transition as they are unable to correct coding issues without viewing the underlying documentation, which is not a typical clearinghouse role. In general, only a provider can change/modify a code, so it is incumbent upon providers to ensure a successful ICD–10 conversion. In many cases, providers' success will be predicated upon timely vendor delivery of ICD–10-compliant software, and coordination must be developed with payer systems and new fee schedules. Providers' practice management systems (PMS) must be programmed to process ICD–10 codes, and, with many providers transitioning to EHRs, there needs to be a well-tested interface between electronic health records and the PMS.

In an informal poll conducted by Edifecs (hereinafter referred to as the Edifecs poll), a health care IT company, with responses from 50 senior health care officials representing a wide range

[14] ''National Health Plan Identifier White Paper,'' prepared by the American Medical Association (AMA) Practice Management Center (PMC), September 22, 2009.

[15] Ibid.

[16] ''Version 5010 and ID–10 Readiness Assessment: Conducted among Health Care Providers, payers, and Vendors for the Centers for Medicare & Medicaid Services (CMS),'' December, 2011, Prepared by CMS.

[17] ''Survey: ICD–10 Brief Progress,'' February 2012, conducted by the Workgroup for Electronic Data Interchange (WEDI).

of organizations, 37 percent of respondents stated that a 1-year delay would be beneficial for them.[18] According to the Edifecs analysis, ''For those organizations that have the determination to keep moving forward as if the delay had never been announced, it may end up being a true gift on the testing front.'' [19]

In the CMS readiness survey, 75 percent of providers surveyed cited the lack of time and/or staff as a barrier to implementing ICD–10 on time. The survey also indicated that given just 3 additional months, an additional 14 percent of providers would be able to achieve compliance by December 31, 2013. This indicates that a delay would be helpful in overcoming one of the major obstacles to compliance—lack of time—and that a delay of a year would enable providers to achieve not only ''readiness'' in terms of system interoperability, but also give the time for more thorough testing of ICD–10.

B. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354) (as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104–121), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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. Executive Order 13563 also directs agencies not only to engage the public and provide an opportunity to comment on all regulations, but also calls for greater communication across all agencies to eliminate redundancy, inconsistency, and overlapping, as well as outlines processes for improving regulation and regulatory review.

A Regulatory Impact Analysis must be prepared for major rules with economically significant effects ($100 million in 1995 dollars or more in any 1-year). Because of the impact on the health care industry of the adoption, implementation, and use of the HPID and the delay in the compliance date for ICD–10, this rule has been designated an ''economically'' significant regulatory action, under section 3(f)(1) of Executive Order 12866 as it will have an impact of over $100 million on the economy in any 1 year.

The impacts of implementing the HPID and delaying the compliance date for transition to ICD–10 are quite different, and, because of their respective impacts, both provisions of the final rule would be considered economically significant. Accordingly, we have prepared two independent RIAs: One analysis of the impact of the adoption and use of the HPID and one for the impact associated with the delay of the compliance date for transition to ICD–10. These RIAs, to the best of our ability, present the costs and benefits of this final rule, which has been reviewed by the Office of Management and Budget.

The RIA on the delay of ICD–10 follows the RIA on the implementation and use of the HPID.

We anticipate that the adoption of the HPID and the OEID and the additional requirement for organization covered health care providers to require certain non-covered individuals who are prescribers to obtain and use an NPI would result in benefits that outweigh the costs to providers and health plans. We believe that the delay of ICD–10 will have costs to health plans and clearinghouses, though it will be beneficial to a group of providers.

In addition, under section 205 of the UMRA (2 U.S.C. 1535), having considered at least three alternatives for the HPID that are referenced in the section VI.C. of this final rule, HHS has concluded that the provisions in this rule are the most cost effective alternative for implementing HHS' statutory requirements concerning administrative simplification.

We did not consider alternatives to the addition to the NPI requirements that are in this rule. The NPI is the standard identifier for health care providers under HIPAA. Based on ongoing industry feedback, prescriber NPIs are not always available. Therefore, we believe a regulatory requirement closing the prescriber loophole in the NPI rule is necessary to ensure that the remaining prescribers without an NPI obtain one. We estimate that the addition will have little financial impact on industry and is therefore cost effective in its own right.

Similarly, we have considered four alternatives for delaying ICD–10 compliance, and considered comments regarding those alternatives. The summary of the alternatives, the comments, and our responses to the comments are included in the preamble and will not be repeated for the RIA.

The Regulatory Flexibility Act (RFA), as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Small businesses are those with sizes below thresholds established by the Small Business Administration (SBA). Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, most physician practices, hospitals and other health care providers are small entities, either by nonprofit status or by having revenues less than $10 million for physician practices and less than $34.5 million for hospitals in any 1 year.

We have determined that the adoption of the HPID in this final rule will have an impact on a substantial number of small entities and that a regulatory flexibility analysis, an analysis on the impact of this final rule on small entities, is required. The regulatory flexibility analysis on the impact of the adoption of HPID will come after the RIA. The regulatory flexibility analysis for HPID concludes that, although a significant number of small entities may be affected by this final rule, the economic impact on small entities will not be significant.

We have also determined that the delay of the compliance date for the use of the ICD–10 medical code set will have an impact on a substantial number of small entities and this regulatory flexibility analysis will follow the RIA for the delay of ICD–10. The regulatory flexibility analysis for the delay of ICD–10 concludes that small entities will be positively impacted economically by the compliance date delay and that there will be no significant burden.

In addition, section 1102(b) of the Act requires a regulatory impact analysis for ''any rule or regulation proposed under

[18] ''Survey: Industry Reaction to Potential Delay of ICD–10—A Delay will be Costly, but Manageable * * * Unless it's more than a Year,'' February 27, 2012, conducted by Edifecs. The survey's participants included commercial payers (25%), Blue Cross Blue Shield plans (25%), healthcare providers (18%), government entities such as State Medicaid (9%), medical claim clearinghouses (6%), and other healthcare industry organizations (17%).

[19] Ibid.

title XVIII, title XIX, or part B of [the Act] that may have a significant impact on the operations of a substantial number of small rural hospitals.'' This final rule, with regard to the HPID, ICD–10, and NPI provisions, is being finalized under title XI, part C, ''Administrative Simplification,'' of the Act, and, therefore, does not apply. However, we assume that the impact to small rural hospitals will be similar to that of other small providers in terms of the HPID, NPI, and ICD–10 provisions; that is, implementation of the provisions will either not have a significant economic impact, in the case of HPID and NPI provisions. Or, in the case of the ICD–10 provision, there will be a positive impact.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1-year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately $139 million. This final rule contains mandates that would likely impose spending costs on State governments and the private sector, of more than $139 million. We will therefore illustrate the costs of adoption of the HPID to the State governments, specifically the impact to State Medicaid programs, and to the private sector in our consideration of costs to health plans in the RIA. We will also illustrate the costs of the delay of ICD–10 to State Medicaid programs and to the private sector in our consideration of costs to health plans in the RIA that addresses costs and benefits of the delay of compliance of ICD–10.

As to the addition to the NPI requirements, again, since the method for compliance by covered organization health care providers is discretionary and could vary, for example, from a verbal directive to prescribers whom they employ or with whom they contract, to updating employment or contracting agreements, we believe there is no mandate which imposes spending costs on State government or the private sector in any 1 year of $139 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State laws, or otherwise has Federalism implications. The adoption of the HPID in this final rule will not have a substantial direct effect on State or local governments, does not preempt States, or otherwise have Federalism implications. The delay of compliance with ICD–10 in this final rule will not have a substantial direct effect on State or local governments, does not preempt States, or otherwise have Federalism implications.

In the RIA for implementation of the HPID in the April 2012 proposed rule, we used the proposed provision that the HPID would be implemented for use starting in October 2013. In that RIA, we used data projected for 2013 as our baseline, and 2014 as the first year when benefits attributable to use of the HPID would begin. We also assumed that 2013 would be the year in which most of the costs would be incurred, with 2014 and 2015 as the years in which transition costs would be incurred. We projected those benefits and costs out until 2023.

Because this final rule has established a date 4 years from effective date of this rule as the date by which all covered entities will be required to use HPIDs to identify health plans in the standard transactions, we have changed the year that we will use as a baseline from 2013 to 2016. (See section II.E. of this final rule for more information regarding effective and compliance dates.) For the RIA in this final rule, we assume, as we did in the proposed rule, that benefits from the use of the HPID will occur over a ten-year period beginning the first full year covered entities are required to use the HPID in standard transactions. That 10-year period will begin in 2017 and continue through 10 years (that is, through 2026) and transition costs will be incurred in the years 2017 through 2018.

Because we have shifted our costs and savings forward three years, our conclusions on costs and benefits are different from those in the RIA of the April 2012 proposed rule.

B. Consideration of Public Comments Regarding the Impact Analysis

In the April 2012 proposed rule, we solicited additional data that would help us determine more accurately the impact on the various categories of entities affected by the April 2012 proposed rule. We received numerous comments on our analysis of the costs and benefits of implementing the HPID and the delay in the compliance date of ICD–10. We have provided summaries of those comments and our responses.

Some of our assumptions in the April 2012 proposed rule have changed because of new information we received through public comments. However, the assumptions that we changed were based on comments that were qualitative or anecdotal. The comments did not contain new data or estimates that would impact the quantitative estimates with regard to the impact of implementation of HPID and delay of ICD–10 that were made in the April 2012 proposed rule. Therefore, none of the comments we received required us to change the calculations and conclusions of the RIA that we provided in the April 2012 proposed rule with regard to both the HPID and ICD–10 provisions.

We will summarize those comments and the changes we made to the assumptions.

We have maintained or summarized sections of the RIA that we provided in the April 2012 proposed rule in which comments were made or new information was provided within the comments. We removed or summarized sections of the RIA where we received no comments.

Although we have not changed any of the calculations or conclusions of the RIA that we provided in the April 2012 proposed rule with regard to the ICD–10 provisions of that rule, we have duplicated the summary tables from the April 2012 proposed rule that illustrate those calculations for reference.

C.

In deciding to adopt the HPID as the format for the national unique health plan identifier, we considered a number of alternatives, on which we solicited public and stakeholder comments. As noted, we did not consider alternatives to the addition to the NPI requirements.

We did not receive comments with regard to the alternatives considered in the April 2012 proposed rule regarding the HPID and the NPI. For more detail about the alternatives we considered, please refer to the April 2012 proposed rule. Having received no comments meriting a change in policy, we are finalizing the policy to adopt an HPID that is a 10-digit, all-numeric identifier with a Luhn check-digit as the 10th digit.

D. Impacted Entities—HPID and NPI

All HIPAA covered entities may be affected by the HPID standard as detailed in this final rule although, as we estimate, only a segment of covered entities will have substantive cost or benefits associated with the adoption of the HPID. Impacted HIPAA covered entities include all health plans, health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard.

Table 3 outlines the estimated number of entities that may be affected by the

HPID and OEID, along with the sources of those data.

TABLE 3—TYPES AND NUMBERS OF AFFECTED ENTITIES

Type	Number	Source
Health Care Providers—Offices of Physicians (includes offices of mental health specialists and substance use treatment practitioners).	234,222	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule *http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf* (based on AMA statistics)
Health Care Providers—Hospitals	5,764	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule *http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf*
Health Care Providers—Nursing and residential Care Facilities not associated with a hospital.	66,464	2007 Economic Census Data—Health Care and Social Assistance (sector 62) using the number of establishments ~NAICS code 623: Nursing Homes & Residential Care Facilities n=76,395 x 87 percent (percent of nursing and residential care facilities not associated with a hospital) = 66,464
Other Health Care Providers—Offices of dentists, chiropractors, optometrists, mental health practitioners, substance use treatment practitioners, speech and physical therapists, podiatrists, outpatient care centers, medical and diagnostic laboratories, home health care services, and other ambulatory health care services, resale of health care and social assistance merchandise (durable medical equipment).	384,192	2007 Economic Census Data—Health Care and Social Assistance (sector 62) using the number of establishments.: ~NAICS code 621: All ambulatory health care services (excluding offices of physicians) = 313,339 (547,561 total − 234,222 offices of physicians) ~NAICS code 62–39600 product code): Durable medical equipment =70,853
Health Plans—Commercial: Impacted commercial health plans considered in this RIA are health insurance issuers; that is, insurance companies, services, or organizations, including HMOs, that are required to be licensed to engage in the business of insurance in a State..	1,827	This number represents the most recent number as referenced in ''Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment,'' Proposed Rule, 2011 **Federal Register** (76 FR 41930), July 15, 2011,'' from *http://federalregister.gov/a/2011-17609*
Health Plans—Government	60	Represents the 56 State Medicaid programs, Medicare, the Veteran's Administration (VHA), and Indian Health Service (IHS), TRICARE
Health Plans—All	1,887	Insurance issuers (n=1,827) + Medicaid agencies + Medicare, VHA, TRICARE, and IHS (n=60)= 1,887 total health plans
Third Party Administrators	750	Summary of Benefits and Coverage and the Uniform Glossary; Notice of Proposed Rulemaking *http://www.gpo.gov/fdsys/pkg/FR-2011-08-22/pdf/2011-21193.pdf*
Transaction Vendors and Clearinghouses	162	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule *http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf*, based on a study by Gartner.
Pharmacy Benefit Managers (PBMs)	60	National Council for Prescription Drug Programs (NCPDP) May 17, 2012 letter to Centers for Medicare & Medicaid Services, Re: CMS–0040–P.

E. Scope and Methodology of the Impact Analysis for the HPID and NPI

This impact analysis estimates the costs and benefits that will be realized through the implementation and use of the HPID. We do not analyze the costs and benefits of the addition to the NPI requirements, apart from the costs associated with applying for an NPI that are already addressed in section V.B. of this final rule concerning the collection of information requirements. Aside from the time necessary to apply, we do not anticipate any financial impact as a result of the addition to the NPI requirements. We asked for comments on this approach.

Comment: A commenter expressed concerns about the burden placed on hospitals that would be incurred in order to meet the addition to the NPI requirements. The commenter noted that NPI requirements would require hospitals and other organization health care providers to maintain a central location where prescribers' NPIs would be tracked as well as provide 24-hour staffing to provide pharmacies with these NPIs.

Response: The preamble makes clear that the rule does not specify how organization covered health care providers should impose the requirement on individual health care providers and that they may have a number of alternatives to do so, for example, through a written agreement, an employment contract, or a directive to abide by the organization health care provider's policies and procedures. Thus, we do not believe compliance with this new requirement will necessarily be burdensome.

In this RIA, we do not analyze the impact of implementation and use of the OEID. The OEID, as finalized herein, is a data element that could be voluntarily used by entities other than health plans. These other entities may include, for example, health care clearinghouses, transaction vendors, and third party administrators that provide administration or management for self-insured group health plans. The range of total entities that may apply for and use an OEID is from zero to approximately 1,000 entities (750 Third party administrators + 169 transaction vendors + 60 Pharmacy Benefit Managers). Therefore, using the methodology employed in this RIA, the cost for implementation of the OEID for other entities ranges from no cost to over $500 million, depending on choices made by those entities. Because of the uncertainty inherent in this range of cost, based on the number of entities that may apply for the OEID we will not attempt to quantify the impact of

applying for or using an OEID beyond this limited analysis. Nor will we include this range of costs in our summary of this RIA. However, we can assume that implementing and using an OEID would be accompanied by a proportional range of costs and benefits akin to the cost and benefits estimated for health plans in this RIA. In the proposed rule, we welcomed stakeholder comment on the number and kind of entities that may apply for and use an OEID.

Comment: A commenter noted that he was unable to ascertain whether Pharmacy Benefit Managers (PBMs), TPAs, transaction vendors and other entities that might want to obtain OEIDs were included in the RIA.

Response: We limited our RIA to the analysis of costs and benefits in relation to the HPID, and not the costs or benefits of the OEID. We concluded that there was no way of projecting how many other entities would ultimately obtain and use an OEID as it is a voluntary enumeration. As such, we did not consider costs or benefits to entities that might want to obtain OEID.

However, we assume that there will be some impact to PBMs, just as we assume that there will be some impact to other entities that may obtain and use an OEID. We have included PBMs in Table 3 as a category of impacted entities, even as we are unable to quantify the impact on PBMs.

We estimate the cost of the Enumeration System to be $1.5 million. The Federal Government will bear the costs associated with the Enumeration System that will enumerate health plans and other entities and maintain their HPID and enumeration information. These include the costs of enumerating health plans and other entities, the cost of maintaining health plan and other entity information in the Enumeration System, and the costs of disseminating HPID and OEID data to the health care industry and others, as appropriate. HHS will develop the Enumeration System, and conduct the application, updating, and data dissemination activities. We will not provide any further analysis of this cost within the narrative of the RIA.

The costs to health plans of applying for an HPID and updating and maintaining the information in the Enumeration System are detailed in section III. of this final rule. We will reflect these costs in the summary of the costs to health plans in this RIA.

While we assume that adoption of the HPID will affect a broad range of health care providers, as illustrated in Table 3, we only examine the costs and benefits of implementation and use of the HPID on two types of health care providers: hospitals and physician practices. We did not analyze the impact to nursing and residential care facilities, dentists, or suppliers of durable medical equipment.

There are two reasons for narrowing the scope of this analysis to only two categories of health care providers: First, we have very little data on the usage of EDI among dentists, suppliers of durable medical equipment, nursing homes, and residential care facilities. The lack of data for these types of health care providers has been noted in other studies on administrative simplification.[20] Second, we assume that the greatest benefits will be gained by hospitals and physician practices as they conduct the majority of standard transactions. In our proposed rule, we welcomed comment from industry and the public as to our assumptions.

We did not include an analysis of the impact on pharmacies because the HPID will not be used extensively in electronic transactions by the pharmacy industry. Therefore, we assume no impact of the HPID on pharmacies.

Comment: A commenter disagreed with the assumption that there would be no impact to pharmacies with regard to implementing and using the HPID. The commenter noted that the HPID/OEID would be used in other areas as defined by the NCPDP and ASC X12. The commenter noted that the pharmacy industry has presented recommendations to NCVHS on specific fields in the NCPDP Telecommunication VD.0 Standard and ASC X12 5010 in which the HPID/OEID might be used, and the commenter included a list of recommendations for where and under what circumstances an HPID might be required to be used.

Response: While the commenter's recommendations of where and under what circumstances the HPID might be used in future ASC X12 and NCPDP standards appear reasonable, they were not considered in the context of the RIA because they went beyond the provisions of the April 2012 proposed rule, and, subsequently, this final rule with regard to required use of the HPID. The commenter did not argue that the pharmacy industry would use the HPID in the manner in which it is required in the provisions of this final rule. Therefore, we did not change the assumption we made regarding the pharmacy industry's use of the HPID as noted in the April 2012 proposed rule: ''[T]he HPID will not be used extensively in electronic transactions by the pharmacy industry'' (77 FR 22979).

With respect to health care providers, only health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a HIPAA transaction standard are considered covered entities under HIPAA.

We assumed that the HPID may be used to identify health plans in nonelectronic transactions as well, but, as this standard is only required for use in HIPAA standard transactions, we have not tried to measure the impact on nonelectronic transactions. The costs and benefits included in this analysis do not include infrastructure or software costs for health care providers who are equipping their practices for the transmittal of electronic transactions for the first time. The costs in this impact analysis include only those that are necessary to implement the HPID.

We include health care clearinghouses and transaction vendors as affected entities in Table 3. Transaction vendors are entities that process claims or payments for other entities, which may include health plans. Transaction vendors may not meet the HIPAA definition of health care clearinghouse, but as used in this context, health care clearinghouses would constitute a subset of transaction vendors. Payment vendors are a type of transaction vendor—a transaction vendor that ''associates'' or ''reassociates'' health care claim payments with the payments' remittance advice for either a health plan or provider. For our purposes here, transaction vendors do not include developers or retailers of computer software, or entities that are involved in installing, programming or maintaining computer software. Health care clearinghouses and transaction vendors may be impacted because their systems would have to accommodate the adoption of the new standards such as the HPID to identify health plans in standard transactions. However, we did not calculate costs and benefits to health care clearinghouses and transaction vendors in this cost analysis because we assume that any associated costs and benefits will be passed on to the health plans or providers, and will be included in the costs and benefits we apply to health plans or providers.

We used the total number of health insurance issuers as the number of commercial health plans that will be affected by this final rule, and used this

[20] ''Excess Billing and Insurance-Related Administrative Costs,'' by James Kahn, in *The Healthcare Imperative; Lowering Costs and Improving Outcomes: Workshop Series Summary,* edited by Pierre L. Yong, Robert S. Saunders, and Leigh Anne Olsen, Institute of Medicine of the National Academies, the National Academies Press, Washington, DC: 2010.

number in our impact analysis. A health insurance issuer is an insurance company, insurance service, or insurance organization, including an HMO, that is required to be licensed to engage in the business of insurance in a State, and that is subject to State law that regulates insurance. Although this number is specific to the individual and small group markets, we assume that many health insurance issuers in the large group market are included in this number because they are likely to market to individuals and small groups as well. While the category or ''health insurance issuers'' represents a larger number of health plans than those included in the NAICs codes for ''Direct Health and Medical Insurance Carriers'' (897 firms), we believe the category of health insurance issuers is a more accurate representation of companies conducting HIPAA transactions. Companies that provide Medicaid managed care plans are included in the category of commercial health plans.

Although self-insured group health plans meet the HIPAA definition of ''health plan,'' we did not include them in this impact analysis. While self-insured group health plans will be required to obtain the HPID, we assumed that, with a few exceptions, such plans do not send or receive HIPAA electronic transactions because most are not involved in the day-to-day activities of a health plan and outsource those services to third party administrators or transaction vendors. Because they do not meet the definition of ''health plans,'' TPAs and transactions vendors are not required to obtain or use an HPID, though they may elect to obtain and use an OEID. The costs and benefits associated with the HPID are applicable only to entities that are directly involved in sending or receiving standard transactions, though we recognize that some of the cost and benefits will trickle down to employers and their employees.

The projection of costs in this RIA is based on the number of health plans that will use the HPID in standard transactions. However, we do not have data concerning how many health plans are actually identified in standard transactions, as opposed to ''other entities'' that are identified in their stead. Therefore, we have no assurance of how many health plans will use the HPID in standard transactions. We base our cost estimates on the highest number of entities that would likely use the HPID in standard transactions. The number of health plans is used as a factor in our calculation of costs, but not in our calculation for savings. Therefore, we took a conservative approach to the costs to health plans which we believe is warranted given the uncertainties in our estimates. In our proposed rule, we solicited industry and stakeholder comments on our assumptions.

Comment: We received a number of comments that expressed concern regarding the validity of the RIA for the HPID because the commenters believed that the purpose and the use of the HPID was unclear.

Response: We cannot project how individual health care entities might implement and use the HPID given their specific business organization and needs. We also believe that, to the extent that the HPID will be used to facilitate transactions in ways that are beyond what is required by the provisions of this final rule, it is not clear what all the downstream effects of adopting a national health plan identifier may be. We believe that the HPID may be used within and outside of the transactions in ways that we have not required or envisioned. However, the required use of the HPID was specified in the preamble of the April 2012 proposed rule. The only required use of the HPID in this final rule is that if a health plan is identified in the standard transactions, a covered entity must identify a health plan using a HPID.

The RIA put forward in the April 2012 proposed rule is based on the HPID being used as required by the provisions of this final rule. We agree that there is uncertainty in projecting and estimating the benefits and costs, even given this specific usage. We emphasize that the RIA is based on the premise that the HPID is a foundational standard that will facilitate the routing of all standardized transactions, but not necessarily directly related to specific benefits. We deliberately did not claim in the April 2012 proposed rule that the HPID would be directly responsible for cost savings due to its required use in the standard transactions, with the exception of attributing some cost benefit to time savings in routing certain transactions. The cost savings, we believe, are derived from an efficiency in routing transactions which, in turn, will incentivize more health care entities to use those transactions.

Comment: A commenter stated that the cost savings outlined in the April 2012 proposed rule was conducted prior to the implementation of Version 5010 and projected savings are therefore questionable.

Response: While much of the RIA in the April 2012 proposed rule was developed before the January 1, 2012 implementation of Version 5010, some of the baseline assumptions and data were based on the cost and savings estimates of Version 5010 as included in the RIA of the Modifications final rule. The RIA was also written under the assumption that the HPID would be used in Version 5010 standard transactions. That being said, the benefits of the HPID are only tangentially related to the benefits of Version 5010, and we do not believe the implementation of Version 5010 has a direct affect on the savings or costs of implementing and using HPID.

Comment: A commenter suggested that we only move forward to adopt the HPID when the savings to be realized from its use exceeded the cost of its implementation.

Response: As illustrated in Table 12, our analysis concludes that the savings outweighs the cost, so it is reasonable to assume that we should move forward to adopt the HPID. We reiterate that we based many of our calculations on the assumption that the HPID is a foundational standard that will enable other initiatives and efficiencies to be built off of it. HPID cannot be viewed as an individual band-aid that fixes a specific problem. Instead, HPID is part of a broader picture of standardizing billing and insurance-related transactions and tasks.

F. Costs Associated with HPID and NPI

1. Costs of HPID to Health Plans

Health plans will bear most of the cost of implementing the HPID. We estimate the cost to health plans to implement and use an HPID will be 25 percent of the costs that the impact analysis in the Modifications final rule calculated in order for industry to implement Version 5010 of the standard transactions. As noted previously, implementation of the HPID will be analogous to—yet significantly less than—implementation of Version 5010 because the same systems will be affected, and, in both cases, there are both implementation and transition costs.

For more detail on the justification for using 25 percent of the cost estimates in the Modifications final rule, please refer to the April 2012 proposed rule.

The estimate that HPID implementation and transition will be 25 percent of the cost of Version 5010 is a conservative estimate, we believe, and it is probable that the costs will be much less. However, by estimating HPID implementation at 25 percent of the cost of Version 5010, we are able to reflect the uncertainty in our calculations because our calculations maintain the range of minimum and maximum costs from the Modifications final rule.

In addition, the cost estimates from the Modifications final rule have been adjusted down because we estimate there will be fewer health plans impacted by this rule than are impacted by the Modifications final rule. For costs associated with applying for and obtaining an HPID, see section V.A. of this final rule. In our proposed rule, we solicited comments and data from the industry and other stakeholders on this assumption, but received no substantive comments in this regard.

While we expect these costs will accrue between the time the final rule is published and the date the HPID is fully implemented, for purposes of simplification we have placed all system implementation costs—including those for small health plans—in 2016. Transition costs will occur from 2017 through 2018.

TABLE 4—HPID COST FOR COMMERCIAL AND GOVERNMENT HEALTH PLANS*

	Cost category	Minimum cost estimate per modifications rule (in millions)	Maximum cost estimate per modifications rule (in millions)	Applied percentage	Minimum estimated cost of implementing HPID (in millions)	Maximum estimated cost of implementing HPID (in millions)
Commercial Health Plans**	System Implementation	$1935.0	$3870.5	25%	$483.76	$967.63
	Transition (Year 2 and 3) ...	341.5	683.0	25%	85.37	170.76
Government Health Plans (Medicare, Medicaid, VHS, TRICARE, IHS).	System Implementation	281.0	537.8	25%	70.25	134.45
	Transition (Year 2 and 3) ...	49.6	94.9	25%	12.40	23.73
All Health Plans	Enrollment and Updates***	.....	.....	.....	0.18	0.18
	System Implementation	.....	.....	.....	554.19	1102.26
	Transition (Year 2 and 3) ...	.....	.....	.....	97.77	194.48
Total	.....	.....	.....	.....	651.95	1296.74

* Based on 2012 dollars

** Minimum and maximum cost estimates per Modifications Rule for commercial health plans is adjusted to account for a lesser number of health plans considered than is estimated in the Modifications Rule.

*** See section V.A of this final rule; Collection of Information Requirements, for calculations on enrollment to HPID enumeration system.

2. Costs of HPID for Physician Practices and Hospitals

Covered physician practices and hospitals will be required to use the HPID in standard transactions. Health care providers that do not conduct covered transactions electronically (for example, by submitting a paper claim that the health plan subsequently transmits electronically to a secondary payer) could also use the HPID, but would not be required to do so. Implementation costs for covered physician practices and hospitals depend on whether they generate claims directly or use a health care clearinghouse or transaction vendor.

If covered physician practices and hospitals submit claims directly, they would incur implementation costs in converting their systems to accommodate the HPID. Some covered health care providers may choose to use the services of software system vendors, billing companies, transaction vendors, and/or health care clearinghouses to facilitate the transition to the HPID. These health care providers would incur costs in the form of potential fee increases from billing agents or health care clearinghouses. For example, if a health care provider pays a fee to a billing agent or health care clearinghouse to process its health care transactions, the billing agent or health care clearinghouse might increase the cost to perform this service for the health care provider.

Table 5 illustrates the costs to covered hospitals and physician practices. Again, the costs are 25 percent of the costs estimated in the Modifications proposed and final rules. In our proposed rule, we invited stakeholder comment on our assumptions and method for estimating the implementation costs, but received no comments in this regard.

TABLE 5—HPID COSTS TO COVERED HOSPITALS AND PHYSICIAN PRACTICES*

I	II	III	IV	V	VI	VII
	Cost category	Minimum cost estimate per modifications rule (in millions)	Maximum cost estimate per modifications rule (in millions)	Applied percentage	Estimated cost of implementing HPID (in millions)	Maximum estimated cost of implementing HPID (in millions)
Hospitals	System Implementation	$1042.5	$2085.9	25%	$260.63	$521.48
	Transition (Year 2 and 3) ...	184.0	368.1	25%	45.99	92.03
Physician Practices	System Implementation	486.8	973.6	25%	121.70	243.40

TABLE 5—HPID COSTS TO COVERED HOSPITALS AND PHYSICIAN PRACTICES *—Continued

I	II	III	IV	V	VI	VII
	Cost category	Minimum cost estimate per modifications rule (in millions)	Maximum cost estimate per modifications rule (in millions)	Applied percentage	Estimated cost of implementing HPID (in millions)	Maximum estimated cost of implementing HPID (in millions)
	Transition (Year 2 and 3) ...	85.9	171.8	25%	21.48	42.95
All Providers (Total)	System Implementation	1529.3	3059.5	25%	382.33	764.88
	Transition (Year 2 and 3) ...	269.9	539.9	25%	67.47	134.98
Total	.....	.....	.....	.....	449.80	899.86

* Based on 2012 dollars

G. Savings Associated With HPID and NPI

1. Savings to Health Plans

In our proposed rule, we identified two areas in which health plans will experience savings due to the adoption of HPID: a reduction in the number of pended claims and an increased use of electronic health care transactions.

Comment: A commenter disagreed with the savings analysis stating that the savings to be realized are from Version 5010 implementation and not due to use of the HPID.

Response: The savings and benefits associated with the HPID are not the same as the savings that were calculated in the Modifications final rule, although we derive the costs associated with the HPID by using the Modification final rule costs as a baseline.

The savings associated with the HPID are derived from an increase in three transactions and from the number of pended claims that we have projected will be decreased on account of better routing through use of the HPID . In contrast, the savings associated with Version 5010 implementation are based on benefits in three areas: Better standards or savings due to improved claims standards, cost savings due to new users of claims standards, and operational savings or savings due to increased auxiliary standards usage.

In both this final rule and the Modifications final rule, some of the cost savings are based on an increase in electronic transactions. However, the specific electronic transactions that will be affected are different in the two rules, and the calculations used to link savings to the increase are different.

2. Pended Claims

Pended claims are claims that necessitate a manual review by the health plan. Pended claims are more expensive than ''clean'' claims, which do not require a manual review or additional information in order to be processed. We are projecting a 5 to 10 percent annual reduction of pended claims as attributable to implementation of the HPID. We have calculated the savings that would come from this estimated projection as resulting from: data about claims receipts from the trade association America's Health Insurance Plans (AHIP),[21] information about eligibility transactions from the Oregon Provider and Payer Survey,[22] and data from the Modifications proposed and final rules.

One of the main goals of the use of the HPID is to have a consistent identifier for each health plan for use in standard transactions. This lack of a single identifier has resulted in the need for manual intervention to resolve eligibility questions and billing and payment issues when there are inconsistent approaches for identifying health plans. Covered health care providers would no longer have to keep track of and use multiple identifiers for a single health plan. After the initial outlay for changes to their systems, health care providers would be able to consistently identify the health plan to which they must submit claims.

According to AHIP, 14 percent of all claims were pended by health plans.[23] Assuming 6.8 billion claims will be submitted in 2017, as is projected in the Modifications proposed rule, this calculates to about 950 million pended claims (Table 6, Column 2).

We assumed that pended claims will decrease by a minimum of 5 percent to a maximum of 10 percent annually attributable to use of the HPID (Table 6, Columns 4 and 6). This estimate is based on an AHIP survey entitled, ''An Updated Survey of Health Care Claim Receipt and Processing Times.'' The survey concluded that 35 percent of all claims are pended because they are duplicate claims (or assumed to be duplicate claims), 12 percent are pended because of the lack of necessary information, 5 percent because of coordination of benefits (COB), and 1 percent because of invalid codes.[24] The HPID may help alleviate these particular pended claims issues by enabling the automation of the COB process [25] and providing for more accurate routing of claims to the correct payer. This conclusion presumes that providing an HPID will lead to a measurable reduction of duplicate claims and/or claims pended because of a lack of necessary information. There is a large measure of uncertainty in this assumption and, as noted, the HPID would be foundational for subsequent activities such as the automation of the COB process. By itself, though, the HPID does not automate any processes. To reflect the uncertainty, we apply a range of percentages to the assumption.

According to AHIP, it costs a health plan $0.85 to reply electronically to a ''clean'' claim submission and $2.05 to reply to claims that ''necessitate manual or other review cost.'' Therefore, a health plan could save $1.20 per claim by automating a claim otherwise needing manual review (Table 6, Column 3). In order to calculate the savings from a 5 to 10 percent decrease in pended claims due to implementation of the HPID, we

[21] ''An Updated Survey of Health Care Claims Receipt and Processing Times, May 2006,'' America's Health Insurance Plans (AHIP) Center for Policy and Research.

[22] A comprehensive survey of 55 percent of Oregon's hospitals and 225 of the State's ambulatory clinics. *http://www.oregon.gov/OHPPR/HEALTHREFORM/AdminSimplification/Docs/FinalReport_AdminSimp_6.3.10.pdf.*

[23] AHIP, 2006.

[24] ''An Updated Survey of Health Care Claims Receipt and Processing Times, May 2006,'' America's Health Insurance Plans (AHIP) Center for Policy and Research.

[25] ''National Health Plan Identifier White Paper,'' prepared by the American Medical Association (AMA) Practice Management Center (PMC), September 22, 2009.

multiply the projected number of pended claims (Table 6, Column 2) times 5 percent for the low estimate and 10 percent for the high estimate. We then multiplied the high and low range of numbers of pended claims that will be avoided due to use of HPID times the $1.20 per claim that can be saved.

In considering how to project this cost avoidance, we decided that the 5 to 10 percent savings should continue each year over the 10 years starting the first full year the HPID is required for use in standard transactions, 2017, resulting in a savings of approximately $776 million to $1.6 billion. As stated previously, we consider the HPID standard adopted in this final rule to be foundational standards that will be built upon by future operating rules and regulations over the next decade.

TABLE 6—ANNUAL SAVINGS TO HEALTH PLANS DUE TO DECREASE IN PENDED CLAIMS

[In millions]*

Year	Number of pended claims annually (in millions)**	Cost to review a pended claim***	LOW number of pended claims (5%) that will be avoided attributable to HPID (in millions)	LOW total annual savings through reduction in pended claims (in millions)	HIGH number of pended claims (10%) that will be avoided attributable to HPID (in millions)	HIGH total annual savings through reduction in pended claims (in millions)
(Col. 2)	(Col. 3)	(Col. 4)	(Col. 5)	(Col. 6)	(Col. 1)	(Col. 7)
2017	952.0	$1.35	47.6	$64.3	95.2	$128.5
2018	994.0	1.35	49.7	67.1	99.4	134.2
2019	1036.0	1.35	51.8	69.9	103.6	139.9
2020	1077.4	1.35	53.9	72.7	107.7	145.5
2021	1120.5	1.35	56.0	75.6	112.1	151.3
2022	1165.4	1.35	58.3	78.7	116.5	157.3
2023	1212.0	1.35	60.6	81.8	121.2	163.6
2024	1260.5	1.35	63.0	85.1	126.0	170.2
2025	1310.9	1.35	65.5	88.5	131.1	177.0
2026	1363.3	1.35	68.2	92.0	136.3	184.0
Total				776		1,551

* Based on 2012 dollars
** Based on 14% of total number of annual claims as projected in Modifications proposed rule.
*** AHIP, 2006, adjusted to 2012 dollars.

Comment: A commenter stated that the 5 to 10 percent reduction in pended claims was a gross overestimate. The commenter, representing a health plan, stated that the health plan has a front end clearinghouse that verifies eligibility and then routes transactions or rejects them. The commenter stated that they anticipate no reduction in pended claims volume.

Response: We appreciate the commenter's perspective, although we have no certitude as to how widespread this way of filtering claims may be among health plans. We received no other comments about our calculations or assumptions with regard to our estimate on decreased pended claims. Therefore, we are maintaining the estimates and calculations on our assumptions in this regard.

Comment: A commenter expressed concerned that the cost savings analysis did not reflect the efficiency gained by the HPID as proposed by the April 2012 proposed rule and adopted by this final rule. The commenter stated that the time and cost savings as stated in the April 2012 proposed rule could only be achieved if the health plan was enumerated down to the product level. Another commenter stated similarly that the cost savings estimated in the proposed rule could not be realized without the adoption of an HPID that was much more granular; that is, an HPID that identified the entity that holds the participation contract with the physician, an identification of the patient-specific benefit plan, and the claim specific fee schedule identifier.

Response: The provisions in the April 2012 proposed rule and this final rule do not require health plans to enumerate to the product level. However, we do believe that, even at the level in which health plans must enumerate as per this final rule, there will be the savings that we estimate herein. One of the above-referenced commenters noted that, if health plans were enumerated at a more granular level than that which we have adopted in this final rule, then the need for manual processes in 80 to 85 percent of the transactions could be eliminated. The estimated cost savings in this final rule, derived from use of the HPID as it is adopted, is based, partly, on a decrease in a particular manual process—the process that stems from processing pended claims. However, the decrease in this manual process is substantially less than what the commenter envisioned were health plans to enumerate at a lower level.

We estimated a 5 to 10 percent decrease in total pended claims based on the reasoning that a standard HPID used in the standard transactions would improve routing and so decrease a small number of pended claims. We do not presume to infer that the HPID, as it is adopted, will decrease a large proportion of manual processes related to eligibility and claim submissions.

In this final rule, we maintain the range of savings, as presented in the April 2012 proposed rule that is possible through implementation of the HPID.

3. Increase in Electronic Transmittal of Three Standard Transactions

The implementation of all administrative simplification initiatives mandated by the Affordable Care Act are expected to streamline HIPAA electronic transactions, make them more consistent, and decrease the dependence on manual intervention in the transmission of health care and payment information. This, in turn, will drive more health care providers and health plans to utilize electronic transactions in their operations. Each transaction that moves from a nonelectronic, manual transmission of information to an electronic transaction, brings with it material and time cost

savings by virtue of reducing or eliminating the paper, postage, and equipment and additional staff time required to conduct paper-based transactions.

We estimate an annual increase of 1 (LOW) to 2 (HIGH) percent in the use of the eligibility for a health plan transaction and the health care claim status transaction attributable to the implementation of the HPID from 2017 through 2026 as illustrated in Table 7. We estimate an annual increase of 2 (LOW) to 3 (HIGH) percent in the use of the electronic remittance advice transaction resulting from the adoption of the HPID. These are not annual increases in percentage points, but rather percent increases in the use of electronic transactions from the year before. The impact of the HPID on the electronic health care payment and remittance advice transaction is more than the impact on the other two transactions because NCVHS testimony supported the notion that the greatest impact of a standardized health plan identifier would be on the payment process.[26]

For more detail regarding our assumptions and calculations in this regard, please refer to the April 2012 proposed rule.

We estimate that the savings to health plans because of increased usage in three transactions will be at least $850 million within 10 years of HPID use in transactions. Health plan savings are summarized in Table 7.

The results of this calculation are higher in cost savings than the results of the same calculation in the April 2012 proposed rule. We have projected that the number of overall health care information transactions—electronic and nonelectronic—increases with every year. The overall number of health care information transactions is a primary factor in our projection of savings derived from an increase in electronic transactions. Because the cost savings begins in 2017 in this final rule, in contrast to 2014 as was assumed in the April 2012 proposed rule, there is an increase in the cost savings of this rule when compared to the April 2012 proposed rule.

TABLE 7—ANNUAL COST SAVINGS FOR HEALTH PLANS FROM INCREASE DUE TO HPID IN VOLUME OF THREE ELECTRONIC TRANSACIONS *

I	II	III	IV	V	VI	VII
	Savings from increase in eligibility for a health plan transaction attributable to HPID		Savings from increase in health care claim status transaction attributable to HPID		Savings from increase in health care payment and remittance advice transaction attributable to HPID (remittance advice only)	
Year	LOW annual cost savings attributable to HPID (in millions)	HIGH annual cost savings attributable to HPID (in millions)	LOW annual cost savings attributable to HPID (in millions)	HIGH annual cost savings attributable to HPID (in millions)	LOW annual cost savings attributable to HPID (in millions)	HIGH annual cost savings attributable to HPID (in millions)
2017	$41.5	$72.2	$7.4	$12.3	$9.2	$23.0
2018	44.8	83.0	8.1	14.7	11.0	27.6
2019	48.4	89.7	8.9	16.2	12.4	33.1
2020	52.3	96.8	9.8	17.8	13.8	37.1
2021	56.5	104.6	10.8	19.6	15.5	41.5
2022	61.0	113.0	11.9	21.6	17.4	46.5
2023	63.4	122.0	12.5	23.8	19.5	52.1
2024	66.0	126.9	13.1	24.9	20.6	58.4
2025	68.6	131.9	13.7	26.2	21.9	61.9
2026	71.4	137.2	14.4	27.5	23.2	65.6

Cumulative Annual Cost Savings:
LOW: $849 million.
HIGH: $1,728 million.
* Based on 2012 dollars.

TABLE 8—TOTAL SAVINGS FOR COMMERCIAL AND GOVERNMENTAL HEALTH PLANS *

[In millions]

I	II	III	IV	V	VI
Savings from decrease in pended claims		Savings from increase in usage of EDI in three transactions		Total savings for health plans	
LOW $776	HIGH $1,551	LOW $849	HIGH $1,729	LOW $1,625	HIGH $3,280

* Based on 2012 dollars.

4. Savings to Health Care Providers

We have quantified two areas of savings for health care providers. First, time and money will be saved at an administrative-level because of a decrease in claims issues that require manual intervention. Medical practices will experience these administrative savings by virtue of decreased time spent interacting with health plans. Second, material savings will be derived because of an increase in the number of

[26] Tammy Banks, Director, Practice Management Center and Payment Advocacy, ''Testimony By The American Medical Association,'' National Committee on Vital and Health Statistics Subcommittee on Standards, July 19, 2010.

transactions that are conducted electronically, as we explained in our discussion of the potential impact of this rule on health plans.

a. Time Savings for Health Care Providers

One of the main goals of the use of the HPID is to have a consistent identifier for each health plan for use in standard transactions. The lack of a single identifier has resulted in the need for manual intervention to resolve eligibility questions and billing and payment issues when there are inconsistent approaches for identifying health plans. Covered health care providers would no longer have to keep track of and use multiple identifiers for a single controlling health plan. After the initial outlay for changes to their systems, health care providers would be able to simplify their billing systems and processes and reduce administrative expenses.

The HPID would also assist and simplify coordination of benefits. Health plans that have sole or shared fiduciary responsibilities for payment would be more readily identified, and the movement of information among these entities would be enhanced. According to a 2009 study published in Health Affairs, approximately 60 hours per physician per week are spent on average interacting with health plans when the time spent by the single physician, the staff, and the physician practice's administration are totaled.[27] Of the time spent interacting with health plans, 88 percent was spent on authorizations and claims/billing issues.

We believe the implementation of an HPID will eliminate some of the manual intervention that is required when there are questions or errors identifying the entity responsible for eligibility of a patient or the payment of a claim. We estimate that the implementation and use of an HPID by health plans would save a physician's practice a number of phone calls and emails otherwise required to investigate or verify the identifier needed for the health plan or to manually investigate claims that have been rejected by health plans. Of the 60 hours reported previously, our estimate would be that 15 minutes to 30 minutes per week—or .4 to .8 percent of the total time spent interacting with health plans—could be eliminated if the HPID were implemented.

In our proposed rule, we solicited stakeholder input on our basic assumptions, but we received no comments in this regard. Therefore, we have retained those basic assumptions. For more details on our assumptions and calculations, please refer to the April 2012 proposed rule.

As a result of use of the HPID in the standard transactions, we anticipate that the time physicians in physician practices will spend per week interacting with health plans will slightly decrease, resulting in a cost avoidance of approximately $1.4 to $2.8 billion.

The estimated range of cost avoidance represent an increase in the estimates that were made in the April 2012 proposed rule because the savings in this rule are calculated starting in 2017 while the savings in the proposed rule started in 2014. Due to an increase in the anticipated number of physicians, the cost avoidance is higher in this final rule than it was in the April 2012 proposed rule (Table 9).

Due to a lack of baseline data regarding other providers and physicians working in hospitals, we have not calculated any similar anticipated decrease in time for other providers and physicians working in hospitals. We assume, though, that hospitals, because they typically consolidate their billing functions, will have analogous savings to physicians in physician practices, albeit less on a ''per physician'' basis.

TABLE 9—PHYSICIAN SAVINGS THROUGH DECREASE IN TIME INTERACTING WITH HEALTH PLANS

	I	II	III	IV	V	VI	VII
Year	Hours spent per week per physician interacting with health plans	LOW to HIGH percent of time interacting with health plans (Col I) saved per week per physician attributable to HPID (15 to 30 minutes)	Total annual cost per single physician to interact with health insurance plans	LOW reduction in cost per year per physician attributable to HPID	HIGH reduction in cost per year per physician attributable to HPID	Number of physicians	LOW to HIGH total savings per year attributable to HPID (in millions)
2017	60	0.4 to 0.8%	$81,523	$ 340	$679	352,103	$120 to $239.2
2018	60	0.4 to 0.8%	83,969	350	700	355,568	$124 to $248.8
2019	60	0.4 to 0.8%	86,488	360	721	359,033	$129 to $258.8
2020	60	0.4 to 0.8%	89,082	371	742	362,498	$135 to $269.1
2021	60	0.4 to 0.8%	91,755	382	765	366,561	$140 to $280.3
2022	60	0.4 to 0.8%	94,507	394	788	370,625	$146 to $291.9
2023	60	0.4 to 0.8%	97,343	389	779	374,688	$146 to $292
2024	60	0.4 to 0.8%	100,263	401	802	378,752	$152 to $304
2025	60	0.4 to 0.8%	103,271	413	826	382,815	$158 to $316
2026	60	0.4 to 0.8%	106,369	425	851	382,815	$163 to $326
Total							$1,413 to $2,826

* In 2012 dollars.

b. Increase in Three Transactions

The second area of savings for health care providers is the per transaction savings of moving from nonelectronic to electronic transactions. We used the same assumptions on the number and rate of increase of three electronic transactions methodology as illustrated for health plans in Table 7. However, the savings per transaction for health care providers differ from the savings that health plans will realize, as reflected in Table 14. We estimate an annual increase of 1 (LOW) to 2 (HIGH) percent in the use of the eligibility for a health plan transaction and the health care claim status transaction attributable to implementation of the HPID over the

[27] Lawrence P. Casalino, S. Nicholson, D.N. Gans, T. Hammons, D. Morra, T. Karrison and W. Levinson, ''What does it cost physician practices to interact with health insurance plans?'' Health Affairs, 28(4)(2009):w533–w543.

next 10 years as illustrated in Table 10. We estimate an annual increase of 1 (LOW) to 3 (HIGH) percent in the use of the electronic health care payment and remittance advice transaction (in the health care electronic funds transfers (EFT) remittance advice transaction). The savings in each column are a product of the number increase in each transaction, with high and low ranges, multiplied by the cost savings of each move to an electronic transaction.

For a more detailed description of the basic assumptions and calculations we used to arrive at the savings associated with these three transactions, please see the April 2012 proposed rule.

TABLE 10—ANNUAL COST SAVINGS FOR PROVIDERS FROM INCREASE DUE TO HPID IN VOLUME OF THREE ELECTRONIC TRANSACTIONS *

I	II	III	IV	V	VI	VII
	Savings from increase in eligibility for a health plan transaction attributable to HPID		Savings from increase in health care claim status transaction attributable to HPID		Savings from increase in health care payment and remittance advice transaction attributable to HPID/OEID (remittance advice only)	
Year	LOW annual cost savings attributable to HPID (in millions)	HIGH annual cost savings attributable to HPID (in millions)	LOW annual cost savings attributable to HPID (in millions)	HIGH annual cost savings attributable to HPID (in millions)	LOW annual cost savings attributable to HPID (in millions)	HIGH annual cost savings Attributable to HPID (in millions)
2017	$26.62	$46.30	$4.72	$7.87	$3.36	$8.41
2018	28.75	53.24	5.19	9.44	4.04	10.09
2019	31.05	57.50	5.71	10.39	4.52	12.11
2020	33.53	62.10	6.28	11.42	5.06	13.56
2021	36.22	67.07	6.91	12.57	5.67	15.19
2022	39.11	72.43	7.60	13.82	6.35	17.01
2023	40.68	78.23	7.98	15.21	7.11	19.05
2024	42.31	81.36	8.38	15.97	7.54	21.34
2025	44.00	84.61	8.80	16.77	7.99	22.62
2026	45.76	88.00	9.24	17.60	8.47	23.98

Cumulative Annual Cost Savings:
LOW: $499 million.
HIGH: $985 million.
* Based on 2012 dollars.

To summarize health care provider savings, providers can expect savings from two indirect consequences of the implementation of a health plan identifier, as demonstrated in Table 11: the cost avoidance of a decrease in administrative time spent by physician practices interacting with health plans, and a cost savings for physician practices and hospitals for every transaction that moves from a manual transaction to an electronic transaction.

TABLE 11—TOTAL HEALTH CARE PROVIDER HPID SAVINGS *

[In millions]

I	II	III	IV	V	VI
Savings from decrease in provider time spent interacting with health plans		Savings from increase in usage of EDI in three transactions		Total savings for providers	
LOW $1,413	HIGH $2,826	LOW $499	HIGH $985	LOW $1,912	HIGH $3,811

* Based on 2012 dollars.

H. Summary for the HPID and NPI

TABLE 12—HPID SUMMARY TABLE FOR HEALTH CARE INDUSTRY

	I	II	III	IV	V	VI
	Savings (in millions)		Costs (in millions)		Range of return on investment (in millions)	
	LOW	HIGH	LOW	HIGH	LOW (low savings/high costs)	HIGH (high savings/low costs)
Commercial and Governmental Health Plans	$1,625	$3,280	$652	$1,297	$328	$2,628
Health Care Providers	1,912	3,811	451	901	1,011	3,360

TABLE 12—HPID SUMMARY TABLE FOR HEALTH CARE INDUSTRY—Continued

	I	II	III	IV	V	VI
Total	3,537	7,091	1,103	2,198	1,339	5,988

* Calculated in 2012 dollars.

I. Regulatory Flexibility Analysis of the HPID and NPI

The Regulatory Flexibility Act (RFA) of 1980 (Pub. L. 96–354) requires agencies to describe and analyze the impact of the final rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities.

In the April 2012 proposed rule, we used a baseline threshold of 3 percent of revenues to determine if a rule would have a significant economic impact on affected small entities (Table 13).

Table 13, Column II shows the number of small entities as discussed in the April 2012 proposed rule. Table 13, Column III shows revenues that were reported for 2009 in the Survey of Annual Services (*http://www.census.gov/services/sas_data.html*). Table 13, Column IV shows the costs to health care providers for implementation of the HPID, as described in the RIA. The estimated high range of costs was used. Table 13, Column V shows the percent of the small entity share of implementation costs as a percent of the small entity revenues.

In the April 2012 proposed rule we concluded that the anticipated economic effect of this rule on small entities would not exceed or even come close to meeting the threshold of 3 percent of revenues.

We did not receive any comments regarding the RFA in the April 2012 proposed rule, therefore we make no changes to the assumptions, calculations, and conclusions to that analysis. Based on that analysis, we certify that the HPID provision of this final rule would not have a significant economic impact on a substantial number of small entities.

TABLE 13—ANALYSIS OF THE BURDEN OF IMPLEMENTATION OF HPID ON SMALL COVERED ENTITIES *

I	II	III	IV	V
Entities	Total number of small entities	Revenues or receipts (in millions)	Maximum cost of implementation of HPID (in millions)	Implementation cost revenue receipts (percent)
Physician practices	220,100	$359,853	$288	0.0014
Hospitals	6,500	729,870	645	0.00033

* In 2012 dollars.

J. Alternatives Considered for the ICD–10

Faced with growing evidence that a group of providers would not be ready for the transition to ICD–10 by October 1, 2013, and the possibility that payment for millions of health care claims would be delayed, we considered a number of options before proposing a 1-year delay in the compliance date in the April, 2012 proposed rule. We list these options in the preamble and summarize the public comments we received concerning them. Our responses are included in the preamble.

We decided that Option 4 was the most effective in mitigating the significant systemic disruption and payment delays that could have resulted from a large percentage of providers who might not have been ready to implement ICD–10 this October 1; and, in addition, as the RIA in this final rule suggests, Options 4 is most likely to minimize the costs of delay and to maximize the benefits to providers who need more time to implement.

K. Impacted Entities—ICD–10

All HIPAA covered entities may be affected by a delay in the compliance date of ICD–10 in this rule. Covered entities include all health plans, health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard.

Table 4 outlines the number of covered entities that may be affected by a delay in ICD–10, along with the sources of those data. These are the same entities that will be affected by HPID.

While covered entities are required to transition to ICD–10, many other entities not required to abide by HIPAA (such as workers' compensation programs and automobile and personal liability insurers) currently use ICD–9 for a variety of purposes. Because their operational and business needs often intersect with covered entities, for practical and business purposes these other entities may voluntarily transition to ICD–10 alongside HIPAA covered entities. The ICD codes are used in nearly every sector of the medical and health industry.

Comment: A commenter noted that it was inaccurate to state that workers' compensation programs and automobile and personal liability insurers are not required to abide by HIPAA but may voluntarily do so. The association noted that Medicare has mandatory Medicare Secondary Payer reporting requirements for non group health plans (NGHPs) for liability insurance, no-fault insurance, and workers' compensation. Included in these required data elements for NGHP is the appropriate ICD–9 for the reported injury with mandated transition to ICD–10 when it is implemented.

Response: We agree with the commenter and refine our language to recognize that, while many health care entities are not required by HIPAA to comply with the code sets, standards and operating rules therein, these same health care entities may be required by other state and federal laws or trade agreements to use ICD codes, as is the case with Medicare's reporting requirements.

L. Scope and Methodology of the Impact Analysis for ICD–10

This impact analysis estimates the costs and benefits of a delay in compliance with ICD–10. We are analyzing only the impact of a delay, not the impact of ICD–10 implementation, which we addressed in the 2008 ICD–10 proposed rule (73 FR

49476) and the January 2009 ICD–10 final rule (74 FR 3328).

Despite the broad utilization of ICD codes that extends beyond covered entities, with one exception our analysis is restricted only to those entities as only they fall under the auspices of this final rule. With respect to health care providers, only health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a HIPAA transaction standard are covered entities. The one area for which we provide additional analysis is the cost to educational institutions to educate students being trained in ICD–10 coding because such training costs have been of particular concern to industry and have been included in the previous **Federal Register** ICD–10 rules cost analyses.

Moreover, while we assume that a delay in the implementation of ICD–10 will affect a broad range of health care providers, as illustrated in Table 4, we only examine the costs and benefits of a delay on two types of health care providers—hospitals and physician practices. We do not analyze the impact on other industry sectors, including, but not limited to, nursing and residential care facilities, dentists, durable medical equipment (DME) suppliers, or pharmacies for various reasons. Consistent with our previous impact analysis in the 2008 ICD–10 proposed rule, we continue to have very little data on the use of EDI among dentists, DME suppliers, nursing homes, and residential care facilities. The lack of data for these types of health care providers has been noted in other studies on administrative simplification.[28] We assume that the greatest benefits will be gained by hospitals and physician practices as they conduct the majority of standard transactions, although it cannot be assumed that the costs will necessarily be borne by physician practices and hospitals only. We have not included an analysis of the impact on pharmacies because pharmacies typically do not use ICD codes in their routine course of business so we assume there is no impact on pharmacies.

We include health care clearinghouses and transaction vendors as affected entities in Table 4. Transaction vendors are entities that process claims or payments for other entities such as health plans. Transaction vendors may not meet the HIPAA definition of health care clearinghouse, but, as used in this context, health care clearinghouses would constitute a subset of transaction vendors. Payment vendors also would be a type of transaction vendor—a transaction vendor that ''associates'' or ''reassociates'' health care claim payments with the payments' remittance advice for either a health plan or provider. For our purposes, transaction vendors do not include developers or retailers of computer software, or entities that are involved in installing, programming or maintaining computer software. Health care clearinghouses and transaction vendors will be impacted because they will need to transition their systems to accept ICD–10 codes. However, we did not calculate costs and benefits to health care clearinghouses and transaction vendors in this cost analysis because, as in our previous impact analysis in the August 2008 ICD–10 proposed rule, we assume that any associated costs and benefits will be passed on to the health plans or providers and will be included in the costs and benefits we apply to health plans or providers.

Although self-insured group health plans meet the HIPAA definition of ''health plan,'' we did not include them in this impact analysis. While self-insured group health plans will be required to implement ICD–10, we assume that, with a few exceptions, such plans do not send or receive HIPAA electronic transactions because most are not involved in the day-to-day activities of a health plan and outsource those services to TPAs or transaction vendors.

However, we do include TPAs in this RIA. Although TPAs do not meet the definition of ''health plans'' and therefore are not required by HIPAA to use code sets such as ICD–10, as a practical matter they will be required to make the transition in order to continue to conduct electronic transactions on the part of self-insured group health plans. However, the impact of a delay of the compliance date of ICD–10 on TPAs will be similar to the commercial insurer cost/benefit impact profile since they serve a similar function and will have to implement and test their systems in the same manner as health plans. Therefore, when we refer to ''commercial health plans'' in this RIA we will be including TPAs, and we include all TPAs in the category of ''small health plans'' in the RFA.

In the proposed rule, we stated that ''Software vendors will incur considerable responsibility and cost with respect to ICD–10 implementation, but we do not analyze the cost of delay to software vendors as they ultimately pass their costs to their clients'' (77 FR 22991).

Comment: A commenter disagreed with our assumption that software vendors will pass on any incurred costs to their clients. The commenter noted that his organization had incurred costs nearing $1 billion and that further costs would be incurred with a delay. The commenter stated that the update to ICD–10 is part of the normal regulatory update process and that no conversion costs are passed on to the health plans or providers. Another commenter made a similar statement with regard to software vendors, but added that there are clearinghouses as well that make regulatory changes to their software without costs to their clients. Both commenters suggested including the costs to clearinghouses and vendors in the cost analysis.

Response: After consideration of the public comment received, we are revising our assumption with regard to software vendors and clearinghouses passing their costs of ICD–10 changes on to their clients, and recognize that there will be substantial costs associated with any delay for software vendors and clearinghouses in and of themselves. However, beyond anecdotal evidence, we do not have data on the numbers of software vendors or clearinghouses who will be affected or what the financial burden or benefit will be for software vendors or clearinghouses as a group. Therefore, we will not attempt to quantify the impact to software vendors or clearinghouses in this RIA.

M. Cost Avoidance of a 1-Year Delay in the ICD–10 for the Health Care Industry

Our analysis of industry benefit is based on cost avoidance. That is, we anticipate that there will be greater costs associated with the compliance date of October 1, 2013 than if the compliance date were to be delayed 1 year. Therefore, our analysis will demonstrate the costs associated with the current compliance date of October 2013, and apply those as savings or benefits attributable to a delayed compliance date.

The assumption behind these savings is that a specific number of physicians and hospitals will not be prepared to use ICD–10 by October 1, 2013. This lack of readiness would engender a number of costly consequences.

Estimates on the benefit of a 1-year delay are subject to considerable variation. A delay in the ICD–10 compliance date increases the

[28] ''Excess Billing and Insurance-Related Administrative Costs,'' by James Kahn, in *The Healthcare Imperative; Lowering Costs and Improving Outcomes: Workshop Series Summary,* edited by Pierre L. Yong, Robert S. Saunders, and Leigh Anne Olsen, Institute of Medicine of the National Academies, the National Academies Press, Washington, DC: 2010.

opportunity for a successful, timely transition and provides an opportunity to reduce disruptions in health care delivery and payment. A basic assumption in this projection of a benefit is that entities will take the 1-year delay to become compliant and to conduct robust testing as discussed previously. This is possible, but by no means inevitable, even if a vigorous public/private campaign is undertaken to promote and assist with compliance and testing.

Based on the CMS readiness survey, we will use the percentage of providers who believed they would not be compliant by October 1, 2013 (26 percent) as our high estimate and the percentage of providers who believed they would not be compliant by December 31, 2013 (12 percent) as our low estimate. We based our estimates of the cost of not delaying the compliance date of ICD–10 on the projection that 12 to 26 percent of providers will not be ready or will not have appropriately tested for implementation of ICD–10 by October 1, 2013.

We recognize that the survey does not represent a statistically valid sample of providers, but we have no other recent data with which to base our readiness estimates.

The total savings attributable to the 1-year compliance date delay is based on the premise that providers who are not ready for ICD–10 will submit claims to payers that will be automatically returned beginning on the October 1, 2013 compliance date. We calculate the cost avoidance of a 1-year delay in the compliance date of ICD–10 based on two probable scenarios: Returned claims will: (1) cause expensive manual intervention on the part of both providers and health plans in order for the ''not ready'' providers to be paid; and (2) financially impact providers by potentially requiring them to take out loans or apply for lines of credit to be able to continue to provide health care in the face of delayed payments. We apply calculations to each of these scenarios in the analysis that follows. Although the cost to manually process returned claims will ostensibly occur from, roughly, October 1, 2013 through March, 2014, for simplicity sake our calculations reflect a cost avoidance that is calculated for 1 year only—the year 2014.

A halt to the payment process for 12 to 26 percent of all providers has a greater effect than requiring manual intervention and requiring business loans or lines of credit. In some cases, a payment delay may pose a serious threat to the continued operation of some providers. For example, many health care safety net clinics operate with no more than 30 to 60 days of cash on hand, so any prolonged delay would threaten such entities' viability.

We also anticipated that health care services for a great number of patients will be adversely affected or interrupted because providers will need to spend more time to obtain health care claim payments leaving less time to render health care services.

We received no substantive comments with regard to our calculations and estimates of the cost avoidance of a 1-year delay in the compliance date of ICD–10 as described in the April 2012 final rule. We have provided the estimates and results of our calculations in the summary Table 17.

While there is a high level of uncertainty in terms of all of our assumptions, we believe it illustrative to make the calculation in order to demonstrate the affect that a delay in payments will have on small physician practices.

Comment: A commenter noted that the cost avoidance calculations are based on the assumption that certain costs will be completely avoided if the compliance date is delayed for 1 year. However, the commenter also noted that if providers are not prepared a year later, then all that will occur will be a delay of these costs, not an avoidance.

Response: We agree that if the delay is not used by the industry to be better prepared for the ICD–10 transition, then there will be no cost avoided by the delay. While there is no guarantee that the delay will translate into better preparation on the part of all health care entities, we anticipate that additional testing, outreach and education efforts will be targeted to help endangered segments, such as small providers, to achieve

N. Costs of a 1-Year Delay of Implementation of ICD–10 for Health Plans

1. Cost for Commercial Health Plans and TPAs

Health plans are a varied group in terms of size, and the cost of a delay is calculated using a range that reflects this variance. We assume that system costs for health plans to transition to ICD–10 have already been budgeted and funds already spent. A delay of a year for ICD–10 compliance primarily will allow entities more time to thoroughly test, but the testing and the continued maintenance of contracts and personnel required for the transition will be 1 year longer than was originally budgeted. In fact, one of the main issues for entities that argue against a delay is the concern that their companies would divert funds currently dedicated to the transition to ICD–10 to other priorities.

Table 14 illustrates the calculation of 10 to 30 percent of the total costs of health plans' ICD–10 system implementation and training as the range of costs for a 1-year delay. For simplicity sake, we have calculated all costs as if they occurred in the calendar year 2014.

TABLE 14—COST IN 2014 OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10*

Health insurer categories	Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7	Col. 8	Col. 9
	Number of health plans	LOW total cost per health plan (in millions)	HIGH total cost per health plan (in millions)	LOW total implementation/training for all health plans in category (col. 1 * col 2)	HIGH total implementation/training for all health plans in category (col. 1 * col. 3)	LOW percent of total cost for a 1-year delay	HIGH percent of total cost for 1-year delay	LOW estimate of 1-year delay (in millions)	HIGH estimate of 1-year delay (in millions)
National	6	$50.40	$100.80	$302.40	$604.80	10	30	$30.24	$181
Multi Regional	6	24.00	40.32	144.00	241.92	10	30	14.40	73
Large	75	14.40	24.19	1080.00	1814.40	10	30	108.00	544
Mid-Sized	325	3.60	6.05	1170.00	1965.60	10	30	117.00	589
TPAs and Small Health Plans	2166	1.20	2.02	2599.20	4366.66	10	30	259.92	1310
Total								530	2,698

*Calculated in 2012 Dollars.

2. Cost of a 1-Year Delay for CMS Health Plans

The Medicare program reports that it is prepared to be ICD–10 compliant on October 1, 2013. The CMS components affected by an ICD–10 transition delay estimate that there will be additional costs for extending contracts for systems programming and testing work and extended staff training and associated development costs. It is estimated that a 1-year delay in ICD–10 compliance would be reflected by additional work at an estimated total cost of $5 to $10 million in addition to funding already requested for the coming fiscal years.

3. Cost of a 1-Year Delay in the Compliance Date of ICD–10 for State Medicaid Agencies

State Medicaid Agencies (SMAs) were queried informally during routine status update calls in February 2012 regarding potential mitigation strategies for ICD–10 implementation. Thirty-nine SMAs responded, representing all regions of the country from predominantly rural to densely populated States. We have extrapolated from these responses as best we could to present a quantitative assessment of costs and benefits.

In Table 15, we calculate the cost to SMAs of a 1-year delay in the compliance date of ICD–10. We use the following assumptions:

• Based on the informal poll of SMAs, we assume that 37 percent or 20 SMAs would be ready for the October 1, 2013 compliance date. Therefore, the assumption is that 21 SMAs would be affected negatively by a delay.

• We assume that $4 million is the low estimate for a cost increase, as exemplified by the rural State that provided that estimate, while $7 million is the high estimate for a cost increase, as reported by an SMA. The high estimate is derived from a SMA that anecdotally described its costs per year of delay. For simplicity sake, we have calculated all costs as occurring in calendar year 2014. One State Medicaid program commented that a 1-year delay in the compliance date would add $5 million to the overall cost of implementation, and this supports our assumption of high and low costs.

TABLE 15—COST IN 2014 TO STATE MEDICAID AGENCIES OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10*

# of State Medicaid that would be negatively affected	LOW cost of a 1-year delay per state agency (in millions)	HIGH cost of a 1-year delay per state agency (in millions)	LOW cost of a 1-year delay for Medicaid agencies (in millions)	HIGH cost of a 1-year delay for Medicaid agencies (in millions)
21	$4	$7	$83	$145

* In 2012 dollars.

2. Cost of a 1-Year Delay for Providers

We expect that many, if not most, hospitals and large provider organizations have already spent funds in preparation for the ICD–10 transition. As with health plans, any delay in compliance date will add costs because large providers must maintain the personnel and renegotiate contracts necessary to lengthen preparations an extra year. Likewise, large providers must maintain technological resources for an extra year.

Because the October 1, 2013 compliance date is more than a year out, it is likely that few small physician practices have invested a modest amount of money and resources into the implementation of and training for ICD–10, although they may have begun planning and budgeting for the transition and may have contracts in place with vendors to purchase tools to manage the transition. While we recognize that there will be costs, we assume that these costs are negligible and that the extra time to prepare for the transition, as will be possible with a 1 year compliance date delay, will be more beneficial than costly for small providers. Therefore, we will not include small providers (under 50 physicians) in the cost analysis for providers.

Table 16 illustrates the calculations for the cost to hospitals and large physician practices.

TABLE 16*—COST TO HOSPITALS AND LARGE PHYSICIAN PRACTICES IN 2014 FOR 1–YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 ***

	Hospitals: 400 or more beds	Hospitals: 100-400 beds	Hospitals: Fewer than 100 beds	Large physician practices (over 100 physicians)	Mid sized physician groups (50-100 physicians)	Total cost of ICD–10 implementation (in millions)	LOW cost for 1-Yr delay (10% of current implementation costs) (in millions)	HIGH cost of 1-Yr delay (30% of current implementation costs) (in millions)
Number of entities	521	2486	2757	393	590			
LOW Cost Per Entity (in millions)	$1.85	$0.62	$0.12	$2.46	$0.5			
HIGH Cost Per Entity (in millions)	$6.16	$1.85	$0.31	$7.39	$1.48			
Total LOW (in millions)	$963	$1,531	$339	$968	$291	$4,093	$409	$1,227
Total HIGH (in millions)	$3209	$4,594	$850	$2,905	$872.17	$12,429	$1,243	$3,728

* Numbers are rounded, so totals may not reflect sum of numbers shown.
** Adjusted to 2012 dollars.
*** High and low ranges from Nolan 2003, adjusted to 2012 dollars.

Comment: A commenter took issue with assumptions that we derived from the Edifecs poll. The commenter noted that the conclusions of the poll were based on a small sample of representatives from the various categories of health care entities, specifically providers.

Response: We agree with the commenter about the Edifecs poll. However, it is the only information we have, however scant, that specifically addresses the question of a delay and its costs. We used the Edifecs poll to arrive at one assumption in this RIA of the impact of a 1-year delay in the compliance date of ICD–10: A 1-year delay will cost an additional 10 to 30 percent of what commercial health plans and large providers have already budgeted on the ICD–10 transition to date.

Comment: Some commenters questioned the total cost to health care entities of transitioning to ICD–10 that we used as an assumption to calculate the cost of a 1-year delay. One commenter noted that our costs were higher than what was calculated in the January 16, 2009 ICD–10 final rule, and a number of commenters suggested that we conduct a robust survey of how much the transition is actually costing by polling health care entities that are in preparation for the transition. Other commenters also suggested conducting different kind of studies and further analyses in order to better make a decision on an ICD–10 compliance date. For example, one commenter suggested that a full examination be made of ICD–9–CM code development and allocation process and that necessary codes to that code set be assigned quickly.

Response: While we recognize that more robust data and further analysis could better substantiate a cost analysis—and, thus, better inform policy decisions– the purpose of this impact analysis was to help inform whether the health care industry necessitated a delay in the ICD–10 compliance date and, if so, to inform a policy as to the length of that delay. However, a great many of the comments insisted that the regulations that would adopt a compliance date be published as soon as possible in order that unreasonable costs and obstacles not be created while the rule itself was being developed. Thus, it was not deemed prudent to conduct a robust survey in order to obtain what is truly budgeted for the implementation of ICD–10.

We received no data or substantive arguments during the public comment period that our estimated cost of implementation was either too much or too little; only observations and anecdotes that the calculations were less accurate than they could be and based on surveys and polls that had questionable validity. We received some data from commenters on the cost of implementation from specific organizations: One commenter noted that it had dedicated $40 million to date on preparing for the ICD–10 transition. This is considerably above our estimates. Another commenter stated that, although they had started planning and dedicating resources to the transition, they had not expended any funds with regard to training or technical modifications. This is considerably less than our estimates. In light of the fact that there were no substantive arguments—or contradictory data—offered through public comment against our calculations, we continue to rely upon them in this final rule.

O. Summary for ICD–10

Our RIA confirms the need for a delay in the compliance date of ICD–10. In spite of the lack of conclusive data with regard to the overall status of the health care industry's preparation for the transition and the variables inherent in making projections on such a transition, it is apparent that a significant number of providers would not be ready for the original October 1, 2013 compliance date. If a significant number of providers would not be ready, it follows that there could be delays in the payment of health care claims and risk that disrupted cash flow to providers could affect access to health services. We have attempted to quantify a number of the consequences of such a disruption in this RIA, but possible disruptions in patient care are not quantifiable.

Given the risk of disruption in health care claim payments, we sought to measure the negative effects of a delay in the compliance date in this RIA. Although all the data we cite may not be statistically valid, there is a cost to every day that the date of ICD–10 compliance is delayed for entities that have already invested significant resources preparing for the transition. It is also likely that the consequences of a delay would affect entities and industries beyond the HIPAA covered entities that are required to use the code set. The cost to students and educational institutions in the RIA are but one example of this.

Weighing the risks and consequences of a disruption to health care claim payments with an apparent increased cost of delay to the estimated 75 percent of covered entities who would be able to comply October 1, 2013, we believe that a one-year delay in the implementation date strikes the best regulatory balance. It is our best judgment that, to go forward with the original compliance date would risk disruptions on many levels, while a delay of any more than a year would incur costs that could not be justified in the name of avoiding risk.

We summarize the low and high estimates of a 1-year delay in the compliance date for ICD–10 in Table 17.

The total costs and cost avoidance of a delay in the compliance date will likely be incurred over a 12-month period; however, due to the range in impacted entities, including educational institutions, those 12 months may span different dates and different budget periods. Given the diversity of budgeting in the industry, there is no precise way of calculating how much of the cost and cost avoidance falls outside of the October 1, 2013 to October 1, 2014 delay in compliance date. For simplicity sake, we calculate all cost avoidance and costs of a delay in the compliance date for ICD–10 as occurring in the calendar year 2014.

In Table 17, the net cost avoidance is illustrated with a—

- Low net estimate that reflects the low estimate of cost avoidance less the high estimate of costs;
- High net estimate that reflects the high estimate of cost avoidance less the low estimate of costs; and
- Medium net cost avoidance that reflects the average cost avoidance less the average cost.

TABLE 17—SUMMARY OF COST AVOIDANCE AND COSTS IN 2014 OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 *

	LOW (in millions)	HIGH (in millions)	MEAN (average) (in millions)
Cost Avoidance for Providers (manual submission of claims)	$1,385	$3,001	$2,193
Cost Avoidance for Providers (cost of loan interest)	1,446	3,134	2,290

TABLE 17—SUMMARY OF COST AVOIDANCE AND COSTS IN 2014 OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 *—Continued

	LOW (in millions)	HIGH (in millions)	MEAN (average) (in millions)
Cost Avoidance for Health Plans (manual submission of claims)	804	1,742	1,273
TOTAL COST AVOIDANCE FROM A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD-10	3,635	7,877	5,756
Cost to Commercial Health plans	530	2,698	1,614
Cost to Medicare	5	10	8
Cost to State Medicaid Agencies	83	145	114
Cost to Large Providers	409	3,728	2,069
Cost to Students	4	4	4
TOTAL COST OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10	1,031	6,586	3,808

* Calculated in 2012 dollars.

TABLE 18—COST AVOIDANCE LESS COST (NET) OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10

[In millions] *

Low Net Estimate (Low Cost Avoidance with High Costs).	– $2,950
High Net Estimate (High Cost Avoidance with Low Costs).	6,846
Mean Net Cost Avoidance (average)	1,948

* Calculated in 2012 dollars.

P. Regulatory Flexibility Analysis: Impact on Small Entities of a Delay in the Compliance Date of ICD–10

The Regulatory Flexibility Act (RFA) of 1980 (Pub. L. 96–354) requires agencies to describe and analyze the impact of the final rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. According to the Small Business Administration's size standards, a small entity is defined as follows according to health care categories: Offices of Physicians are defined as small entities if they have revenues of $10 million or less; most other health care providers (dentists, chiropractors, optometrists, mental health specialists) are small entities if they have revenues of $7 million or less; hospitals are small entities if they have revenues of $34.5 million or less. (For details, see the SBA's Web site at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf* Refer to Sector 62—Health Care and Social Assistance).

We stated in the April 2012 proposed rule that there were a number of health maintenance organizations (HMOs) that are small entities by virtue of their nonprofit status even though few if any of them are small by SBA size standards. There are approximately one hundred such HMOs. We also assumed, for purposes of the RFA, that all physician practices and hospitals were small entities. Accordingly, we found in the April 2012 proposed rule that a one-year delay in implementation of the ICD–10 will affect a ''substantial number'' of small entities.

However, as illustrated in Tables 19 and20, we concluded in the April 2012 proposed rule that the 1-year delay in the compliance date of ICD–10 will be more beneficial to small and nonprofit entities than it will be burdensome. Based on that analysis, we certify that the provisions related to ICD–10 in this final rule would not have a significant economic impact on a substantial number of small entities.

Comment: One commenter stated that it was impossible to see how we could arrive at the conclusion that the final rule would not affect small entities when the cost to implement ICD–10 is so high. The commenter noted that it was rather falsehearted for us to state, as we did in the April 2012 proposed rule, that we were only analyzing the impact of the delay, not the impact of the ICD–10 implementation that we addressed in the August 2008 proposed rule. Instead, our latest cost estimates of implementing ICD–10—that the commenter viewed as improperly documented and misleading—should have triggered a re-review of the RIA conducted in the August 2008 proposed rule.

Response: The RIA of the April 2012 proposed rule, and this final rule, are focused on the impact of the provision of the proposed and final rule; that is, a delay in the compliance date of ICD–10. As noted in this RFA, a delay will be beneficial for small entities, otherwise there is no reason to go forward with a delay. We cannot revisit cost/benefits of implementing ICD–10, at least to the extent it was done so in the August 2008 proposed rule, because this rule does not mandate ICD–10; it delays it. As for our estimates on costs and cost avoidance of a delay in the compliance date of ICD–10, we believe that we have been transparent in admitting that our calculations are based on some studies and polls that lack statistical validity. Weighing industry's need for clarity on the ICD–10 compliance date and the need to meet high standards of analysis by conducting a comprehensive study or poll, we believed that an expedient answer on the compliance date would be more beneficial to industry's financial and business needs.

TABLE 19—COSTS AND BENEFITS IN 2014 OF A DELAY IN THE COMPLIANCE DATE OF ICD–10 FOR PROVIDERS

[Small Entities] *

	Physician practices with less than 50 physicians	Physician practices with 50 to 100 physicians	Physician practices with more than 100 physicians	Hospitals with less than 100 beds	Hospitals with 100 to 400 beds.	Hospitals with more than 400 beds	Totals
Number of Entities	233,239	590	393	2,757	2,486	521	239,986
LOW Costs (in millions)	$.00	$29.07	$97	$34	$153	$96	$409
HIGH Costs (in millions)	$.00	$261.65	$871	$255	$1,378	$963	$3,728

TABLE 19—COSTS AND BENEFITS IN 2014 OF A DELAY IN THE COMPLIANCE DATE OF ICD–10 FOR PROVIDERS—Continued

[Small Entities] *

	Physician practices with less than 50 physicians	Physician practices with 50 to 100 physicians	Physician practices with more than 100 physicians	Hospitals with less than 100 beds	Hospitals with 100 to 400 beds.	Hospitals with more than 400 beds	Totals
LOW Cost Avoidance (in millions)	$1,446	$.00	$.00	$.00	$.00	.00	$1,446
HIGH Cost Avoidance (in millions)	$3,134	$.00	$.00	$.00	$.00	.00	$3,134

* Both cost and cost avoidance occur in 2014. In 2012 dollars.

TABLE 20—COSTS AND COST AVOIDANCE IN 2014 FOR NON–PROFIT HEALTH PLANS FOR A 1–YEAR DELAY OF THE COMPLIANCE DATE FOR ICD–10 *

	Number of non profit health plans	LOW COST per health plan (in millions)	HIGH COST per health plan (in millions)	LOW COST AVOIDANCE (in millions)	HIGH COST AVOIDANCE (in millions)
Blue Cross Blue Shield	38	$1.44	$7.26	$88.26	$122.21
HMO	100	.12	.60	4.02	5.57
Total	$.00	$1.56	7.86	92.28	127.77

* Both cost and cost avoidance occur in 2014. In 2012 dollars.

Q. Summary and Accounting Statement for HPID, NPI and ICD–10

Table 21 summarizes the impacts of this final rule, including the costs and benefits of implementation of the HPID and the costs and cost avoidance of a 1-year delay in the compliance date of ICD–10. The costs and benefits of implementation of the HPID are calculated over an 11-year period, 2016 through 2026, while the cost avoidance and costs of the delay of the compliance date of ICD–10 will all occur in 2014.

TABLE 21—SUMMARY OF COSTS AND SAVINGS/COST AVOIDANCE, OF IMPLEMENTATION OF HPID, NPI AND A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10

[In millions]*

	LOW	HIGH	MEAN
Total Savings/Cost Avoidance	$7,172	$14,968	$11,070
Total Costs	2,134	8,784	5,459

* Costs and savings of HPID are calculated over 11 years, 2016 through 2026. Costs and cost avoidance of a delay in the compliance date of ICD–10 are calculated over 1 year, 2014. In 2012 dollars.

In Table 22, the LOW estimate Net Savings/Cost Avoidance is calculated using the LOW Savings/Cost Avoidance minus the HIGH estimated Costs; that is, the worst case scenario in terms of low benefits and high costs. The HIGH estimate Net Savings/Cost Avoidance is estimated using the HIGH Savings/Cost Avoidance minus the LOW estimated Costs; that is, the best case scenario in terms of high benefits and low costs. The Mean Net Savings/Cost Avoidance is the average of the best case scenario and the worst case scenario.

TABLE 22—SUMMARY OF NET COST AVOIDANCE/SAVINGS OF IMPLEMENTATION OF HPID, NPI, AND A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10

[In 2012 dollars]

	LOW NET SAVINGS (cost avoidance/savings less HIGH costs) (in millions)	HIGH NET SAVINGS (cost avoidance/savings less LOW costs) (in millions)	MEAN NET SAVINGS (in millions)
Net Savings/Cost Avoidance	−$1,612	$12,834	$5,611

As required by OMB Circular A–4,[29] Tables 23, 24, and 25 are accounting statements showing the classification of the expenditures associated with the provisions of this final rule. Table 23 provides our best estimate of the costs and benefits associated with the implementation and use of the HPID. Table 24 provides our best estimates of the costs and benefits associated with a 1-year delay in the compliance date of ICD–10. Table 25 provides a combined estimate of the costs and benefits associated with implementation and use of HPID and a 1-year delay in the compliance date of ICD–10.

TABLE 23—ACCOUNTING STATEMENT FOR HPID IMPLEMENTATION: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2016 TO FY 2026

[In millions of 2012 dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized Monetized benefits:				
7% Discount	$348	$246	$525	RIA.
3% Discount	329	246	506	RIA.
Qualitative (un-quantified) benefits.	HPID: Environmental (electronic over paper), patient benefits (more staff time), benefits from a decrease in time interacting with health plans for hospitals, dentists, suppliers of durable medical equipment, nursing homes, and residential care facilities, and providers other than physician practices.			
COSTS:				
Annualized Monetized costs:				
7% Discount	$203	$135	$270	RIA and Collection of Information.
3% Discount	172	115	229	RIA and Collection of Information.
Qualitative (unquantified) costs.	HPID: Cost for system changes for dentists, suppliers of durable medical equipment, nursing homes, residential care facilities, and providers other than physician practices and hospitals.	None	None.	
TRANSFERS:				
Annualized monetized transfers: "on budget".	N/A	N/A	N/A.	
From whom to whom?	N/A	N/A	N/A.	
Annualized monetized transfers: "off-budget".	N/A	N/A	N/A.	

TABLE 24—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR 1-YEAR DELAY OF ICD–10 COMPLIANCE DATE FOR 2014

[In millions of 2012 dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized Monetized benefits:				
7% Discount	$5,756	$3,635	$7,874	RIA.
3% Discount	5,756	3,635	7,874	RIA.
Qualitative (unquantified) benefits.	Avoidance of returned health care claims.			
COSTS:				
Annualized Monetized costs:				
7% Discount	$3,808	$1,031	$6,586	RIA and Collection of Information.
3% Discount	3,808	1,031	6,586	RIA and Collection of Information.
Qualitative (unquantified) costs.	Downstream costs of a delayed return on investment for covered entities.	None	None.	
TRANSFERS:				

[29] "Circular A–4," September 17, 2003, Office of Management and Budget (OMB), *http://www.whitehouse.gov/omb/circulars_a004_a-4/.*

TABLE 24—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR 1-YEAR DELAY OF ICD–10 COMPLIANCE DATE FOR 2014—Continued

[In millions of 2012 dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
Annualized monetized transfers: "on budget".	N/A	N/A	N/A.	
From whom to whom?	N/A	N/A	N/A.	
Annualized monetized transfers: "off-budget".	N/A	N/A	N/A.	

TABLE 25—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR HPID IMPLEMENTATION AND 1-YEAR DELAY OF ICD–10 COMPLIANCE DATE, FROM FY 2014 TO FY 2026

[In millions of 2012 dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized Monetized benefits:				
7% Discount	$916	$613	$1,292	RIA.
3% Discount	795	540	1,134	RIA.
Qualitative (unquantified) benefits.	HPID: Environmental (electronic over paper), patient benefits (more staff time), benefits from a decrease in time interacting with health plans for hospitals, dentists, suppliers of durable medical equipment, nursing homes, and residential care facilities, and providers other than physician practices. DELAY IN COMPLIANCE DATE FOR ICD-10: Avoidance of returned health care claims.			
COSTS:				
Annualized Monetized costs:				
7% Discount	$596	$229	$963	RIA and Collection of Information.
3% Discount	493	191	795	RIA and Collection of Information.
Qualitative (unquantified) costs.	HPID: Cost for system changes for dentists, suppliers of durable medical equipment, nursing homes, residential care facilities, and providers other than physician practices and hospitals.			
	DELAY IN COMPLIANCE DATE OF ICD–10: Downstream costs of a delayed return on investment for covered entities.	None	None.	
TRANSFERS:				
Annualized monetized transfers: "on budget".	N/A	N/A	N/A.	
From whom to whom?	N/A	N/A	N/A.	
Annualized monetized transfers: "off-budget".	N/A	N/A	N/A.	

List of Subjects in 45 CFR Part 162

Administrative practice and procedures, electronic transactions, health facilities, health insurance, hospitals, incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in this preamble, the Department of Health and Human Services amends 45 CFR part 162 to read as follows:

PART 162—ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 162 continues to read as follows:

Authority: Secs. 1171 through 1180 of the Social Security Act (42 U.S.C. 1320d–1320d–9), as added by sec. 262 of Pub. L. 104–191, 110 Stat 2021–2031, sec. 105 of Pub. L. 110–233, 122 Stat. 881–922, and sec. 264 of Pub. L. 104–191, 110 Stat 2033–2034 (42 U.S.C. 1320d–2(note)), and secs. 1104 and 10109 of Pub L. 111–148, 124 Stat 146–154 and 915–917.

Subpart A—General Provisions

■ 2. Section 162.103 is amended by adding the definitions of ''Controlling health plan (CHP),'' ''Covered health care provider,'' and ''Subhealth plan (SHP)'' to read as follows:

§ 162.103 Definitions.

* * * * *

Controlling health plan (CHP) means a health plan that—

(1) Controls its own business activities, actions, or policies; or

(2)(i) Is controlled by an entity that is not a health plan; and

(ii) If it has a subhealth plan(s) (as defined in this section), exercises sufficient control over the subhealth plan(s) to direct its/their business activities, actions, or policies.

Covered health care provider means a health care provider that meets the definition at paragraph (3) of the definition of ''covered entity'' at § 160.103.

* * * * *

Subhealth plan (SHP) means a health plan whose business activities, actions, or policies are directed by a controlling health plan.

Subpart D—Standard Unique Health Identifier for Health Care Providers

§ 162.402 [Removed and Reserved]

■ 3. Section 162.402 is removed and reserved.

■ 4. Section 162.404 is amended as follows:

■ A. Redesignating paragraph (a) as paragraph (a)(1).

■ B. Adding paragraph (a)(2).

The addition reads as follows:

§ 162.404 Compliance dates of the implementation of the standard unique health identifier for health care providers.

(a) * * *

(2) An organization covered health care provider must comply with the implementation specifications in § 162.410(b) by May 6, 2013.

* * * * *

■ 5. Section 162.410 is amended as follows:

■ A. Redesignating paragraph (b) as paragraph (c).

■ B. Adding a new paragraph (b).

The addition reads as follows:

§ 162.410 Implementation specifications: Health care providers.

* * * * *

(b) An organization covered health care provider that has as a member, employs, or contracts with, an individual health care provider who is not a covered entity and is a prescriber, must require such health care provider to—

(1) Obtain an NPI from the National Plan and Provider Enumeration System (NPPES); and

(2) To the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

* * * * *

■ 6. Part 162 is amended by adding subpart E to read as follows:

Subpart E—Standard Unique Health Identifier for Health Plans

Sec.
162.502 [Reserved]
162.504 Compliance requirements for the implementation of the standard unique health plan identifier.
162.506 Standard unique health plan identifier.
162.508 Enumeration System.
162.510 Full implementation requirements: Covered entities.
162.512 Implementation specifications: Health plans.
162.514 Other entity identifier.

Subpart E—Standard Unique Health Identifier for Health Plans

§ 162.502 [Reserved]

§ 162.504 Compliance requirements for the implementation of the standard unique health plan identifier.

(a) *Covered entities.* A covered entity must comply with the implementation requirements in § 162.510 no later than November 5, 2014.

(b) *Health plans.* A health plan must comply with the implementation specifications in § 162.512 no later than one of the following dates:

(1) A health plan that November 5, 2014.

(2) A health plan that is a small health plan–

November 5, 2014.

§ 162.506 Standard unique health plan identifier.

(a) *Standard.* The standard unique health plan identifier is the Health Plan Identifier (HPID) that is assigned by the Enumeration System identified in § 162.508.

(b) *Required and permitted uses for the HPID.* (1) The HPID must be used as specified in § 162.510 and § 162.512.

(2) The HPID may be used for any other lawful purpose.

§ 162.508 Enumeration System.

The Enumeration System must do all of the following:

(a) Assign a single, unique—

(1) HPID to a health plan, provided that the Secretary has sufficient information to permit the assignment to be made; or

(2) OEID to an entity eligible to receive one under § 162.514(a), provided that the Secretary has sufficient information to permit the assignment to be made.

(b) Collect and maintain information about each health plan that applies for or has been assigned an HPID and each entity that applies for or has been assigned an OEID, and perform tasks necessary to update that information.

(c) If appropriate, deactivate an HPID or OEID upon receipt of sufficient information concerning circumstances justifying deactivation.

(d) If appropriate, reactivate a deactivated HPID or OEID upon receipt of sufficient information justifying reactivation.

(e) Not assign a deactivated HPID to any other health plan or OEID to any other entity.

(f) Disseminate Enumeration System information upon approved requests.

§ 162.510 Full implementation requirements: Covered entities.

(a) A covered entity must use an HPID to identify a health plan that has an HPID when a covered entity identifies a health plan in a transaction for which the Secretary has adopted a standard under this part.

(b) If a covered entity uses one or more business associates to conduct standard transactions on its behalf, it must require its business associate(s) to use an HPID to identify a health plan that has an HPID when the business associate(s) identifies a health plan in a transaction for which the Secretary has adopted a standard under this part.

§ 162.512 Implementation specifications: Health plans.

(a) A controlling health plan must do all of the following:

(1) Obtain an HPID from the Enumeration System for itself.

(2) Disclose its HPID, when requested, to any entity that needs the HPID to identify the health plan in a standard transaction.

(3) Communicate to the Enumeration System any changes in its required data elements in the Enumeration System within 30 days of the change.

(b) A controlling health plan may do the following:

(1) Obtain an HPID from the Enumeration System for a subhealth plan of the controlling health plan.

(2) Direct a subhealth plan of the controlling health plan to obtain an HPID from the Enumeration System.

(c) A subhealth plan may obtain an HPID from the Enumeration System.

(d) A subhealth plan that is assigned an HPID from the Enumeration System must comply with the requirements that apply to a controlling health plan in paragraphs (a)(2) and (a)(3) of this section.

§ 162.514 Other entity identifier.

(a) An entity may obtain an Other Entity Identifier (OEID) to identify itself if the entity meets all of the following:

(1) Needs to be identified in a transaction for which the Secretary has adopted a standard under this part.

(2) Is not eligible to obtain an HPID.

(3) Is not eligible to obtain an NPI.

(4) Is not an individual.

(b) An OEID must be obtained from the Enumeration System identified in § 162.508.

(c) *Uses for the OEID.* (1) An other entity may use the OEID it obtained from the Enumeration System to identify itself or have itself identified on all covered transactions in which it needs to be identified.

(2) The OEID may be used for any other lawful purpose.

■ 7. Section 162.1002 is amended by revising paragraph (b) introductory text and paragraph (c) introductory text to read as follows:

§ 162.1002 Medical data code sets.

* * * * *

(b) For the period on and after October 16, 2003 through September 30, 2014:

* * * * *

(c) For the period on and after October 1, 2014:

* * * * *

Dated: August 21, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: August 22, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–21238 Filed 8–24–12; 12:00 pm]

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FEDERAL REGISTER

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Part III

Department of the Treasury

Office of the Comptroller of the Currency

12 CFR Parts 34 and 164

Board of Governors of Federal Reserve System

12 CFR Part 226

National Credit Union Administration

12 CFR Part 722

Bureau of Consumer Financial Protection

12 CFR Part 1026

Federal Housing Finance Agency

12 CFR Part 1222

Appraisals for Higher-Risk Mortgage Loans; Proposed Rule

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 34 and 164

[Docket No. OCC–2012–0013]

RIN 1557–AD62

BOARD OF GOVERNORS OF FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Docket No. R–1443]

RIN 7100–AD90

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 722

RIN 3133–AE04

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

[Docket No. CFPB–2012–0031]

RIN 3170–AA11

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1222

RIN 2590–AA58

Appraisals for Higher-Risk Mortgage Loans

AGENCIES: Board of Governors of the Federal Reserve System (Board); Bureau of Consumer Financial Protection (Bureau); Federal Deposit Insurance Corporation (FDIC); Federal Housing Finance Agency (FHFA); National Credit Union Administration (NCUA); and Office of the Comptroller of the Currency, Treasury (OCC).

ACTION: Proposed rule; request for public comment.

SUMMARY: The Board, Bureau, FDIC, FHFA, NCUA, and OCC (collectively, the Agencies) are proposing to amend Regulation Z, which implements the Truth in Lending Act (TILA), and the official interpretation to the regulation. The proposed revisions to Regulation Z would implement a new TILA provision requiring appraisals for ''higher-risk mortgages'' that was added to TILA as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act. For mortgages with an annual percentage rate that exceeds the average prime offer rate by a specified percentage, the proposed rule would require creditors to obtain an appraisal or appraisals meeting certain specified standards, provide applicants with a notification regarding the use of the appraisals, and give applicants a copy of the written appraisals used.

DATES: Comments must be received on or before October 15, 2012, except that comments on the Paperwork Reduction Act analysis in part VIII of the Supplementary Information must be received on or before November 5, 2012.

ADDRESSES: Interested parties are encouraged to submit written comments jointly to all of the Agencies. Commenters are encouraged to use the title ''Appraisals for Higher-Risk Mortgage Loans'' to facilitate the organization and distribution of comments among the Agencies. Commenters also are encouraged to identify the number of the specific question for comment to which they are responding. Interested parties are invited to submit written comments to:

Board: You may submit comments, identified by Docket No. R–1443 or RIN 7100–AD90, by any of the following methods:

- *Agency Web Site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include the docket number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Address to Robert deV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments will be made available on the Board's Web site at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9:00 a.m. and 5:00 p.m. on weekdays.

Bureau: You may submit comments, identified by Docket No. CFPB–2012–0031 or RIN 3170–AA11, by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Monica Jackson, Office of the Executive Secretary, Bureau of Consumer Financial Protection, 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier in Lieu of Mail:* Monica Jackson, Office of the Executive Secretary, Bureau of Consumer Financial Protection, 1700 G Street NW., Washington, DC 20552.

All submissions must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. In general, all comments received will be posted without change to *http://www.regulations.gov.* In addition, comments will be available for public inspection and copying at 1700 G Street NW., Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect the documents by telephoning (202) 435–7275.

All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or social security numbers, should not be included. Comments will not be edited to remove any identifying or contact information.

FDIC: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Agency Web site: http://www.FDIC.gov/regulations/laws/federal/propose.html*
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments/Legal ESS, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivered/Courier:* The guard station at the rear of the 550 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.
- *Email: comments@FDIC.gov.*

Comments submitted must include ''FDIC'' and ''Truth in Lending Act (Regulation Z).'' Comments received will be posted without change to *http://www.FDIC.gov/regulations/laws/federal/propose.html,* including any personal information provided.

FHFA: You may submit your comments, identified by regulatory information number (RIN) 2590–AA58, by any of the following methods:

- *Email:* Comments to Alfred M. Pollard, General Counsel, may be sent by email to *RegComments@fhfa.gov.* Please include ''RIN 2590–AA58'' in the subject line of the message.

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by email to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by the Agency. Please include ''RIN 2590–AA58'' in the subject line of the message.

• *Hand Delivered/Courier:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590–AA58, Federal Housing Finance Agency, Eighth Floor, 400 Seventh Street SW., Washington, DC 20024. The package should be logged in at the Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.

• *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590–AA58, Federal Housing Finance Agency, Eighth Floor, 400 Seventh Street SW., Washington, DC 20024.

Copies of all comments will be posted without change, including any personal information you provide, such as your name, address, and phone number, on the FHFA Internet Web site at *http://www.fhfa.gov.* In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., Eastern Time, at the Federal Housing Finance Agency, Eighth Floor, 400 Seventh Street SW., Washington, DC 20024. To make an appointment to inspect comments, please call the Office of General Counsel at (202) 649–3804.

NCUA: You may submit comments, identified by RIN 3133–AE04, by any of the following methods (Please send comments by one method only):

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *NCUA Web Site: http://www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx.* Follow the instructions for submitting comments.

• *Email:* Address to *regcomments@ncua.gov.* Include ''[Your name] Comments on Appraisals for High Risk Mortgage Loans'' in the email subject line.

• *Fax:* (703) 518–6319. Use the subject line described above for email.

• *Mail:* Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

• *Hand Delivery/Courier in Lieu of Mail:* Same as mail address.

You can view all public comments on NCUA's Web site at *http://www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx* as submitted, except for those we cannot post for technical reasons. NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9:00 a.m. and 3:00 p.m. To make an appointment, call (703) 518–6546 or send an email to *OGCMail@ncua.gov.*

OCC: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by the Federal eRulemaking Portal or email, if possible. Please use the title ''Appraisals for Higher-Risk Mortgage Loans'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

• *Federal eRulemaking Portal—''regulations.gov'':* Go to *http://www.regulations.gov.* Click ''Advanced Search''. Select ''Document Type'' of ''Proposed Rule'', and in ''By Keyword or ID'' box, enter Docket ID ''OCC–2012–0013'', and click ''Search''. If proposed rules for more than one agency are listed, in the ''Agency'' column, locate the notice of proposed rulemaking for the OCC. Comments can be filtered by Agency using the filtering tools on the left side of the screen. In the ''Actions'' column, click on ''Submit a Comment'' or ''Open Docket Folder'' to submit or view public comments and to view supporting and related materials for this rulemaking action. Click on the ''Help'' tab on the Regulations.gov home page to get information on using Regulations.gov, including instructions for submitting or viewing public comments, viewing other supporting and related materials, and viewing the docket after the close of the comment period.

• *Email: regs.comments@occ.treas.gov.*

• *Mail:* Office of the Comptroller of the Currency, 250 E Street SW., Mail Stop 2–3, Washington, DC 20219.

• *Fax:* (202) 874–5274.

• *Hand Delivery/Courier:* 250 E Street SW., Mail Stop 2–3, Washington, DC 20219.

You must include ''OCC'' as the agency name and ''Docket ID OCC–2012–0013'' in your comment. In general, OCC will enter all comments received into the docket and publish them on the Regulations.gov Web site without change, including any business or personal information that you provide such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this notice of proposed rulemaking by any of the following methods:

• *Viewing Comments Electronically:* Go to *http://www.regulations.gov.* Click ''Advanced Search''. Select ''Document Type'' of ''Public Submission'', and in ''By Keyword or ID'' box enter Docket ID ''OCC–2012–0013'', and click ''Search''. If comments from more than one agency are listed, the ''Agency'' column will indicate which comments were received by the OCC. Comments can be filtered by Agency using the filtering tools on the left side of the screen.

• *Viewing Comments Personally:* You may personally inspect and photocopy comments at the OCC, 250 E Street SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–4700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

You may also view or request available background documents and project summaries using the methods described above.

FOR FURTHER INFORMATION CONTACT:

Board: Lorna Neill or Mandie Aubrey, Counsels, Division of Consumer and Community Affairs, at (202) 452–3667, or Carmen Holly, Supervisory Financial Analyst, Division of Banking Supervision and Regulation, at (202) 973–6122, Board of Governors of the Federal Reserve System, Washington, DC 20551.

Bureau: Michael Scherzer or John Brolin, Counsels, or William W. Matchneer, Senior Counsel, Division of Research, Markets, and Regulations, Bureau of Consumer Financial Protection, 1700 G Street NW., Washington, DC 20552, at (202) 435–7000.

FDIC: Beverlea S. Gardner, Senior Examination Specialist, Risk Management Section, at (202) 898–3640, Sumaya A. Muraywid, Examination Specialist, Risk Management Section, at (573) 875–6620, Glenn S. Gimble, Senior Policy Analyst, Division of Consumer Protection, at (202) 898–6865, Mark Mellon, Counsel, Legal Division, at (202) 898–3884, or Kimberly Stock,

Counsel, Legal Division, at (202) 898–3815, or 550 17th St NW., Washington, DC 20429.

FHFA: Susan Cooper, Senior Policy Analyst, (202) 649–3121, Lori Bowes, Policy Analyst, Office of Housing and Regulatory Policy, (202) 649–3111, or Ming-Yuen Meyer-Fong, Assistant General Counsel, Office of General Counsel, (202) 649–3078, Federal Housing Finance Agency, 400 Seventh Street SW., Washington, DC 20024.

NCUA: Chrisanthy Loizos and Pamela Yu, Staff Attorneys, or Frank Kressman, Associate General Counsel, Office of General Counsel, at (703) 518–6540, or Vincent Vieten, Program Officer, Office of Examination and Insurance, at (703) 518–6360, or 1775 Duke Street, Alexandria, Virginia 22314.

OCC: Robert L. Parson, Appraisal Policy Specialist, (202) 874–5411, Carolyn B. Engelhardt, Bank Examiner (Risk Specialist—Credit), (202) 874–4917, Charlotte M. Bahin, Senior Counsel or Mitchell Plave, Special Counsel, Legislative & Regulatory Activities Division, (202) 874–5090, Krista LaBelle, Counsel, Community and Consumer Law, (202) 874–5750.

SUPPLEMENTARY INFORMATION:

I. Overview

The Truth in Lending Act (TILA), 15 U.S.C. 1601 *et seq.,* seeks to promote the informed use of consumer credit by requiring disclosures about its costs and terms. TILA requires additional disclosures for loans secured by consumers' homes and permits consumers to rescind certain transactions that involve their principal dwelling. For most types of creditors, TILA directs the Bureau to prescribe regulations to carry out the purposes of the law and specifically authorizes the Bureau, among other things, to issue regulations that contain such classifications, differentiations, or other provisions, or that provide for such adjustments and exceptions for any class of transactions, that in the Bureau's judgment are necessary or proper to effectuate the purposes of TILA, or prevent circumvention or evasion of TILA.[1] 15 U.S.C. 1604(a). TILA is implemented by the Bureau's Regulation Z, 12 CFR part 1026, and the Board's Regulation Z, 12 CFR part 226. Official Interpretations provide guidance to creditors in applying the rules to specific transactions and interprets the requirements of the regulation. *See* 12 CFR parts 226, Supp. I, and 1026, Supp. I.

On July 21, 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act)[2] was signed into law. Section 1471 of the Dodd-Frank Act establishes a new TILA section 129H, which sets forth appraisal requirements applicable to ''higher-risk mortgages.'' Specifically, new TILA section 129H does not permit a creditor to extend credit in the form of a higher-risk mortgage loan to any consumer without first:

- Obtaining a written appraisal performed by a certified or licensed appraiser who conducts a physical property visit of the interior of the property.
- Obtaining an additional appraisal from a different certified or licensed appraiser if the purpose of the higher-risk mortgage loan is to finance the purchase or acquisition of a mortgaged property from a seller within 180 days of the purchase or acquisition of the property by that seller at a price that was lower than the current sale price of the property. The additional appraisal must include an analysis of the difference in sale prices, changes in market conditions, and any improvements made to the property between the date of the previous sale and the current sale.
- Providing the applicant, at the time of the initial mortgage application, with a statement that any appraisal prepared for the mortgage is for the sole use of the creditor, and that the applicant may choose to have a separate appraisal conducted at the applicant's expense.
- Providing the applicant with one copy of each appraisal conducted in accordance with TILA section 129H without charge, at least three (3) days prior to the transaction closing date.

New TILA section 129H(f) defines a ''higher-risk mortgage'' with reference to the annual percentage rate (APR) for the transaction. A higher-risk mortgage is a ''residential mortgage loan'' secured by a principal dwelling with an APR that exceeds the average prime offer rate (APOR) for a comparable transaction as of the date the interest rate is set—

- By 1.5 or more percentage points, for a first lien residential mortgage loan with an original principal obligation amount that does not exceed the amount for the maximum limitation on the original principal obligation of a mortgage in effect for a residence of the applicable size, as of the date of such interest rate set, pursuant to the sixth sentence of section 305(a)(2) of the Federal Home Loan Mortgage Corporation Act (12 U.S.C. 1454);
- By 2.5 or more percentage points, for a first lien residential mortgage loan having an original principal obligation amount that exceeds the amount for the maximum limitation on the original principal obligation of a mortgage in effect for a residence of the applicable size, as of the date of such interest rate set, pursuant to the sixth sentence of section 305(a)(2) of the Federal Home Loan Mortgage Corporation Act (12 U.S.C. 1454); and
- By 3.5 or more percentage points for a subordinate lien residential mortgage loan.

The definition of ''higher-risk mortgage'' expressly excludes qualified mortgages, as defined in TILA section 129C, as well as reverse mortgage loans that are qualified mortgages as defined in TILA section 129C.

New TILA section 103(cc)(5) defines the term ''residential mortgage loan'' as any consumer credit transaction that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling or on residential real property that includes a dwelling, other than a consumer credit transaction under an open-end credit plan. 15 U.S.C. 1602(cc)(5).

New TILA section 129H(b)(4)(A) requires the Agencies to jointly prescribe regulations to implement the property appraisal requirements for higher-risk mortgages. 15 U.S.C. 1639h(b)(4)(A). Section 1400 of the Dodd-Frank Act requires that final regulations to implement these provisions be issued by January 21, 2013.

II. Summary of the Proposed Rule

The Agencies issue this proposal to implement the appraisal requirements for extensions of credit for ''higher-risk mortgage loans'' required by the Dodd-Frank Act, Title XIV, Subtitle F (Appraisal Activities). As required by the Act, this proposal was developed jointly by the Board, the Bureau, the FHFA, the FDIC, the NCUA, and the OCC. The Act generally defines a ''higher-risk mortgage'' as a closed-end consumer credit transaction secured by a principal dwelling with an APR exceeding certain statutory thresholds. These rate thresholds are substantially similar to rate triggers currently in Regulation Z for ''higher-priced mortgage loans,'' a category of loans to which special consumer protections

[1] For motor vehicle dealers as defined in section 1029 of the Dodd-Frank Act, TILA directs the Board to prescribe regulations to carry out the purposes of TILA and authorizes the Board to issue regulations that contain such classifications, differentiations, or other provisions, or that provide for such adjustments and exceptions for any class of transactions, that in the Board's judgment are necessary or proper to effectuate the purposes of TILA, or prevent circumvention or evasion of TILA. 15 U.S.C. 5519; 15 U.S.C. 1604(a).

[2] Public Law 111–203, 124 Stat. 1376.

apply.[3] In general, loans are ''higher-risk mortgage loans'' under this proposed rule if the APR exceeds the APOR by 1.5 percent for first-lien loans, 2.5 percent for first-lien jumbo loans, and 3.5 percent for subordinate-lien loans.[4]

Consistent with the statute, the proposal would exclude ''qualified mortgages'' from the definition of higher-risk mortgage loan. The Bureau will define ''qualified mortgage'' when it finalizes the proposed rule issued by the Board to implement the Dodd-Frank Act's ability-to-repay requirements in TILA section 129C. 15 U.S.C. 1639c; 76 FR 27390, May 11, 2011 (2011 ATR Proposal). In addition, the Agencies propose to rely on exemption authority granted by the Dodd-Frank Act to exempt the following additional classes of loans: (1) reverse mortgage loans; and (2) loans secured solely by residential structures, such as many types of manufactured homes.

Consistent with the statute, the proposal would allow a creditor to make a higher-risk mortgage loan only if the following conditions are met:

- The creditor obtains a written appraisal;
- The appraisal is performed by a certified or licensed appraiser;
- The appraiser conducts a physical property visit of the interior of the property;
- At application, the applicant is provided with a statement regarding the purpose of the appraisal, that the creditor will provide the applicant a copy of any written appraisal, and that the applicant may choose to have a separate appraisal conducted at the expense of the applicant; and
- The creditor provides the consumer with a free copy of any written appraisals obtained for the transaction at least three (3) business days before closing.

In addition, as required by the Act, the proposal would require a higher-risk mortgage loan creditor to obtain an additional written appraisal, at no cost to the borrower, under the following circumstances:

- The higher-risk mortgage loan will finance the acquisition of the consumer's principal dwelling;
- The seller is selling what will become the consumer's principal dwelling acquired the home within 180 days prior to the consumer's purchase agreement (measured from the date of the consumer's purchase agreement); and
- The consumer is acquiring the home for a higher price than the seller paid, although comment is requested on whether a threshold price increase would be appropriate.

The additional written appraisal, from a different licensed or certified appraiser, generally must include the following information: an analysis of the difference in sale prices (*i.e.,* the sale price paid by the seller and the acquisition price of the property as set forth in the consumer's purchase agreement), changes in market conditions, and any improvements made to the property between the date of the previous sale and the current sale.

The proposal also includes a request for comments to address a proposed amendment to the method of calculation of the APR that is being proposed as part of other mortgage-related proposals issued for comment by the Bureau. In the Bureau's proposal to integrate mortgage disclosures (2012 TILA–RESPA Proposal), the Bureau is proposing to adopt a more simple and inclusive finance charge calculation for closed-end credit secured by real property or a dwelling.[5] As the finance charge is integral to the calculation of the APR, the Agencies believe it is possible that a more inclusive finance charge could increase the number of loans covered by this rule. The Agencies note that the Bureau currently is seeking data to assist in assessing potential impacts of a more inclusive finance charge in connection with the 2012 TILA–RESPA Proposal and its proposal to implement the Dodd-Frank Act provision related to ''high-cost mortgages'' (2012 HOEPA Proposal).[6]

The Agencies also note that the Bureau is seeking comment on whether replacing APR with an alternative metric may be warranted to determine whether a loan is covered by the 2012 HOEPA Proposal,[7] as well as by the proposal to implement the Dodd-Frank Act's escrow requirements in TILA section 129D. 15 U.S.C. 1639d; 76 FR 11598, March 2, 2011 (2011 Escrow Proposal). The alternative metric would also have implications for the 2011 ATR Proposal. One possible alternative metric discussed in those proposals is the ''transaction coverage rate'' (TCR), which would exclude all prepaid finance charges not retained by the creditor, a mortgage broker, or an affiliate of either.[8] The new rate triggers for both ''high-cost mortgages'' and ''higher-risk mortgages'' under the Dodd-Frank Act are based on the percentage by which the APR exceeds APOR. Given this similarity, the Agencies also seek comment as to whether a modification should be considered for this rule as well, and if so, what type of modification. Accordingly, higher-risk mortgage loan is defined in the alternative as calculated by either the TCR or APR, with comment sought on both approaches. As explained further below in the section-by-section analysis of the Supplementary Information, the Agencies are relying on their exemption authority under section 1471 of the Dodd-Frank Act to propose an alternative definition of higher-risk mortgage. TILA section 129H(b)(4)(B), 15 U.S.C. 1639h(b)(4)(B).

III. Legal Authority

As noted above, TILA section 129H(b)(4)(A), added by the Dodd-Frank Act, requires the Agencies to jointly prescribe regulations implementing section 129H. 15 U.S.C. 1639h(b)(4)(A). In addition, TILA section 129H(b)(4)(B), grants the Agencies the authority to jointly exempt, by rule, a class of loans from the requirements of TILA section 129H(a) or section 129H(b) if the Agencies determine that the exemption is in the public interest and promotes the safety and soundness of creditors. 15 U.S.C. 1639h(b)(4)(B).

IV. Section-by-Section Analysis

For ease of reference, the Supplementary Information refers to the section numbers of the rules that would be published in the Bureau's Regulation Z at 12 CFR 1026.XX. As explained further in the section-by-section analysis of § 1026.XX(e), the rules would be published separately by the Board, the Bureau and the OCC. No substantive difference among the three sets of rules is intended. The NCUA and FHFA propose to adopt the rules as published in the Bureau's Regulation Z at 12 CFR 1026.XX, by cross-referencing these rules in 12 CFR 722.3 and 12 CFR part 1222, respectively. The FDIC proposes to not cross-reference the Bureau's Regulation Z at 12 CFR 1026.XX.

[3] Added to Regulation Z by the Board pursuant to the Home Ownership and Equity Protection Act of 1994 (HOEPA), the ''higher-priced mortgage loan'' rules address unfair or deceptive practices in connection with subprime mortgages. See 73 FR 44522, July 30, 2008; 12 CFR 1026.35.

[4] The ''higher-priced mortgage loan'' rules apply the 2.5 percent over APOR trigger for jumbo loans only with respect to a requirement to establish escrow accounts. See 12 CFR 1026.35(b)(3)(v).

[5] *See* 2012 TILA–RESPA Proposal, pp. 101–127, 725–28, 905–11 (published July 9, 2012), available at *http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_integrated-mortgage-disclosures.pdf.*

[6] *See* 2012 HOEPA Proposal, pp. 44, 149–211 (published July 9, 2012), *available at http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_high-cost-mortgage-protections.pdf.*

[7] *See* 2012 HOEPA Proposal at 39–50, 218, 246.

[8] *See* 75 FR 58539, 58660–62 (Sept. 24, 2010); 76 FR 11598, 11609, 11620, 11626 (March 2, 2011).

Section 1026.XX Appraisals for Higher-Risk Mortgage Loans

XX(a) Definitions

Proposed § 1026.XX(a) sets forth four definitions, discussed below, for purposes of § 1026.XX. The Agencies request comment on whether additional terms should be defined for purposes of this rule, and how best to define those terms in a manner consistent with TILA section 129H.

XX(a)(1) Certified or Licensed Appraiser

TILA section 129H(b)(3) defines ''certified or licensed appraiser'' as a person who ''(A) is, at a minimum, certified or licensed by the State in which the property to be appraised is located; and (B) performs each appraisal in conformity with the Uniform Standards of Professional Appraisal Practice and title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, and the regulations prescribed under such title, as in effect on the date of the appraisal.'' 15 U.S.C. 1639h(b)(3). Consistent with the statute, proposed § 1026.XX(a)(1) would define ''certified or licensed appraiser'' as a person who is certified or licensed by the State agency in the State in which the property that secures the transaction is located, and who performs the appraisal in conformity with the Uniform Standards of Professional Appraisal Practice (USPAP) and the requirements applicable to appraisers in title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (FIRREA title XI) (12 U.S.C. 3331 *et seq.*), and any implementing regulations, in effect at the time the appraiser signs the appraiser's certification.

Proposed § 1026.XX(a)(1) generally mirrors the statutory language in TILA section 129H(b)(3) regarding State licensing and certification. However, the proposed definition uses the defined term ''State agency'' to clarify that the appraiser must be certified or licensed by a State agency that meets the standards of FIRREA title XI. Specifically, proposed § 1026.XX(a)(4) defines the term ''State agency'' to mean a ''State appraiser certifying and licensing agency'' recognized in accordance with section 1118(b) of FIRREA title XI (12 U.S.C. 3347(b)) and any implementing regulations.[9] *See also* section-by-section analysis of § 1026.XX(a)(4), below.

Uniform Standards of Professional Appraisal Practice (USPAP)

Proposed § 1026.XX(a)(1) uses the term ''Uniform Standards of Professional Appraisal Practice.'' Proposed comment XX(a)(1)–1 clarifies that USPAP refers to the professional appraisal standards established by the Appraisal Standards Board of the ''Appraisal Foundation,'' as defined in FIRREA section 1121(9). 12 U.S.C. 3350(9). The Agencies believe that this terminology is appropriate for consistency with the existing definition in FIRREA title XI.

TILA section 129H(b)(3) would require that the appraisal be performed in conformity with USPAP ''as in effect on the date of the appraisal.'' 15 U.S.C. 1639h(b)(3). The proposed definition of ''certified or licensed appraiser'' and proposed comment XX(a)(1)–1 clarify that the ''date of appraisal'' is the date on which the appraiser signs the appraiser's certification. Thus, the relevant edition of USPAP is the one in effect at the time the appraiser signs the appraiser's certification.

Appraiser's certification. Proposed comment XX(a)(1)–2 clarifies that the term ''appraiser's certification'' refers to the certification that must be signed by the appraiser for each appraisal assignment as specified in USPAP Standards Rule 2–3.[10]

FIRREA and Implementing Regulations

As previously noted, TILA section 129H(b)(3) defines ''certified or licensed appraiser'' as a person who is certified or licensed as an appraiser and ''performs each appraisal in accordance with [USPAP] and title XI of [FIRREA], and the regulations prescribed under such title, as in effect on the date of the appraisal.'' 15 U.S.C. 1639h(b)(3). Proposed § 1026.XX(a)(1) provides that the relevant provisions of FIRREA title XI and its implementing regulations are those selected portions of FIRREA title XI requirements ''applicable to appraisers,'' in effect at the time the appraiser signs the appraiser's certification. As discussed in more detail below, proposed comment XX(a)(1)–3 clarifies that the relevant standards ''applicable to appraisers'' are found in regulations prescribed under FIRREA section 1110 (12 U.S.C. 3339) ''that relate to an appraiser's development and reporting of the appraisal,'' but not those that relate to the review of the appraisal under paragraph (3) of FIRREA section 1110.

Section 1110 of FIRREA directs each Federal financial institutions regulatory agency (*i.e.,* each Federal banking agency[11]) to prescribe ''appropriate standards for the performance of real estate appraisals in connection with federally related transactions under the jurisdiction of each such agency or instrumentality.'' 12 U.S.C. 3339. These standards must require, at a minimum—(1) that real estate appraisals be performed in accordance with generally accepted appraisal standards as evidenced by the appraisal standards promulgated by the Appraisal Standards Board of the Appraisal Foundation; and (2) that such appraisals shall be written appraisals. 12 U.S.C. 3339(1) and (2). The Dodd-Frank Act added a third standard—that real estate appraisals be subject to appropriate review for compliance with USPAP—for which the Federal banking agencies must prescribe implementing regulations. FIRREA section 1110(3), 12 U.S.C. 3339(3). FIRREA section 1110 also provides that each Federal banking agency may require compliance with additional standards if the agency determines in writing that additional standards are required to properly carry out its statutory responsibilities. 12 U.S.C. 3339. Accordingly, the Federal banking agencies have prescribed appraisal regulations implementing FIRREA title XI that set forth, among other requirements, minimum standards for the performance of real estate appraisals in connection with ''federally related transactions,'' which are defined as real estate-related financial transactions that a Federal banking agency engages in, contracts for, or regulates, and that require the services of an appraiser.[12] 12 U.S.C. 3339, 3350(4).

The Agencies are proposing to interpret the ''certified or licensed appraiser'' definition in TILA section 129H(b)(3) to incorporate provisions of the Federal banking agencies' requirements in FIRREA title XI and implementing regulations ''applicable to appraisers,'' which the Agencies have clarified through proposed comment XX(a)(1)–3 as the regulations that ''relate to an appraiser's development and reporting of the appraisal.'' While the Federal banking agencies' requirements, pursuant to this authority

[9] If the Appraisal Subcommittee of the Federal Financial Institutions Examination Council issues certain written findings concerning, among other things, a State agency's failure to recognize and enforce FIRREA title XI standards, appraiser certifications and licenses issued by that State are not recognized for purposes of title XI and appraisals performed by appraisers certified or licensed by that State are not acceptable for federally-related transactions. 12 U.S.C. 3347(b).

[10] *See* Appraisal Standards Bd., Appraisal Fdn., Standards Rule 2–3, USPAP (2012–2013 ed.) at U–29, *available at http://www.uspap.org.*

[11] The Federal banking agencies are the Board, the FDIC, the OCC, and the NCUA.

[12] *See* OCC: 12 CFR part 34, Subpart C; FRB: 12 CFR part 208, subpart E, and 12 CFR part 225, subpart G; FDIC: 12 CFR part 323; and NCUA: 12 CFR part 722.

and their authority to establish safety and soundness regulations, apply to an institution's ordering and review of an appraisal, the Agencies propose that the definition of ''certified or licensed appraiser'' incorporate only FIRREA title XI's minimum standards related to the appraiser's performance of the appraisal.

The Agencies propose this interpretation on the grounds that it is consistent with TILA section 129H. 15 U.S.C. 1639h. Congress included language requiring that appraisals be performed in conformity with FIRREA within the definition of ''certified or licensed appraiser'' under TILA section 129H(b)(3). 15 U.S.C. 1639h(b)(3). Thus, the Agencies believe that Congress intended to limit FIRREA's requirements to those that apply to the *appraiser's* performance of the appraisal, rather than the FIRREA requirements that apply to a creditor's ordering and review of the appraisal.

Proposed comment XX(a)(1)–3 would also clarify that the requirements of FIRREA section 1110(3) that relate to the ''appropriate review'' of appraisals are not relevant for purposes of whether an appraiser is a certified or licensed appraiser under proposed § 1026.XX(a)(1). The Agencies do not propose to interpret ''certified or licensed appraiser'' to include regulations related to appraisal review under FIRREA section 1110(3) because these requirements relate to an institution's responsibilities after receiving the appraisal, rather than to how the certified or licensed appraiser performs the appraisal.

The Agencies recognize that FIRREA title XI applies by its terms to ''federally related transactions'' involving a narrower category of institutions than the group of lenders that fall within TILA's definition of ''creditor.'' [13] However, by cross-referencing FIRREA in the definition of ''certified or licensed appraiser,'' the Agencies believe that Congress intended all creditors that extend higher-risk mortgage loans, such as independent mortgage banks, to obtain appraisals from appraisers who conform to the standards in FIRREA related to the development and reporting of the appraisal.

Question 1: The Agencies invite comment on this interpretation. For example, do commenters believe that Congress intended that FIRREA title XI requirements would only apply to the subset of higher-risk mortgage loans that are already covered by FIRREA (*i.e.,* federally related transactions with a transaction value greater than $250,000 not otherwise exempted from FIRREA's appraisal requirements [14])? If so, do commenters believe the longstanding existence of USPAP Advisory Opinion 30 lends support to this approach? [15]

The Agencies have not identified specific FIRREA regulations that relate to the appraiser's development and reporting of the appraisal. The Federal banking agencies' regulations implementing title XI of FIRREA include ''minimum standards'' requiring, for example, that the appraisal be based on the definition of market value in their regulations,[16] and that appraisals be performed by State-licensed or certified appraisers in accordance with their FIRREA regulations. The Federal banking agencies' regulations also include standards on ''appraiser independence,'' including that the appraiser not have a direct or indirect interest, financial or otherwise, in the property being appraised.

Question 2: The Agencies request comment on whether a final rule should address any particular FIRREA requirements applicable to appraisers related to the development and reporting of the appraisal.

''Certified'' versus ''licensed'' appraiser. Neither TILA section 129H nor the proposed rule defines the individual terms ''certified appraiser'' and ''licensed appraiser,'' or specifies when a certified appraiser or a licensed appraiser must be used. Instead, the proposed rule, consistent with paragraphs (b)(1) and (b)(2) of TILA section 129H, would require that creditors obtain an appraisal performed by ''a certified or licensed appraiser.'' *See* proposed § 1026.XX(a)(1); 15 U.S.C. 1639h(b)(1), (b)(2). Certified and licensed appraisers generally differ based on the examination, education, and experience requirements necessary to obtain each credential. Existing State and Federal law and regulations require the use of a certified appraiser rather than a licensed appraiser for certain types of transactions. For example, the Federal banking agencies' FIRREA appraisal regulations define ''State certified appraiser'' [17] and ''State licensed appraiser,'' [18] and specify the use of a certified appraiser based on the complexity of the residential property and the dollar amount of the transaction.[19] Several State agencies do not issue licensed appraiser credentials and issue different certified appraiser credentials (*i.e.,* a certified residential appraiser and a certified general appraiser) based on the type of property.

Question 3: The Agencies request comment on whether the rule should address the issue of when a creditor must use a certified appraiser rather than a licensed appraiser.

Further, the proposed rule does not specify competency standards. In selecting an appraiser for a particular appraisal assignment, creditors typically consider an appraiser's experience, knowledge, and educational background to determine the individual's competency to appraise a particular property and in a particular market. The Competency Rule in USPAP requires appraisers to determine, prior to accepting an assignment, that they can perform the assignment competently.

[13] TILA section 103(g), 15 U.S.C. 1602(g) (implemented by § 1026.2(a)(17)).

[14] Under title XI of FIRREA, the Federal banking agencies were granted the authority to identify categories of real estate-related financial transactions that do not require the services of an appraiser to protect Federal financial and public policy interests or to satisfy principles of safe and sound lending (e.g., transactions with a transaction value equal to or less than $250,000 do not require the services of an appraiser under the Federal banking agencies' regulations). For a discussion of these regulatory exemptions, see Interagency Appraisal and Evaluation Guidelines, 75 FR 77450, 77465–68 (Dec. 10, 2010).

[15] USPAP Advisory Opinion 30 is a long-standing advisory opinion issued by the Appraisal Standards Board of the Appraisal Foundation, which holds that USPAP creates an obligation for appraisers to recognize and adhere to applicable assignment conditions, including, for federally related transactions, FIRREA title XI and the regulations prescribed under such title. *See* Appraisal Standards Bd., Appraisal Fdn., Advisory Op. 30, *available at http://www.uspap.org.*

[16] The Federal banking agencies' appraisal regulations define ''market value'' to mean the most probable price which a property should bring in a competitive and open market under all conditions requisite to a fair sale, the buyer and seller each acting prudently and knowledgeably, and assuming the price is not affected by undue stimulus. See OCC: 12 CFR 34.42(g); FDIC: 12 CFR 323.2(g); FRB: 12 CFR 225.62(g); and NCUA: 12 CFR 722.2(g). Implicit in this definition is the consummation of a sale as of a specified date and the passing of title from seller to buyer under conditions whereby—(1) buyer and seller are typically motivated; (2) both parties are well informed or well advised, and acting in what they consider their own best interest; (3) a reasonable time is allowed for exposure in the open market; (4) payment is made in terms of cash in U.S. dollars or in terms of financial arrangements comparable thereto; and (5) the price represents the normal consideration for the property sold unaffected by special or creative financing or sales concessions granted by anyone associated with the sale. *Id.*

[17] *See* OCC: 12 CFR 34.42(j); FDIC: 12 CFR 323.2(j); FRB: 12 CFR 225.62(j); and NCUA: 12 CFR 722.2(j).

[18] *See* OCC: 12 CFR 34.42(k); FDIC: 12 CFR 323.2(k); FRB: 12 CFR 225.62(k); and NCUA: 12 CFR 722.2(k).

[19] For example, the Federal banking agencies' appraisal regulations require that a ''State certified appraiser'' be used for ''[a]ll federally related transactions having a transaction value of $1,000,000 or more'' and for ''[a]ll complex 1-to 4 family residential property appraisals rendered in connection with federally related transactions * * * if the transaction value is $250,000 or more.'' See, e.g., OCC: 12 CFR 34.43(d).

See USPAP, Competency Rule.[20] The Federal banking agencies' FIRREA appraisal regulations provide that a State certified or licensed appraiser may not be considered competent solely by virtue of being certified or licensed.[21]

Question 4: The Agencies request comment on whether the rule should address the issue of appraiser competency.

The Agencies acknowledge that creditors not otherwise subject to FIRREA title XI may have questions about how to comply with the requirement to obtain an appraisal from a ''certified or licensed appraiser'' who performs an appraisal in conformity with the requirements applicable to appraisers in title XI of FIRREA and any implementing regulations. The Agencies also note that all creditors, including those already subject to FIRREA, may have questions about how FIRREA regulations relating to the development and reporting of the appraisal may be interpreted for purposes of applying TILA's civil liability provisions, *see* TILA section 139, 15 U.S.C. 1640, including the liability provision for willful failures to obtain an appraisal as required by TILA section 129H. *See* TILA section 129H(e), 15 U.S.C. 1639h(e). To address these concerns, the Agencies are proposing a safe harbor for compliance with TILA section 129H at § 1026.XX(b)(2). See the section-by-section analysis of proposed § 1026.XX(b)(2), below.

XX(a)(2) Higher-Risk Mortgage Loans

New TILA section 129H(f) defines a ''higher-risk mortgage'' as a residential mortgage loan secured by a principal dwelling with an APR that exceeds the APOR for a comparable transaction by a specified percentage as of the date the interest rate is set. 15 U.S.C. 1639(f). New TILA section 103(cc)(5) defines the term ''residential mortgage loan'' as any consumer credit transaction that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling or on residential real property that includes a dwelling, other than a consumer credit transaction under an open-end credit plan. 15 U.S.C. 1602(cc)(5).

Proposed § 1026.XX(a)(2) would define the term ''higher-risk mortgage loan'' for purposes of § 1026.XX. Consistent with TILA sections 129H(f) and 103(cc)(5), proposed § 1026.XX(a)(2)(i) provides that a ''higher-risk mortgage loan'' is a closed-end consumer credit transaction secured by the consumer's principal dwelling with an APR that exceeds the APOR for a comparable transaction as of the date the interest rate is set by a specified percentage depending on the type of transaction. The proposed rule uses the phrase ''a closed-end consumer credit transaction secured by the consumer's principal dwelling'' in place of the statutory term ''residential mortgage loan'' throughout § 1026.XX(a)(2). The Agencies have elected to incorporate the substantive elements of the statutory definition of ''residential mortgage loan'' into the proposed definition of ''higher-risk mortgage loan'' rather than using the term itself to avoid inadvertent confusion of the term ''residential mortgage loan'' with the term ''residential mortgage transaction,'' which is an established term used throughout Regulation Z and defined in § 1026.2(a)(24). *Compare* 15 U.S.C. 1602(cc)(5) (defining ''residential mortgage loan'') *with* 12 CFR 1026.2(a)(24) (defining ''residential mortgage transaction''). Accordingly, the proposed regulation text differs from the express statutory language, but with no intended substantive change to the scope of TILA section 129H.

Principal Dwelling

Proposed comment XX(a)(2)(i)–1 clarifies that, consistent with other sections of Regulation Z, under proposed § 1026.XX(a)(2)(i) a consumer can have only one principal dwelling at a time. Proposed comment XX(a)(2)(i)–1 states that the term ''principal dwelling'' has the same meaning as in § 1026.2(a)(24), and expressly cross references existing comment 2(a)(24)–3, which further explains the meaning of the term. Consistent with this comment, a vacation home or other second home would not be a principal dwelling. However, if a consumer buys or builds a new dwelling that will become the consumer's principal dwelling within a year or upon the completion of construction, the proposed comment clarifies that the new dwelling is considered the principal dwelling.

Average Prime Offer Rate

Proposed comment XX(a)(2)(i)–2 would cross-reference existing comment 35(a)(2)–1 for guidance on APORs. Existing comment 35(a)(2)–1 clarifies that APORs are APRs derived from average interest rates, points, and other loan pricing terms currently offered to consumers by a representative sample of creditors for mortgage transactions that have low-risk pricing characteristics. Other pricing terms include commonly used indices, margins, and initial fixed-rate periods for variable-rate transactions. Relevant pricing characteristics include a consumer's credit history and transaction characteristics such as the loan-to-value ratio, owner-occupant status, and purpose of the transaction. Currently, to obtain APORs, the Board, which currently publishes the APORs, uses a survey of creditors that both meets the criteria of § 1026.35(a)(2) and provides pricing terms for at least two types of variable rate transactions and at least two types of non-variable rate transactions. An example of such a survey, and the survey that is currently used to calculate APORs, is the Freddie Mac Primary Mortgage Market Survey.® As of the date of this proposed rule, the table of APORs is published by the Board; however, the Bureau will assume the responsibility for publishing all of the elements of the table in the future.

Comparable Transaction

Proposed comment XX(a)(2)(i)–3 cross-references guidance in existing comments 35(a)(2)–2 and 35(a)(2)–4 regarding how to identify the ''comparable transaction'' in determining whether a transaction meets the definition of a ''higher-risk mortgage loan'' under § 1026.XX(a)(2)(i). As these comments indicate, the table of APORs published by the Bureau will provide guidance to creditors in determining how to use the table to identify which APOR is applicable to a particular mortgage transaction. Consistent with the Board's current practices, the Bureau intends to publish on the internet, in table form, APORs for a wide variety of mortgage transaction types based on available information. For example, the Board publishes a separate APOR for at least two types of variable rate transactions and at least two types of non-variable rate transactions. APORs are APRs derived from average interest rates, points and other loan pricing terms currently offered to consumers by a representative sample of creditors for mortgage transactions that have low-risk pricing characteristics. Currently, the Board calculates an APR, consistent with Regulation Z (*see* 12 CFR 1026.22 *and* appendix J to part 1026), for each transaction type for which pricing terms are available from a survey, and estimates APRs for other types of transactions for which direct survey data are not available based on the loan pricing terms available in the survey and other information. However, data are not available for some types of mortgage transactions, including reverse mortgages. In addition, the Board publishes on the internet the

[20] *See* Appraisal Standards Bd., Appraisal Fdn., Competency Rule, USPAP (2012–2013 ed.) at U–11.

[21] *See* OCC: 12 CFR 34.46(b); FDIC: 12 CFR 323.6(b); FRB: 12 CFR 225.66(b); and NCUA: 12 CFR 722.6(b).

methodology it uses to arrive at these estimates.[22]

Date APR is Set

Proposed comment XX(a)(2)(i)–4 would cross-reference existing comment 35(a)(2)–3 for guidance on the date the APR is set. Existing comment 35(a)(2)–3 clarifies that a transaction's APR is compared to the APOR as of the date the transaction's interest rate is set (or ''locked'') before consummation. The comment notes that sometimes a creditor sets the interest rate initially and then re-sets it at a different level before consummation. Accordingly, under the proposal, for purposes of § 1026.XX(a)(2)(i), the creditor should use the last date the interest rate for the mortgage is set before consummation.

''Higher-Risk Mortgage Loan'' Versus ''Higher-Priced Mortgage Loan''

TILA section 129H(f) defines the term ''higher-risk mortgage'' in a similar manner to the existing Regulation Z definition of ''higher-priced mortgage loan.'' 12 CFR 1026.35(a). However, the statutory definition of higher-risk mortgage differs from the existing regulatory definition of higher-priced mortgage loan in several important respects. First, the statutory definition of higher-risk mortgage expressly excludes loans that meet the definition of a ''qualified mortgage'' under TILA section 129C. In addition, the statutory definition of higher-risk mortgage includes an additional 2.5 percentage point threshold for first-lien jumbo mortgage loans, while the definition of higher-priced mortgage loan contains this threshold only for purposes of applying the requirement to establish escrow accounts for higher-priced mortgage loans. *Compare* TILA section 129H(f)(2), 15 U.S.C. 1639h(f)(2), *with* 12 CFR 1026.35(a)(1) *and* 1026.35(b)(3). The Agencies have concerns that the use of two such similar terms within the same regulation may cause confusion to both consumers and industry. However, given that the definitions of the two terms differ in significant ways, the Agencies are proposing, consistent with the statute, to define and use the term ''higher-risk mortgage loan'' when establishing the scope of proposed § 1026.XX.

Question 5: The Agencies request comment on whether the concurrent use of the defined terms ''higher-risk mortgage loan'' and ''higher-priced mortgage loan'' in different portions of Regulation Z may confuse industry or consumers and, if so, what alternative approach the Agencies could take to implementing the statutory definition of ''higher-risk mortgage loan'' consistent with the requirements of TILA section 129H. 15 U.S.C. 1639h.

In addition, proposed § 1026.XX uses the term ''higher-risk mortgage loan'' instead of the statutory term ''higher-risk mortgage'' for clarity and consistency with § 1026.35, which uses the term ''higher-priced mortgage loan.'' 12 CFR 1026.35(a).

XX(a)(2)(i)(A) and (a)(2)(i)(B)

Trigger for First Lien Loans

Consistent with TILA section 129H(f)(2)(A)–(B), paragraphs (a)(2)(i)(A) and (a)(2)(i)(B) of proposed § 1026.XX set the following thresholds for the amount by which the APR must exceed the applicable APOR for a loan secured by a first lien to qualify as a higher-risk mortgage loan:

- By 1.5 or more percentage points, for a loan with a principal obligation at consummation that does not exceed the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac.
- By 2.5 or more percentage points, for a loan with a principal obligation at consummation that exceeds the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac.

Paragraphs (a)(2)(i)(A) and (a)(2)(i)(B) of proposed § 1026.XX include several non-substantive changes from the statutory language for clarity and consistency with § 1026.35(b)(3)(v). For an exemption from the requirement to escrow for property taxes and insurance for ''higher-priced mortgage loans,'' § 1026.35(b)(3)(v) defines a ''jumbo'' loan as: ''[A] transaction with a principal obligation at consummation that exceeds the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac.'' In particular, the proposal would use the phrase ''for a loan secured by a first lien with'' in place of the statutory phrase ''in the case of a first lien residential mortgage loan having.'' *See* 15 U.S.C. 1639h(f)(2)(A)–(B). As discussed above, all of the elements of the statutory definition of the term ''residential mortgage loan'' are incorporated into proposed § 1026.XX(a)(2)(i). The proposed rule also uses the phrase ''for the maximum principal obligation eligible for purchase by Freddie Mac'' in place of the statutory phrase ''pursuant to the sixth sentence of section 305(a)(2) the Federal Home Loan Mortgage Corporation Act,'' for consistency with § 1026.35(b)(3)(v) and without intended substantive change.

XX(a)(2)(i)(C)

Trigger for Subordinate-Lien Loans

Consistent with TILA section 129H(f)(2)(C), proposed § 1026.XX(a)(2)(i)(C) provides that the APR must exceed the applicable APOR by 3.5 or more percentage points for a loan secured by a subordinate lien to qualify as a higher-risk mortgage loan. In addition, for the reasons discussed above, proposed § 1026.XX(a)(2)(i)(C) uses the phrase ''for a loan secured by a subordinate lien'' in place of the statutory phrase ''for a subordinate lien residential mortgage loan.'' 15 U.S.C. 1639h(f)(2)(C).

Alternative Calculation Method: Transaction Coverage Rate

In the Bureau's 2012 TILA–RESPA Proposal, the Bureau is proposing to adopt a simpler and more inclusive finance charge calculation for closed-end credit secured by real property or a dwelling.[23] The finance charge is integral to the calculation of the APR, which is designed to serve as a benchmark in TILA disclosures for consumers to evaluate the overall cost of credit.

Currently, TILA and Regulation Z allow creditors to exclude various fees or charges from the finance charge, including most real estate-related closing costs. Consumer groups, creditors, and some government agencies have long been dissatisfied with the ''some fees in, some fees out'' approach to the finance charge. The 2012 TILA–RESPA Proposal would maintain TILA's definition of a finance charge as a fee or charge payable directly or indirectly by the consumer and imposed directly or indirectly by the creditor as an incident to the extension of credit. However, the proposal would require the creditor to include in the finance charge most charges by third parties. The Bureau's 2012 TILA–RESPA proposal discusses the potential benefits to consumers of making the APR a more accurate and useful comparison tool and to industry

[22] *See http://www.ffiec.gov/ratespread/newcalchelp.aspx#9.*

[23] *See* 2012 TILA–RESPA Proposal, pp. 101–127, 725–28, 905–11 (July 9, 2012), available at *http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_integrated-mortgage-disclosures.pdf*). This proposal is similar to the simpler, more inclusive finance charge proposed by the Board in its 2009 proposed amendments to Regulation Z containing comprehensive changes to the disclosures for closed-end credit secured by real property or a consumer's dwelling. *See* 74 FR 43232, 43241–45 (Aug. 26, 2009).

of using simpler calculations to reduce compliance burden and litigation risk.[24]

A simpler and more inclusive finance charge, however, would increase the APR for most mortgage loans. However, the Agencies currently lack sufficient data to model the amount by which this change would increase the APR or how the increase in turn would affect the number of loans that will exceed the statutory threshold for higher-risk mortgages. The Agencies note that the Bureau is seeking data to assist in assessing potential impacts of a more inclusive finance charge in connection with the Bureau's 2012 TILA–RESPA Proposal [25] and its 2012 HOEPA Proposal.[26]

Under TILA section 129H(f), to determine whether a loan is a higher-risk mortgage loan, the loan's APR is measured against the benchmark APOR. 15 U.S.C. 1639h(f). The APOR is not a market wide average of the APR but, instead, is derived from average interest rates, points, and other loan pricing terms such as margins and indices. Currently, the APOR is based on the Freddie Mac Primary Mortgage Market Survey (PMMS) of pricing by a representative sample of creditors on transactions with low-risk pricing characteristics. There are some important differences between the fees and charges used in the calculation of the APR and APOR. In particular, the APOR consistently includes the contract interest rate and ''total points,'' [27] but the reporting of other origination fees is not consistently included. Thus, the APOR derived from such surveys likely understates the actual cost to consumers of the low-risk loans intended to form the benchmark.

By contrast, the finance charge used to calculate the APR currently includes both discount points and origination fees, together with most other charges the creditor retains and certain third-party charges. By including additional creditor and third-party charges, the proposed more inclusive finance charge would widen the disparity between APR and APOR and potentially push more loans into the ''higher-risk mortgage loan'' category, though by how much is uncertain.

As noted, the Bureau, in connection with its 2012 TILA–RESPA Proposal, is proposing a more inclusive finance charge. The Agencies are aware that the more inclusive finance charge has implications for several rulemakings, including this proposal regarding higher-risk mortgage appraisal rules, the Bureau's 2012 HOEPA Proposal,[28] as well as the 2011 ATR Proposal and the 2011 Escrow Proposal. Each of these proposals separately discusses the impacts of the more inclusive finance charge and potential modifications, and the Agencies believe that it is helpful to do so in this proposal as well. This approach permits assessment of the impacts and the merits of any modifications on a rule-by-rule basis.

Question 6: Accordingly, this proposal seeks comment on whether and how to account for the implications of a more inclusive finance charge on the scope of higher-risk mortgage coverage.

If the Bureau adopts a more inclusive finance charge, one way potentially to reduce the disparity between the resulting APR and the APOR for purposes of different regulatory thresholds would be to modify the numeric threshold that triggers coverage. The Bureau sought comment on such an approach in the 2012 HOEPA proposal, as one of two alternatives, but lacked the data necessary to propose a specific numeric modification. The Agencies similarly lack such data for higher-risk mortgages. However, unlike the Bureau's authority to adjust the threshold triggers in HOEPA, TILA section 129H does not give the Agencies express authority to revise the numeric threshold triggers for purposes of determining which loans are higher-risk mortgage loans. 15 U.S.C. 1639h. *See also* TILA section 103(bb)(2)(A) and (B), 15 U.S.C. 1639h(bb)(2)(A) and (B).

An alternative approach would be to use a ''transaction coverage rate'' (TCR) for the APR as the metric for determining whether a closed-end loan is a higher-risk mortgage loan subject to § 1026.XX. This is the other alternative on which the Bureau seeks comment in the 2012 HOEPA Proposal.[29] Under this approach, the TCR would be calculated in a manner similar to how the APR is calculated, except that the prepaid finance charge used for the TCR calculation would include only charges retained by the creditor, a mortgage broker, or an affiliate of either.[30] The TCR would not reflect other closing costs that would be included in the broader finance charge for purposes of calculating the APR that would be disclosed to consumers. For example, the APR resulting from the proposed more inclusive finance charge would reflect third-party charges such as title insurance premiums, but the TCR would not. *See* 75 FR 58539, 58661; 76 FR 11598, 11626. Thus, a creditor would calculate the TCR to determine coverage, but the new APR would be used for consumer disclosures.

If the Bureau adopts a more inclusive finance charge, the Agencies will consider whether to adopt the TCR in this rule. This alternative would allow creditors to exclude some fees from the ''rate'' used to determine if a loan is a ''higher-risk mortgage loan.'' By excluding these fees, it is possible fewer loans would be covered by the rule. Accordingly, to adopt the TCR, the Agencies would rely on their authority to exempt a class of loans from the requirements of the rule if the Agencies determine the exemption is in the public interest and promotes the safety and soundness of creditors. TILA section 129H(b)(4)(B), 15 U.S.C. 1639h(b)(4)(B). The Agencies believe that use of the TCR could have both advantages and disadvantages with respect to being in the public interest and promoting the safety and soundness of creditors. One advantage would be that loans that Congress may not have intended to be treated as higher-risk mortgage loans would remain not covered by the higher-risk mortgage appraisal requirements. On the other hand, some loans that Congress intended to be treated as higher-risk mortgages might end up not being covered by the higher-risk mortgage

[24] *See* 2012 TILA–RESPA Proposal at 101–27, 600–08.

[25] *See* 2012 TILA–RESPA Proposal at, *e.g.,* 101–12.

[26] *See* 2012 HOEPA Proposal, pp. 44, 149–211 (July 9, 2012), *available at http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_high-cost-mortgage-protections.pdf.*

[27] Freddie Mac defines ''total points'' to include both ''discount [points] and origination fees that have historically averaged around one point.'' *See http://www.freddiemac.com/pmms/abtpmms.htm.* The Agencies understand that it is not clear that survey respondents are consistent in their reporting or in including origination fees not expressed as a point.

[28] *See* 2012 HOEPA Proposal (July 9, 2012), available at *http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_high-cost-mortgage-protections.pdf.*

[29] *See* 2012 HOEPA Proposal at 39–50, 218, 246. The transaction coverage rate has been proposed previously by the Board for substantially similar reasons in a proposal related to mortgages in 2010, *see* 75 FR 58539, 58660–62, Sept. 24, 2010 (2010 Mortgage Proposal), and 2011 Escrow Proposal, *see* 76 FR 11598, 11609, 11620, 11626, March 2, 2011.

[30] *See* 2012 HOEPA Proposal at 46–47. The wording of the Board's proposed definition of ''transaction coverage rate'' varied slightly between the 2010 Mortgage Proposal and the 2011 Escrow Proposal as to treatment of charges retained by mortgage broker affiliates. In its 2012 HOEPA Proposal, the Bureau proposes to use the 2011 Escrow Proposal version, which would include charges retained by broker affiliates. The Agencies believe that this approach is consistent with the rationale articulated by the Board in its earlier proposals and with certain other parts of the Dodd-Frank Act that distinguish between charges retained by the creditor, mortgage broker, or affiliates of either company. *See, e.g.,* Dodd-Frank Act section 1403.

appraisal requirements. This is because the TCR as proposed would exclude some third-party fees that are currently included in the finance charge, such as upfront mortgage guaranty insurance premiums paid to independent third-party providers. The Agencies expect to analyze the potential differential as data become available.

Another potential disadvantage is that adopting a TCR for determining coverage would require a creditor to make an additional calculation to determine whether a loan is subject to TILA section 129H. Creditors would continue to be required to calculate the APR to provide required disclosures to the consumer. Additionally, creditors would have to calculate the TCR to determine whether the loan is subject to the requirements of this rule. On the other hand, if the Bureau adopts both the more inclusive finance charge and the TCR modification in a final rule pursuant to the 2012 HOEPA Proposal and 2011 Escrow Proposal, adopting the TCR modification in the higher-risk mortgage rule could ensure consistency across rules.

Question 7: Comments are invited on both the potential for TCR to introduce additional complexity in enforcement and litigation contexts [31] and any possible additional burden for the industry.

In light of the uncertainty regarding whether the Bureau will adopt a more inclusive finance charge and the potential impact of that change, the Agencies have proposed two alternative versions of § 1026.XX(a)(2)(i), similar to those proposed by the Bureau in connection with the 2012 HOEPA Proposal. Alternative 1 would define the threshold for higher-risk mortgages based on APR. Alternative 2 would use TCR. The Agencies would not adopt Alternative 2 if the Bureau does not change the definition of finance charge. As noted above, if the Agencies were to adopt Alternative 2, the Agencies would rely on their exemption authority set forth in TILA section 129H(b)(4)(B). 15 U.S.C. 1639h(b)(4)(B). The Agencies would reference the definition of ''transaction coverage rate'' provided in the Board's proposed § 226.45(a)(2)(i), proposed by the Bureau to be codified in § 1026.35(a)(2)(i), along with the guidance provided in its associated commentary. The Agencies also would reference the definition of ''average prime offer rate'' proposed by the Bureau to be codified in § 1026.35(a)(2)(ii). This is the approach to defining TCR (and APOR) that the Bureau is proposing in the 2012 HOEPA Proposal. *See* 2012 HOEPA Proposal at 46–47, 218.[32]

Again, the Agencies do not currently have sufficient data to model the impact of the more inclusive finance charge on coverage of the higher-risk mortgage loan requirements.[33] Similarly, the Agencies lack data to assess whether the benefits and costs of those requirements are significantly different as to the loans that would be affected by the more inclusive finance charge.

Question 8: The Agencies therefore seek comment on the impacts the proposed more inclusive finance charge would have on application of the higher-risk mortgage loan requirements, and whether it would be in the public interest and promote the safety and soundness of creditors to modify the triggers for higher-risk mortgage loans to approximate more closely the coverage levels under the finance charge and APR as currently calculated.

Question 9: If potential modifications are warranted, the Agencies also seek comment on what methods may be appropriate, including use of the TCR in lieu of APR, or other methods commenters may suggest. The appraisal provisions of the Dodd-Frank Act are intended to protect lenders, consumers and investors against fraudulent and inaccurate appraisals. With this in mind, commenters are invited to address the relative costs and benefits of any modification in the context of the higher-risk mortgage loan appraisal proposal, including any potential impact on the market. Where possible, comments should include supporting data. In particular, data regarding the amount of charges currently considered prepaid finance charges and the amount of charges currently excluded from the finance charge would enable the Agencies to make an informed assessment of the impacts a more inclusive finance charge would have on the higher-risk mortgage loan rule, and may be useful as well to the Bureau in considering other affected rules.

XX(a)(2)(ii)

Exclusions from the Definition of Higher-Risk Mortgage Loan

Consistent with the express language of TILA section 129H(f) and pursuant to the Agencies' general exemption authority set forth in TILA section 129H(b)(4)(B), the proposed rule would expressly exclude certain classes of consumer credit transactions from the definition of higher-risk mortgage loan. 15 U.S.C. 1639h(b)(4)(B) and (f). Specifically, proposed § 1026.XX(a)(2)(ii)) excludes from the definition of higher-risk mortgage loan the following:

- Any loan that is a qualified mortgage loan as defined in § 1026.43(e);
- A reverse-mortgage transaction as defined in § 1026.33(a).
- A loan secured solely by a residential structure.

Each of these proposed exclusions from the definition of higher-risk mortgage loan is discussed in more detail below.

XX(a)(2)(ii)(A)

Qualified Mortgage Loans

TILA section 129H(f) expressly excludes from the definition of higher-risk mortgage any loan that is a qualified mortgage as defined in TILA section 129C and a reverse mortgage loan that is a qualified mortgage as defined in TILA section 129C. 15 U.S.C. 1639(f). Rather than implement one exclusion for qualified mortgages and a separate exclusion for any reverse mortgage loans that may be defined by the Bureau as qualified mortgages, proposed § 1026.XX(a)(2)(ii) would exclude a qualified mortgage loan as defined in § 1026.43(e) which would cover all qualified mortgages as defined by TILA section 129C as implemented in regulations of the Bureau. The Agencies believe that this single broad exclusion promotes clarity because the broader term ''qualified mortgage'' as defined in § 226.43(e) of the 2011 ATR Proposal, includes any reverse mortgage loan that the Bureau may define by regulation as a qualified mortgage.

The Agencies note that as of the date of this proposal, the Bureau has not yet

[31] Agency examiners and enforcement staff, as well as consumers seeking to determine whether they are entitled to the higher-risk mortgage protections, would have to know how to determine and calculate the TCR and how to verify a creditor's TCR calculation to ascertain whether the appraisal protections should apply to a given transaction.

[32] In the Board's 2010 Mortgage Proposal, the definition of ''transaction coverage rate'' was proposed in § 226.35(a)(2)(i), and the definition of ''average prime offer rate'' in existing § 226.35(a)(2) would have been redesignated as § 226.35(a)(2)(ii) for organizational purposes. The Board's 2011 Escrow Proposal contained parallel provisions, although they were set forth in a proposed new § 226.45(a)(2)(i) and (ii).

[33] In its 2009 mortgage proposal, the Board relied on a 2008 survey of closing costs conducted by Bankrate.com that contains data for hypothetical $200,000 loans in urban areas. *See* 74 FR 43232, 43244 (Aug. 26, 2009). Based on that data, the Board estimated that 3 percent of loans would be reclassified as ''higher-priced loans'' (which are similar to ''higher-risk mortgages'') if the definition of finance charge was expanded. See id. The Agencies are considering the 2010 version of that survey; however, the data being sought by the Bureau in its 2012 TILA–RESPA Proposal and 2012 HOEPA Proposal as described above would provide more representative information regarding closing and settlement costs that would allow for a more refined analysis of the proposals.

issued final rules implementing TILA section 129C's definition of ''qualified mortgage.'' Prior to the transfer of authority regarding TILA section 129C to the Bureau under the Dodd-Frank Act, the Board issued the 2011 ATR Proposal, which, among other things, would have defined a ''qualified mortgage'' in a new subsection 12 CFR 226.43(e). *See* 76 FR 27390, 27484–85 (May 11, 2011). The Bureau expects to issue a final rule implementing, among other things, the definition of ''qualified mortgage,'' based on the 2011 ATR Proposal.[34]

XX(a)(2)(ii)(B)

Reverse Mortgage Transactions

Proposed § 1026.XX(a)(2)(ii)(B) would exclude reverse mortgage transactions as defined in § 1026.33(a) from the definition of ''higher-risk mortgage loan.'' TILA section 129H(b)(4)(B) authorizes the Agencies to jointly exempt, by rule, a class of loans from the requirements of TILA sections 129H(a) or 129H(b) if the Agencies determine that the exemption is in the public interest and promotes the safety and soundness of creditors. 15 U.S.C. 1639h(b)(4)(B).

Today, the vast majority of reverse mortgage transactions made in the United States are insured by the Federal Housing Administration (FHA) as part of the U.S. Department of Housing and Urban Development's (HUD) Home Equity Conversion Mortgage (HECM) Program.[35] To originate reverse mortgage transactions under HUD's HECM program, a lender must adhere to specific standards, including appraisal requirements similar to those required under proposed § 1026.XX.[36] Moreover, the FHA's HECM program provides protections to both the lender and the borrower. Lenders are guaranteed that they will be repaid in full when the home is sold, regardless of the loan balance or home value at repayment.[37] Borrowers are guaranteed that they will be able to access their authorized loan funds in the future (subject to the terms of the loan), even if the loan balance exceeds the value of the home or if the lender experiences financial difficulty.[38] Borrowers or their estates are not liable for loan balances that exceed the value of the home at repayment—FHA insurance covers this risk.[39]

Another reason that the Agencies propose to exclude reverse mortgage transactions from the definition of higher-risk mortgage loan is that a methodology for determining APORs for reverse mortgage transactions does not currently exist. As explained in the discussion of proposed § 1026.XX(a)(2)(i) above, determining whether a given transaction constitutes a ''higher-risk mortgage loan'' requires lenders to compare a transaction's APR with a published APOR. *See* comments 35(a)(2)–2 and 35(a)(2)–4. The Board currently publishes APORs for types of mortgage transactions potentially subject to proposed § 1026.XX. However, the Board does not currently publish APORs for reverse mortgages because reverse mortgages are exempt from the rules applicable to ''higher-priced mortgage loans'' in § 1026.35, for which the APOR was designed. *See* § 1026.35(a)(2)–(3) .

The Agencies are concerned that providing a permanent exemption for reverse mortgage transactions that are not qualified mortgages would eliminate the consumer protections provided by this rule to populations that rely on such products. Reverse mortgages are complex products that present consumers with a number of issues to evaluate that are different from a typical mortgage transaction, and the potential for reemergence of private reverse mortgage products in the market warrants careful evaluation from a consumer protection standpoint. However, the Agencies believe that exempting reverse mortgage transactions until the Agencies have additional time to study reverse mortgages is in the public interest and promotes the safety and soundness of creditors. The Agencies believe that this exemption is in the public interest because, without a clear way to determine whether a given reverse mortgage is a ''higher-risk mortgage loan,'' creditors face legal uncertainty that may impact credit availability. In addition, the costs associated with legal uncertainty could negatively impact a creditor's safety and soundness.

The Agencies request comment on the appropriateness of this exemption. Additionally, the Agencies seek comment on whether available indices exist that track the APR for reverse mortgages and could be used by the Bureau to develop and publish an APOR for these transactions, or whether such an index could be developed. For example, HUD publishes information on HECMs, including the contract rate.[40] The contract rate does not cover closing costs and insurance associated with reverse mortgages and included in a reverse mortgage APR, but nonetheless may be a starting point for developing a ''higher-risk mortgage loan'' threshold for reverse mortgages similar to the APOR metric used for forward mortgages.

Question 10: The Agencies request comment on whether this approach could be used to develop an index that tracks reverse mortgages. The Agencies also seek specific suggestions for other approaches to developing an index for reverse mortgages.

XX(a)(2)(ii)(C)

Loans Secured Solely by a Residential Structure

The Agencies propose in § 1026.XX(a)(2)(ii)(C) to exclude from the definition of higher-risk mortgage loan any loan secured solely by a residential structure. The Agencies believe that TILA section 129H was intended to apply only to loans secured at least in part by real estate. 15 U.S.C. 1639h. TILA section 129H requires appraisals for higher-risk mortgage loans that conform with, among other provisions, FIRREA title XI. *Id.;* 12 U.S.C. 3331 *et seq.* FIRREA title XI governs appraisals that involve real estate related transactions.[41] Additionally, TILA section 129H requires that appraisals be performed by a ''certified or licensed appraiser.'' TILA section 129H(b)(1), 15 U.S.C. 1639h(b)(1). The term ''certified or licensed appraiser'' has historically been used in Federal regulations to refer to appraisers who are credentialed to appraise real estate.[42]

Further, the Agencies believe that excluding any loan secured solely by a residential structure from the definition of higher-risk mortgage loan is appropriate pursuant to the exemption authority under TILA section 129H(b)(4)(B). The Agencies understand

[34] The cross-reference in the proposed regulation text assumes that the Bureau's final rule regarding qualified mortgages will use the same numbering as in the 2011 ATR Proposal (updated to reflect that the Bureau's Regulation Z is set forth in 12 CFR 1026 rather than 12 CFR 226). If the numbering of the Bureau's final rule regarding qualified mortgages differs from the 2011 ATR Proposal, the Agencies will update the numbering of the cross-reference to the definition of ''qualified mortgage'' when finalizing this proposal.

[35] *See* CFPB, *Reverse Mortgages: Report to Congress* 14, 70–99 (June 28, 2012), available at *http://www.consumerfinance.gov/reports/reverse-mortgages-report.*

[36] *See* 24 CFR 206.1 et seq., and HUD Handbooks 4235.1 and 4330.1 (chapter 13).

[37] *See, e.g.,* CFPB, *Reverse Mortgages: Report to Congress* 18.

[38] *Id.*

[39] *Id.*

[40] *See http://portal.hud.gov/hudportal/HUD?src=/program_offices/housing/rmra/oe/rpts/hecm/hecmmenu* (''Home Equity Conversion Mortgage Characteristics'').

[41] 12 U.S.C. 3331.

[42] *See, e.g.,* 12 CFR 225.63. Under the regulations implementing FIRREA title XI, ''real estate'' is defined in part as ''an identified parcel or tract of land, with improvements. * * *'' 12 CFR 225.62(h).

that loans secured solely by a residential structure, such as a manufactured home, typically more closely resemble titled vehicle loans. For example, manufactured housing industry representatives indicated during outreach calls with the Agencies that traditional real estate appraisals performed by a ''certified or licensed appraiser,'' as defined in TILA section 129H(b)(3) and proposed § 1026.XX(a)(1), are not appropriate or feasible for the majority of manufactured home financing transactions. They indicated that, typically, for new manufactured homes, the home value is based on the sales price listed on the manufactured home's wholesale invoice to the retailer. The wholesale invoice details the cost of the home at the point of manufacture, adding proprietary allowances and calculations to arrive at a ''maximum sales price.'' The manufacturer certifies the authenticity of the invoice and the accuracy of the price paid by the retailer. For used manufactured homes, the home value is most commonly based on the price guides published by trade journals for manufactured homes. Certain variations exist, depending on a number of factors, such as whether the used home is being moved.

In addition, the sales price solely for a manufactured home, but not the land to which it is attached, is typically lower than the cost of both a manufactured home and the land to which it is attached. This may make requiring appraisals with interior property visits extremely expensive relative to the cost of the manufactured home. Taken together, these factors could significantly increase costs for consumers and industry and constrain lending in this area of the housing market. Therefore, the Agencies believe that excluding such transactions from the definition of higher-risk mortgage loan is in the public interest and promotes the safety and soundness of creditors.

At the same time, the Agencies understand based on informal outreach that, for manufactured home loans secured by both a manufactured home and the land to which the home is attached, appraisals performed by certified or licensed appraisers are feasible and that many creditors order such appraisals in underwriting these transactions. Therefore, the Agencies propose to exclude from the rule only loans secured ''solely'' by a residential structure.[43] Accordingly, proposed comment XX(a)(2)(ii)(C)–1 clarifies that, under § 1026.XX(a)(2)(ii)(C), loans secured solely by a residential structure cannot be ''higher-risk mortgage loans.'' Thus, for example, a loan secured by a manufactured home and the land on which it is sited could be a ''higher-risk mortgage loan.'' By contrast, a loan secured solely by a manufactured home cannot be a ''higher-risk mortgage loan.''

Question 11: The Agencies request comment on whether this proposed exclusion is appropriate, and if not, reasonable methods by which creditors could comply with the requirements of this proposed rule when providing loans secured solely by a residential structure. In particular, the Agencies request comment on whether, rather than an appraisal performed by a certified or licensed appraiser, some alternative standards for valuing residential structures securing higher-risk mortgage loans might be feasible and appropriate to include as part of the final rule.

Other Exclusions from the Definition of Higher-Risk Mortgage Loan

Construction loans. In construction loan transactions, an interior visit of the property securing the loan is generally not feasible because construction loans provide financing for homes that are proposed to be built or are in the process of being built. At the same time, the Agencies recognize that construction loans that meet the pricing thresholds for higher-risk mortgage loans may pose many of the same risks to consumers as other types of loans meeting those thresholds.

Question 12: The Agencies request comment on whether to exclude construction loans from the definition of higher-risk mortgage loan. If not, the Agencies seek comment on whether any additional compliance guidance is needed for applying TILA section 129H's appraisal rules to construction loans. Alternatively, the Agencies request comment on whether construction loans should be exempt only from the requirement to conduct an interior visit of the property, and be subject to all other appraisal requirements under the proposed rule.

Bridge loans. Bridge loans are short-term loans typically used when a consumer is buying a new home before selling the consumer's existing home. Usually secured by the existing home, a bridge loan provides financing for the new home (often in the form of the downpayment) or mortgage payment assistance until the consumer can sell the existing home and secure permanent financing. Bridge loans normally carry higher interest rates, points and fees than conventional mortgages, regardless of the consumer's creditworthiness.

The Agencies are concerned about the burden to both creditors and consumers of imposing TILA section 129H's heightened appraisal requirements on short-term financing of this nature. As noted, the Agencies recognize that rates on bridge loans are often higher than on long-term home mortgages, so bridge loans may be more likely to meet the ''higher-risk mortgage loan'' triggers. However, these loans may be useful and even necessary for many consumers. Higher-risk mortgage loans under TILA section 129H would generally be a credit option for less creditworthy consumers, who may be more vulnerable than others and in need of enhanced consumer protections, such as TILA section 129H's special appraisal requirements. However, a bridge loan consumer could be subject to rates that would exceed the higher-risk mortgage loan thresholds even if the consumer would qualify for a non-higher-risk mortgage loan when seeking permanent financing. It is unclear that Congress intended TILA section 129H to apply to loans simply because they have higher rates, regardless of the consumer's creditworthiness or the purpose of the loan.

Question 13: For these reasons, the Agencies request comment on whether to exclude bridge loans from the definition of higher-risk mortgage loan. If not, the Agencies seek comment on whether any additional compliance guidance is needed for applying TILA section 129H's appraisal rules to bridge loans.

Question 14: The Agencies also request comment on whether other classes of loans should be excluded from the definition of higher-risk mortgage loan.

XX(a)(3) National Registry

As discussed in more detail below, to qualify for the safe harbor provided in proposed § 1026.XX(b)(2)(iii) a creditor must verify through the ''National Registry'' that the appraiser is a certified or licensed appraiser in the State in which the property is located as of the date the appraiser signs the appraiser's certification. Under FIRREA section 1109, the Appraisal Subcommittee of

[43] The Agencies are proposing to exclude from the definition of ''higher-risk mortgage loan'' any loans secured solely by a ''residential structure,'' as that term is used in Regulation Z's definition of ''dwelling.'' *See* 12 CFR 1026.2(a)(19). The provision excludes loans that are not secured in whole or in part by land. Thus, for example, loans secured by manufactured homes that are not also secured by the land on which they are sited are excluded from the definition of higher-risk mortgage loan, regardless of whether the manufactured home itself is deemed to be personal property or real property under applicable state law.

the Federal Financial Institutions Examination Council (FFIEC) is required to maintain a registry of State certified and licensed appraisers eligible to perform appraisals in connection with federally related transactions. 12 U.S.C. 3338. For purposes of qualifying for the safe harbor, the proposed rule would require that a creditor must verify that the appraiser holds a valid appraisal license or certification through the registry maintained by the Appraisal Subcommittee. Thus, proposed § 1026.XX(a)(3) would provide that the term ''National Registry'' means the database of information about State certified and licensed appraisers maintained by the Appraisal Subcommittee of the FFIEC.

XX(a)(4) State Agency

TILA section 129H(b)(3)(A) provides that, among other things, a certified or licensed appraiser means a person who is certified or licensed by the ''State'' in which the property to be appraised is located. 15 U.S.C. 1639h(b)(3)(A). As discussed above, proposed § 1026.XX(a)(1) would further clarify that, among other things, a certified or licensed appraiser means a person certified or licensed by the ''State agency'' in the State in which the property that secures the transaction is located. Under FIRREA section 1118, the Appraisal Subcommittee of the FFIEC is responsible for recognizing each State's appraiser certifying and licensing agency for the purpose of determining whether the agency is in compliance with the appraiser certifying and licensing requirements of FIRREA title XI. 12 U.S.C. 3347. In addition, FIRREA section 1120(a) prohibits a financial institution from obtaining an appraisal from a person the financial institution knows is not a State certified or licensed appraiser in connection with a federally related transaction. 12 U.S.C. 3349(a). Accordingly, § 1026.XX(a)(4) would define the term ''State agency'' as a ''State appraiser certifying and licensing agency'' recognized in accordance with section 1118(b) of FIRREA and any implementing regulations.

XX(b) Appraisals Required for Higher-Risk Mortgage Loans

XX(b)(1) In General

Consistent with TILA section 129H(a) and (b)(1), proposed § 1026.XX(b)(1) provides that a creditor shall not extend a higher-risk mortgage loan to a consumer without obtaining, prior to consummation, a written appraisal performed by a certified or licensed appraiser who conducts a physical visit of the interior of the property that will secure the transaction. 15 U.S.C. 1639h(b)(1).

XX(b)(2) Safe Harbor

TILA section 129H(b)(1) requires that appraisals mandated by section 129H be performed by ''a certified or licensed appraiser'' who conducts a physical property visit of the interior of the mortgaged property. 15 U.S.C. 1639h(b)(1). TILA section 129H(b)(3) goes on to define a ''certified or licensed'' appraiser in some detail. 15 U.S.C. 1639h(b)(3). The statute, however, is silent as to how creditors should determine whether the written appraisals they have obtained comply with the statutory requirements under TILA section 129H(b)(1) and (b)(3). To address compliance uncertainties discussed in more detail below, the Agencies are proposing a safe harbor in § 1026.XX(b)(2) that establishes affirmative steps that creditors may follow to satisfy their statutory obligations under TILA section 129H.

TILA section 129H(b)(3) defines a ''certified or licensed appraiser'' as a person who is (1) certified or licensed by the State in which the property to be appraised is located, and (2) performs each appraisal in conformity with USPAP and the requirements applicable to appraisers in FIRREA title XI, and the regulations prescribed under such title, as in effect on the date of the appraisal. 15 U.S.C. 1639h(b)(3). These two elements of the definition of ''certified or licensed appraiser'' are discussed in more detail below.

Certified or Licensed in the State in Which the Property is Located

State certification and licensing of real estate appraisers has become a nationwide practice largely as a result of FIRREA title XI. Pursuant to FIRREA title XI, entities engaging in certain ''federally related transactions'' involving real estate are required to obtain written appraisals performed by an appraiser who is certified or licensed by the appropriate State. 12 U.S.C. 3339, 3341. As noted, to facilitate identification of appraisers meeting this requirement, the Appraisal Subcommittee of the FFIEC maintains an on-line National Registry of appraisers identifying all federally recognized State certifications or licenses held by U.S. appraisers.[44] 12 U.S.C. 3332, 3338.

Performs Appraisals in Conformity With USPAP and FIRREA

Again, TILA section 129H(b)(3) also defines ''certified or licensed appraiser'' as a person who performs each appraisal in accordance with USPAP and FIRREA title XI, and the regulations prescribed under such title, in effect on the date of the appraisal. 15 U.S.C. 1639h(b)(3). USPAP is a set of standards promulgated and interpreted by the Appraisal Standards Board of the Appraisal Foundation, providing generally accepted and recognized standards of appraisal practice for appraisers preparing various types of property valuations.[45] USPAP provides guiding standards, not specific methodologies, and application of USPAP in each appraisal engagement involves the application of professional expertise and judgment.

FIRREA title XI and the regulations prescribed thereunder regulate entities engaging in real estate-related financial transactions that are engaged in, contracted for, or regulated by the Federal banking agencies. *See* 12 U.S.C. 3339, 3350. Pursuant to FIRREA title XI, the Federal banking agencies have issued regulations requiring insured depository institutions and their affiliates, bank holding companies and their affiliates, and insured credit unions to obtain written appraisals prepared by a State certified or licensed appraiser in accordance with USPAP in connection with federally related transactions, including loans secured by real estate, exceeding certain dollar thresholds.[46] Specifically, the banking agencies have issued regulations exempting most federally related transactions with a transaction value of $250,000 or less from the requirement to obtain an appraisal.[47] In addition, the Federal banking agencies have issued a number of guidelines providing formal supervisory guidance on implementation and application of these appraisal requirements.[48]

The scope of creditors subject to FIRREA title XI is narrower than the scope of creditors subject to TILA, and FIRREA title XI and the rules issued

[44] The Agencies are proposing to interpret the state certification or licensing requirement under TILA section 129H(b)(3) to mean certification or licensing by a state agency that is recognized for purposes of credentialing appraisers to perform appraisals required for federally related transactions pursuant to FIRREA title XI.

[45] *See* Appraisal Standards Bd., Appraisal Fdn., USPAP (2012–2013 ed.) available at *http://www.uspap.org.*

[46] *See* OCC: 12 CFR Part 34, Subpart C; FRB: 12 CFR part 208, subpart E, and 12 CFR part 225, subpart G; FDIC: 12 CFR part 323; and NCUA: 12 CFR part 722.

[47] *See* OCC: 12 CFR 34.43(a)(1); FDIC: 12 CFR 323.3(a)(1); FRB: 12 CFR 225.63(a)(1); and NCUA: 12 CFR 722.3(a)(1) (implementing FIRREA section 1113, 12 U.S.C. 3342).

[48] *See, e.g.,* Interagency Appraisal and Evaluation Guidelines, 75 FR 77450 (Dec. 10, 2010).

thereunder do not by their terms directly regulate the conduct of appraisers. However, the Agencies are proposing to interpret TILA section 129H(b)(3)(B) to expand the applicability of certain FIRREA title XI requirements to cover creditors providing higher-risk mortgage loans, pursuant to the mandates of TILA section 129H. 15 U.S.C. 1639h(b)(3)(B). Similarly, the Agencies are proposing to interpret the statute to expand the applicability of these FIRREA title XI requirements to cover higher-risk mortgage loans that are otherwise exempt from the FIRREA title XI appraisal requirements, such as higher-risk mortgage loans of $250,000 or less.

The statute does not specifically address Congress's intent in referencing USPAP and FIRREA title XI. Congress could have amended FIRREA title XI directly to expand the scope of the statute to subject all creditors to its requirements. Instead, Congress inserted language into TILA requiring that the appraisers who perform appraisals in connection with higher-risk mortgage loans comply with USPAP and FIRREA title XI. However, the statute is silent as to the extent of creditors' obligations under the statute to evaluate appraisers' compliance.

Practically speaking, a creditor seeking to determine to a certainty whether an appraiser complied with USPAP for a residential appraisal would face an almost insurmountable challenge. An appraisal performed in accordance with USPAP represents an expert opinion of value. Not only does USPAP require extensive application of professional judgment, it also establishes standards for the scope of inquiry and analysis to be performed that cannot be verified absent substantially re-performing the appraisal. Conclusive verification of FIRREA title XI compliance (which itself incorporates USPAP) poses similar problems. On an even more basic level, it may not be possible for a creditor to determine conclusively whether the appraiser actually performed the interior visit required by TILA section 129H(a). Moreover, TILA subjects creditors to significant liability and risk of litigation, including private actions and class actions for actual and statutory damages and attorneys' fees. 15 U.S.C. 1640. If TILA section 129H is construed to require creditors to assume liability for the appraiser's compliance with these obligations, the Agencies are concerned that it would unduly increase the cost and restrict the availability of higher-risk mortgage loans. Absent clear language requiring such a construction, the Agencies do not believe that the statute should be construed to intend this result.

Accordingly, the Agencies are proposing a safe harbor, described in more detail below, for creditors to ensure compliance with proposed § 1026.XX(b)(1) (implementing TILA section 129H(a) and (b)(1), 15 U.S.C. 1639h(a) and (b)(1)) when the appraiser certifies compliance with USPAP and applicable FIRREA title XI requirements. The Agencies note that a certification of USPAP compliance is already an element of the Uniform Residential Appraisal Report (URAR) form used as a matter of practice in the industry.

The Agencies believe that the safe harbor will be particularly useful to consumers, industry, and courts with regard to the statutory requirement that the appraisal be obtained from a ''certified or licensed appraiser'' who conducts each appraisal in compliance with USPAP and FIRREA title XI. While determining whether an appraiser is licensed or certified by a particular State is straightforward, USPAP and FIRREA provide a broad set of professional standards and requirements. The appraisal process involves the application of subjective judgment to a variety of information points about individual properties; thus, application of these professional standards is often highly context-specific.

The Agencies believe the safe harbor requirements provide reasonable protections to consumers and compliance guidance to creditors. Specifically, under the safe harbor in proposed § 1026.XX(b)(2), a creditor is deemed to have obtained a written appraisal that meets the requirements of § 1026.XX(b)(1) if the creditor:

- Orders that the appraiser perform the appraisal in conformity with USPAP and FIRREA title XI, and any implementing regulations, in effect at the time the appraiser signs the appraiser's certification (§ 1026.XX(b)(2)(i));
- Verifies through the National Registry that the appraiser who signed the appraiser's certification holds a valid appraisal license or certification in the State in which the appraised property is located (§ 1026.XX(b)(2)(ii));
- Confirms that the elements set forth in appendix N to part 1026 are addressed in the written appraisal (§ 1026.XX(b)(2)(iii)); and
- Has no actual knowledge to the contrary of facts or certifications contained in the written appraisal (§ 1026.XX(b)(2)(iv)).

Proposed comment XX(b)(2)–1 clarifies that a creditor that satisfies the conditions in § 1026.XX(b)(2)(i)–(iv) will be deemed to have complied with the appraisal requirements of § 1026.XX(b)(1). In addition, the proposed comment further clarifies that a creditor that does not satisfy the conditions in § 1026.XX(b)(2)(i)–(iv) does not necessarily violate the appraisal requirements of § 1026.XX(b)(1).

Proposed appendix N to part 1026 provides that, to qualify for the safe harbor provided in § 1026.XX(b)(2), a creditor must check to confirm that the written appraisal:

- Identifies the creditor who ordered the appraisal and the property and the interest being appraised.
- Indicates whether the contract price was analyzed.
- Addresses conditions in the property's neighborhood.
- Addresses the condition of the property and any improvements to the property.
- Indicates which valuation approaches were used, and includes a reconciliation if more than one valuation approach was used.
- Provides an opinion of the property's market value and an effective date for the opinion.
- Indicates that a physical property visit of the interior of the property was performed.
- Includes a certification signed by the appraiser that the appraisal was prepared in accordance with the requirements of USPAP.
- Includes a certification signed by the appraiser that the appraisal was prepared in accordance with the requirements of FIRREA title XI, as amended, and any implementing regulations.

Other than the certification for compliance with FIRREA title XI, the items in appendix N are derived from the URAR form used as a matter of practice in the residential mortgage industry. Compliance with the appendix N safe harbor review would require the creditor to check the key elements of the written appraisal and the appraiser's certification on its face for completeness and internal consistency. The proposed rule would not require the creditor to make any independent judgment about or perform any independent analysis of the conclusions and factual statements in the written appraisal. As discussed above, imposing such obligations on the creditor would effectively require it to re-appraise the property. Accordingly, proposed comment XX(b)(2)(iii) clarifies that a creditor need not look beyond the face of the written appraisal and the appraiser's certification to confirm that the elements in appendix N are included in the written appraisal.

However, if the creditor has actual knowledge to the contrary of facts or certifications contained in the written appraisal, the safe harbor does not apply.

Question 15: The Agencies request comment on the appropriateness of the safe harbor, the list of requirements a creditor must satisfy to receive the safe harbor under § 1026.XX(b)(2) and appendix N, and whether the proposed safe harbor should be included in the rule. In addition, the Agencies request comment on whether particular types of transactions exist for which certain information in proposed appendix N would be especially difficult for an appraiser to include in the written appraisal. If so, in these cases, the Agencies seek comment on what alternative information, if any, might be appropriate to require creditors to confirm is included in the appraisal.

XX(b)(3) Additional Appraisal for Certain Higher-Risk Mortgage Loans

XX(b)(3)(i) In General

Under TILA section 129H(b)(2), a creditor must obtain a ''second appraisal'' from a different certified or licensed appraiser if the higher-risk mortgage loan will ''finance the purchase or acquisition of the mortgaged property from a seller within 180 days of the purchase or acquisition of such property by the seller at a price that was lower than the current sale price of the property.'' 15 U.S.C. 1639h(b)(2)(A). The Agencies have implemented this requirement through proposed § 1026.XX(b)(3). The Agencies have interpreted ''second appraisal'' to mean an appraisal in addition to the one required under proposed § 1026.XX(b)(1). Thus, a creditor would be required to obtain two appraisals before extending a higher-risk mortgage loan to finance a consumer's acquisition of the property. This approach is consistent with regulations promulgated by HUD to address property flipping in single-family mortgage insurance programs of the FHA. *See* 24 CFR 203.37a; 68 FR 23370, May 1, 2003; 71 FR 33138, June 7, 2006 (FHA Anti-Flipping Rule, or FHA Rule). In general, under the FHA Anti-Flipping Rule, properties that have been resold within certain recent time periods are ineligible as security for FHA-insured mortgage financing. Specifically, as with TILA section 129H(b)(2) and proposed § 1026.XX(b)(3), the FHA Anti-Flipping Rule requires creditors to determine information about a property's sales history and obtain justification (including, in certain cases, an additional appraisal obtained at no cost to the borrower) supporting an increase in resale price.

When a higher-risk mortgage loan will finance a consumer's acquisition of the property, proposed § 1026.XX(b)(3) would require creditors to apply additional scrutiny to properties being resold for a higher price within a 180-day period. The Agencies believe that the intent of TILA section 129H(b)(2), as implemented in proposed § 1026.XX(b)(3), is to discourage property flipping scams, a practice in which a seller resells a property at an artificially inflated price within a short time period after purchasing it, typically after some minor renovations and frequently relying on an inflated appraisal to support the increase in value.[49] 15 U.S.C. 1639h(b)(2). Consumers who purchase flipped properties at inflated values can be financially disadvantaged if, for example, they incur mortgage debt that exceeds the value of their dwelling. The Agencies recognize that a property may be resold at a higher price within a short timeframe for legitimate reasons, such as when a seller makes valuable improvements to the property or market prices increase. Thus, to ensure the appropriateness of an increased sales price, proposed § 1026.XX(b)(3)(i), implementing TILA section 129H(b)(2)(A), would require an additional appraisal analyzing the property's resale price before a creditor extends a higher-risk mortgage loan to finance the consumer's acquisition of the property. 15 U.S.C. 1639H(b)(2)(A).

The Agencies have replaced the term ''second appraisal'' with ''additional appraisal'' throughout the proposed rule and commentary. The Agencies are proposing this change because the term, ''second,'' may imply that the additional appraisal must be obtained after the first appraisal. Creditors may find it more efficient to order two appraisals at the same time and the Agencies do not intend to imply that, if two appraisals are required under proposed § 1026.XX(b)(3), they must be obtained in any particular order. In addition, creditors may not be able easily to identify which of those two is the ''second appraisal'' for purposes of complying with the prohibition on charging the consumer for any ''second appraisal'' under TILA section 129H(b)(2)(B), as discussed in more detail in the section-by-section analysis of proposed § 1026.XX(b)(3)(v), below. 15 U.S.C. 1639h(b)(2)(B). The Agencies do not believe that using the phrase ''additional appraisal'' would change the substantive requirements of TILA section 129H(b)(2)(A).

Question 16: The Agencies invite comment on this interpretation and whether the phrase, ''additional appraisal,'' should be used in the rule.

Proposed § 1026.XX(b)(3) does not specify which of the two required appraisals a creditor must rely on in extending a higher-risk mortgage loan if the appraisals provide different opinions of value. The Agencies recognize that creditors ordering two appraisals from different certified or licensed appraisers may receive appraisals providing different opinions. However, TILA section 129H does not require that the creditor use any particular appraisal, and the Agencies believe that a creditor should retain discretion to select the most reliable valuation, consistent with applicable safety and soundness obligations and prudential guidance. 15 U.S.C. 1639h. This position is consistent with the interim final rule on valuation independence published by the Board on October 28, 2010,[50] which implemented new requirements in TILA section 129E to ensure the independence of appraisals and other property valuation types for consumer credit transactions secured by the consumer's principal dwelling. 15 U.S.C. 1639e.

Proposed comment XX(b)(3)(i)–1 clarifies that an appraisal previously obtained in connection with the seller's acquisition or the financing of the seller's acquisition of the property cannot be used as one of the two required appraisals under § 1026.XX(b)(3). The Agencies believe that this clarification is consistent with the statutory purpose of TILA section 129H of mitigating fraud on the part of parties to the transaction. 15 U.S.C. 1639h.

Question 17: The Agencies request comment on this proposed clarification.

In addition, proposed § 1026.XX(b)(3)(i) would require that the creditor obtain the additional appraisal prior to consummation of the higher-risk mortgage loan. TILA section 129H(b)(2) does not specifically require that the additional appraisal be obtained

[49] *See* U.S. House of Reps., Comm. on Fin. Servs., *Report on H.R. 1728, Mortgage Reform and Anti-Predatory Lending Act,* No. 111–94, 59 (May 4, 2009) (House Report); Federal Bureau of Investigation, 2010 Mortgage Fraud Report Year in Review 18 (August 2011), available at *http://www.fbi.gov/stats-services/publications/mortgage-fraud-2010/mortgage-fraud-report-2010.*

[50] 75 FR 66554 (Oct. 28, 2010); 12 CFR § 1026.42(c)(3)(iv) (obtaining multiple valuations for the consumer's principal dwelling to select the most reliable valuation does not violate the general prohibitions on coercion of persons preparing valuations or mischaracterizing the value assigned to a consumer's principal dwelling).

prior to consummation of the higher-risk mortgage loan, but the Agencies believe that this proposed timing requirement is necessary to effectuate the statute's policy of requiring creditors to apply greater scrutiny to potentially flipped properties that will secure the transaction. 15 U.S.C. 1639h(b)(2).

Potential Exemptions From the Additional Appraisal Requirement

TILA section 129H(b)(4)(B) permits the Agencies to jointly exempt a class of loans from the additional appraisal requirement if the Agencies determine the exemption ''is in the public interest and promotes the safety and soundness of creditors.'' 15 U.S.C. 1639h(b)(4)(B).

Question 18: The Agencies invite commenters to submit data and other information supporting whether exempting any classes of higher-risk mortgage loans from the additional appraisal requirement would be in the public interest and promote the safety and soundness of creditors. Exemptions to be considered may include higher-risk mortgage loans made in rural areas where finding two independent appraisers may be difficult, as well as the types of transactions that are currently exempted from the restrictions on FHA insurance applicable to property resales in the FHA Anti-Flipping Rule, including, among others, sales by government agencies of certain properties, sales of properties acquired by inheritance, and sales by State- and federally-chartered financial institutions. *See, e.g.,* 24 CFR 203.37a(c).

Regarding a potential exemption from the additional appraisal requirement for higher-risk mortgage loans in ''rural'' areas, a number of industry representatives asserted during outreach with the Agencies that creditors making higher-risk mortgage loans in rural areas might have particular difficulty finding two competent appraisers in order to comply with the additional appraisal requirements of TILA section 129H. 15 U.S.C. 1639h; *see also* section-by-section analysis of § 1026.XX(b)(3)(ii) (discussing the requirement that the two appraisals required be performed by two different appraisers), below.

Question 19: Accordingly, the Agencies request comment on whether, in the final rule, the Agencies should rely on the exemption authority in TILA section 129H(b)(4)(B) to exempt higher-risk mortgage loans made in ''rural'' areas from the additional appraisal requirement. 15 U.S.C. 1639h(b)(4)(B). If so, the Agencies request comment on whether the rule should use the same definition of ''rural'' that is provided in the 2011 ATR Proposal.[51] The Agencies also request that commenters provide data or other information to help demonstrate how such an exemption would serve the public interest and promote the safety and soundness of creditors.

Purchase or Acquisition of the Consumer's Principal Dwelling

Under TILA section 129H(b)(2)(A), an additional appraisal would be required ''if the purpose of a higher-risk mortgage loan is to finance the purchase or acquisition of the mortgaged property'' from a person who is reselling the property within 180 days of purchasing or acquiring the property at a price lower than the current sale price. 15 U.S.C. 1639h(b)(2)(A). As discussed in the section-by-section analysis of proposed § 1026.XX(a)(2), higher-risk mortgage loans are defined by TILA section 129H(f) as loans secured by a consumer's principal dwelling. 15 U.S.C. 1639h(f). Thus, the additional appraisal requirement would not apply to refinances, home-equity loans, or subordinate liens that do not finance the consumer's purchase or acquisition of a principal dwelling. Accordingly, proposed § 1026.XX(b)(3)(i) would require an additional appraisal only when the purpose of a higher-risk mortgage loan is to finance the acquisition of the consumer's ''principal dwelling.''

In addition, the proposal does not use the statutory term ''the mortgaged property.'' TILA section 129H(b)(2)(A), 15 U.S.C. 1639h(b)(2)(A). The Agencies have made this change to be consistent with Regulation Z, which elsewhere uses the term ''principal dwelling.'' Although a property that the consumer has not yet acquired will not at that time be the consumer's actual dwelling, existing commentary to Regulation Z explains that the term ''principal dwelling'' refers to properties that will become the consumer's principal dwelling within a year. As noted in the section-by-section analysis of proposed § 1026.XX(a)(2) (defining ''higher-risk mortgage loan''), proposed comment XX(a)(2)(i)–1 cross-references the existing commentary on the meaning of ''principal dwelling.'' When referring to the date on which the seller acquired the ''property,'' however, the Agencies propose to use the term ''property'' rather than ''principal dwelling'' because the subject property may not have been used as a principal dwelling when the seller acquired and owned it. The Agencies intend the term ''principal dwelling'' and ''property'' to refer to the same property.

XX(b)(3)(i)(A)

Criteria for Whether an Additional Appraisal is Required—Date of Acquisition

''Acquisition'' by the seller. To refer to the events in which the seller purchased or acquired the dwelling at issue, proposed § 1026.XX(b)(3) generally uses the term ''acquisition'' instead of the longer statutory phrase ''purchase or acquisition.'' The Agencies are proposing to use the sole term ''acquisition'' because this term, as clarified in proposed comment XX(b)(3)–1, includes acquisition of legal title to the property, including by purchase. The Agencies have defined ''acquisition'' broadly in order to encompass the broad statutory phrase ''purchase or acquisition.'' Thus, as proposed, the additional appraisal rule in § 1026.XX(b)(3) would apply to the sale of a property previously acquired by the seller through a non-purchase acquisition, such as inheritance, divorce, or gift.

The Agencies question, however, whether an additional appraisal should be required for transactions in which the seller may not have the same motive to earn a quick profit on a short-term investment.

Question 20: The Agencies request that commenters who support applying the rule to higher-risk mortgage transactions where the seller acquired the property without purchasing it explain how doing so would be consistent with the statutory goal of addressing flipping scams. Moreover, if the final rule covers sales of properties acquired by the seller through non-purchase acquisitions, the Agencies request comment on how a creditor should calculate the seller's ''acquisition price.'' For example, in a case where the seller acquired the

[51] As of the date of this proposal, the Bureau has not yet issued final rules implementing TILA section 129C. 15 U.S.C. 1639c. Prior to the transfer of authority regarding TILA section 129C to the Bureau pursuant the Dodd-Frank Act, the Board issued a proposed rule on qualified mortgages (2011 ATR Proposal) that, among other things, would have defined the term ''rural'' in a new § 1026.43(f)(2)(i). See 76 FR 27390 (May 11, 2011). The Bureau expects to issue a final rule implementing, among other things, the definition of ''rural'' and ''qualified mortgage'' based on the 2011 ATR Proposal. This proposed rule assumes that the Bureau's final rule regarding qualified mortgages and defining the term rural will use the same numbering as in the 2011 ATR Proposal (updated to reflect that the Bureau's Regulation Z is set forth in 12 CFR 1026 rather than 12 CFR 226). If the numbering of the Bureau's final rule regarding qualified mortgages and defining the term rural differs from the Board's 2011 ATR Proposal, the Agencies will update the numbering of the cross-reference to the definition of ''qualified mortgage'' when finalizing this proposal.

property by inheritance, the ''sale price'' could be ''zero,'' which could make a subsequent sale offered at any price within 180 days subject to the additional appraisal requirement.

''Acquisition'' by the consumer. For consistency throughout the proposal, the Agencies have used the term ''acquisition'' to refer to acquisitions by both the seller and the consumer. However, as noted above with respect to non-purchase acquisitions by the seller, the Agencies acknowledge that the term ''acquisition'' may be over-inclusive in describing the consumer's transaction, because non-purchase acquisitions by the consumer do not readily appear to trigger the additional appraisal requirement. If the consumer acquired the property by means other than a purchase, he or she likely would not seek a higher-risk mortgage loan to ''finance'' the acquisition. Further, TILA section 129H(b)(2) would apply only if a creditor extends a higher-risk mortgage loan to finance the consumer's acquisition of a property from a seller who paid a price lower than the consumer's price. 15 U.S.C. 1639h(b)(2). If the consumer pays a nominal amount to acquire the property, the Agencies question how frequently the additional appraisal requirement would be triggered—because the seller's acquisition price likely would not be lower than the consumer's ''price.''

Question 21: The Agencies invite comment on whether any non-purchase acquisitions by the consumer may implicate the additional appraisal requirement. If the rule covers non-purchase acquisitions by the consumer, the Agencies invite comment on how a creditor should calculate the consumer's ''sale price.''

Question 22: The Agencies also seek comment on whether the term ''acquisition'' should be clarified to address situations in which a consumer previously held a partial interest in the property, and is acquiring the remainder of the interest from the seller. The Agencies do not expect that fraudulent property flipping schemes would likely occur in this context, but request comment on whether additional clarification about partial interests is warranted.

In this regard, the Agencies note that existing commentary in Regulation Z clarifies that a ''residential mortgage transaction'' does not include transactions involving the consumer's principal dwelling when the consumer had previously purchased and acquired some interest in the dwelling, even though the consumer had not acquired full legal title, such as when one joint owner purchases the other owner's joint interest. *See* Regulation Z comments 2(a)(24)–5(i) and –5(ii); *see also* section-by-section analysis of § 1026.XX(a)(X) (defining ''higher-risk mortgage loan'' and discussing the distinctions between the term ''residential mortgage transaction'' in Regulation Z and ''residential mortgage loan'' in the Dodd-Frank Act).

Question 23: In general, the Agencies invite comment on whether the term ''acquisition'' is the appropriate term to use in connection with both the seller and higher-risk mortgage consumer. The Agencies may further clarify the term or use a different term, such as ''purchase.''

Seller. The Agencies have used the term ''seller'' throughout proposed § 1026.XX(b)(3) to refer to the party conveying the property to the consumer. The Agencies have used this term to conform to the reference to ''sale price'' in TILA section 129H(b)(2)(A), but the Agencies recognize that another term may be more appropriate if any categories of non-sale acquisitions by the consumer exist that should appropriately be covered by the rule.

Agreement. In addition, the Agencies have referred to the consumer's ''agreement'' to acquire the property throughout proposed § 1026.XX(b)(3) to reflect that a ''sale price,'' as referenced in TILA section 129H(b)(2)(A), is typically contained in a legally binding agreement or contract between a buyer and a seller. However, the Agencies recognize that an alternate term may be more appropriate if categories of consumer acquisitions not obtained through an ''agreement'' should appropriately be covered by the rule.

180-day acquisition timeframe. TILA section 129H(b)(2)(A) would require creditors to obtain an additional appraisal for higher-risk mortgage loans that will finance the consumer's purchase or acquisition of the mortgaged property if the following two conditions are met: (1) the consumer is financing the purchase or acquisition of the mortgaged property from a seller within 180 days of the seller's purchase or acquisition of the property; and (2) the seller purchased or acquired the property at a price that was lower than the current sale price of the property. 15 U.S.C. 1639h(b)(2)(A).

For a creditor to determine whether the first condition is met, the creditor would compare two dates: the date of the consumer's acquisition and the date of the seller's acquisition. However, TILA section 129H(b)(2)(A) does not provide specific dates that a creditor must use to perform this comparison. 15 U.S.C. 1639h(b)(2)(A). To implement this provision, the Agencies propose in § 1026.XX(b)(3)(i)(B) to require that the creditor compare (1) the date on which the consumer entered into the agreement to acquire the property from the seller, and (2) the date on which the seller acquired the property. Proposed comment XX(b)(3)(i)(A)–1 provides an illustration in which the creditor determines the seller acquired the property on April 17, 2012, and the consumer's acquisition agreement is dated October 15, 2012; an additional appraisal would not be required because 181 days would have elapsed between the two dates.

Date of the consumer's agreement to acquire the property. Regarding the date of the consumer's acquisition, TILA refers to the date on which the higher-risk mortgage loan is to ''finance the purchase or acquisition of the mortgaged property.'' TILA section 129H(b)(2)(A), 15 U.S.C. 1639h(b)(2)(A). The Agencies have interpreted this term to refer to ''the date of the consumer's agreement to acquire the property.'' Proposed comment XX(b)(3)(i)(A)–2 explains that, in determining this date, the creditor should use a copy of the agreement itself provided by the consumer to the creditor, and use the date on which the consumer and the seller signed the agreement. If the two dates are different, the creditor should use the date on which the last party signed the agreement.

The Agencies believe that use of the date on which the consumer and the seller agreed on the purchase transaction best accomplishes the purposes of the statute. This approach is substantially similar to existing creditor practice under the FHA Anti-Flipping Rule, which uses the date of execution of the consumer's sales contract to determine whether the restrictions on FHA insurance applicable to property resales are triggered. *See* 24 CFR 203.37a(b)(1). The Agencies have not interpreted the date of the consumer's acquisition to refer to the actual date of title transfer to the consumer under State law, or the date of consummation of the higher-risk mortgage loan, because it would be difficult if not impossible for creditors to determine, at the time that they must order an appraisal or appraisals to comply with § 1026.XX, when title transfer or consummation will occur. The actual date of title transfer typically depends on whether a creditor consummates financing for the consumer's purchase. Various factors considered in the underwriting decision, including a review of appraisals, will affect whether the creditor extends the loan. In addition, the Agencies are concerned that even if a creditor could identify a

date certain by which the loan would be consummated or title would be transferred to the consumer, the creditor could potentially set a date that exceeds the 180-day time period to circumvent the requirements of § 1026.XX(b)(3).

Proposed comment XX(b)(3)(i)(A)–2 clarifies that the date the consumer and the seller agreed on the purchase transaction, as evidenced by the date the last party signed the agreement, may not necessarily be the date on which the consumer became contractually obligated under State law to acquire the property. It may be difficult for a creditor to determine the date on which the consumer became legally obligated under the acquisition agreement as a matter of State law. Using the date on which the consumer and the seller agreed on the purchase transaction, as evidenced by their signature and the date on the agreement, avoids operational and other potential issues because the Agencies expect that this date would be facially apparent from the signature dates on the acquisition agreement.

Question 24: The Agencies seek comment on whether this approach provides sufficient clarity to creditors on how to comply while also providing consumers with adequate protection.

Date the seller acquired the property. Regarding the date of the seller's acquisition, TILA section 129H(b)(2)(A) refers to the date of that person's ''purchase or acquisition'' of the property being financed by the higher-risk mortgage loan. 15 U.S.C. 1639h(b)(2)(A). Accordingly, proposed § 1026.XX(b)(3)(i)(A) refers to the date on which the seller ''acquired'' the property. Proposed comment XX(b)(3)(i)–3 clarifies that this refers to the date on which the seller became the legal owner of the property under State law, which the Agencies understand to be, in most cases, the date on which the seller acquired title. The Agencies have interpreted TILA section 129H(b)(2)(A) in this manner because the Agencies understand that creditors, in most cases, will not extend credit to finance the acquisition of a property from a seller who cannot demonstrate clear title. 15 U.S.C. 1639h(b)(2)(A). Also, as discussed above, the Agencies have proposed to use the single term ''acquisition'' because this term is generally understood to include acquisition of legal title to the property, including by purchase. *See* section-by-section analysis of proposed § 1026.XX(b)(3)(i)(A) (discussing the use of the term ''acquisition'' and ''acquire'' in the proposed rule).

To assist creditors with identifying the date on which the seller acquired title to the property, proposed comment XX(b)(3)(i)(A)–3 explains that the creditor may rely on records that provide information as to the date on which the seller became vested as the legal owner of the property pursuant to applicable State law; as explained in proposed comments XX(b)(3)(vi)(A)–1 and –2 and proposed comment XX(b)(3)(vi)(B)–1, the creditor may determine this date through reasonable diligence, requiring reliance on a written source document. The reasonable diligence standard is discussed further below under the section-by-section analysis of § 1026.XX(b)(3)(vi)(A) and (B).

XX(b)(3)(i)(B)

Criteria for Whether an Additional Appraisal is Required—Acquisition Price

TILA section 129H(b)(2)(A) would require creditors to obtain an additional appraisal if the seller acquired the property ''at a price that was lower than the current sale price of the property'' within the past 180 days. 15 U.S.C. 1639h(b)(2)(A). To determine whether this statutory condition has been met, a creditor would have to compare the current sale price with the price at which the seller acquired the property. Accordingly, proposed § 1026.XX(b)(3)(i)(B) implements this requirement by requiring the creditor to compare the price paid by the seller to acquire the property with the price that the consumer is obligated to pay to acquire with property, as specified in the consumer's agreement to acquire the property. Thus, if the price paid by the seller to acquire the property is lower than the price in the consumer's acquisition agreement by a certain amount or percentage to be determined by the Agencies in the final rule, and the seller acquired the property 180 or fewer days prior to the date of the consumer's acquisition agreement, the creditor would be required to obtain an additional appraisal before extending a higher-risk mortgage loan to finance the consumer's acquisition of the property. *See* section-by-section analysis of § 1026.XX(b)(3)(i)(B) discussing the exemption for ''small'' price increases, below.

Price at which the seller acquired the property. TILA section 129H(b)(2)(A) refers to a property that the seller previously purchased or acquired ''at a price.'' 15 U.S.C. 1639h(b)(2)(A). Proposed § 1026.XX(b)(3)(i)(B) refers to the price at which the seller acquired the property; proposed comment XX(b)(3)(i)(B)–1 clarifies that the seller's acquisition price refers to the amount paid by the seller to acquire the property. The proposed comment also explains that the price at which the seller acquired the property does not include the cost of financing the property. This comment is intended to clarify that the creditor should consider only the price of the property, not the total cost of financing the property.

Question 25: The Agencies invite comment on whether additional clarification is needed regarding how a creditor should identify the price at which the seller acquired the property. See also the section-by-section analysis of proposed § 1026.XX(b)(3)(i)(A) (discussing non-purchase acquisitions by the seller).

Question 26: The Agencies are interested in receiving comment on how a creditor would calculate the price paid by a seller to acquire a property as part of a bulk sale that is later resold to a higher-risk mortgage consumer. The Agencies understand that, in bulk sales, a sales price might be assigned to individual properties for tax or accounting reasons, but the Agencies request comment on whether guidance may be needed for determining the sales price of a such property for purposes of proposed § 1026.XX(b)(3)(i)(B). The Agencies request comment on any operational challenges that might arise for creditors in determining purchase prices for homes purchased as part of a bulk sale transaction. The Agencies also invite commenters' views on whether any challenges presented could impede neighborhood revitalization in any way, and, if so, whether the Agencies should consider an exemption from the additional appraisal requirement for these types of transactions altogether.

Proposed comment XX(b)(3)(i)(B)–1 contains a cross-reference to proposed comment XX(b)(3)(vi)(A)–1, which explains how a creditor should determine the seller's acquisition price through reasonable diligence. Proposed comment XX(b)(3)(i)(B)–1 also contains a cross-reference to proposed comment XX(b)(3)(vi)(B)–1, which explains how a creditor may proceed with the transaction if the creditor is unable to determine the seller's acquisition price following reasonable diligence. These proposed comments are discussed in more detail in the section-by-section analysis of § 1026.XX(b)(3)(vi)(A), below. The Agencies understand that, in some cases, a creditor performing typical underwriting and documentation procedures may have difficulty ascertaining the date and price at which the seller acquired the property being financed through a higher-risk mortgage loan. The Agencies believe that, based on recent data

provided by the FHFA, most property resales would not trigger the proposal's conditions requiring an additional appraisal. According to estimates provided by FHFA, approximately five percent of single-family property sales in 2010 reflected situations in which the same property had been sold within a 180-day period.[52] However, in some circumstances, creditors may face obstacles in attempting to determine the necessary transaction date and price information. For example, a creditor may be unable to determine information about the seller's acquisition because of lag times in recording public records. The Agencies also understand that some documents frequently reviewed by creditors as part of their mortgage underwriting procedures may report the date of the seller's acquisition, but report on only nominal amounts of compensation, rather than the actual sales price. Moreover, several ''non-disclosure'' jurisdictions do not make the price at which a seller acquired a property publicly available. In light of these difficulties, the Agencies are proposing a standard of reasonable diligence in determining the seller's acquisition date and price, and are also proposing modifications to the additional appraisal requirement when reasonable diligence does not provide sufficient information about the seller's acquisition date and price. *See* the section-by-section analysis of proposed § 1026.XX(b)(3)(vi)(A) (reasonable diligence) below.

Price the consumer is obligated to pay to acquire the property. TILA section 129H(b)(2)(A) refers to the ''current sale price of the property'' being financed by a higher-risk mortgage loan. 15 U.S.C. 1639h(b)(2)(A). Proposed § 1026.XX(b)(3)(i)(B) refers to ''the price that the consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller.'' Proposed comment XX(b)(3)(i)(B)–2 clarifies that the price the consumer is obligated to pay to acquire the property is the price indicated on the consumer's agreement with the seller to acquire the property that is signed and dated by both the consumer and the seller. Proposed comment XX(b)(3)(i)(B)–2 also explains that the price at which the consumer is obligated to pay to acquire the property from the seller does not include the cost of financing the property to clarify that a creditor should only consider the sale price of the property as reflected in the consumer's acquisition agreement. In addition, the proposed comment refers to proposed comment XX(b)(3)(i)(A)–2 (date of the consumer's agreement to acquire the property) to indicate that this document will be the same document that a creditor may rely on to determine the date of the consumer's agreement to acquire the property. Proposed comment XX(b)(3)(i)(B)–2 explains that the creditor is not obligated to determine whether and to what extent the agreement is legally binding on both parties. The Agencies expect that the price the consumer is obligated to pay to acquire the property will be facially apparent from the consumer's acquisition agreement.

Question 27: The Agencies solicit comment on whether the price at which the consumer is obligated to pay to acquire the property, as reflected in the consumer's acquisition agreement, provides sufficient clarity to creditors on how to comply while providing consumers adequate protection.

Exemption for small price increases. TILA section 129H(b)(2)(A) provides that an additional appraisal is required when the price at which the seller purchased or acquired the property was ''lower'' than the current sale price, but TILA does not define the term ''lower.'' 15 U.S.C. 1639h(b)(2)(A). Thus, as written, the statute would require an additional appraisal for any price increase above the seller's acquisition price. The Agencies do not believe that the public interest or the safety and soundness of creditors would be served if the law is implemented to require an additional appraisal for relatively small increases in price. Accordingly, the Agencies are proposing an exemption to the additional appraisal requirement for relatively small increases in the price. Proposed § 1026.XX(b)(3)(i) contains a placeholder for the amount by which the price at which the seller acquired the property was lower than the resale price: ''The seller acquired the property 180 or fewer days prior to the date of the consumer's agreement to acquire the property from the seller; and [t]he price at which the seller acquired the property was lower than the price that the consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller, by an amount equal to or greater than [XX]''. Although the proposal does not contain a particular price threshold, the Agencies may develop one in the final rule based on public comments received in response to this proposal.

Question 28: The Agencies solicit comment on whether it would be in the public interest and promote the safety and soundness of creditors to include an exemption for transactions that have a sale price that exceeds the seller's purchase price by a particular amount.

The Agencies recognize that there are a variety of ways to determine what constitutes a ''small'' price increase. One approach would be to use a fixed dollar value test. For example, during outreach with the Agencies for this proposal, some consumer advocates suggested requiring an additional appraisal if the resale price is greater than the price at which the seller acquired the property by $1,000.00 or more. A second approach would be to use a fixed percentage test. During informal outreach, different small and regional lender representatives suggested that an exemption for a 10, 15, or 20 percent price increase would be appropriate, with one large lender representative suggesting 25 percent.

Question 29: In light of the diverging views on an appropriate exception, the Agencies have elected to seek public comment on what an appropriate threshold would be rather than provide a particular amount or formula in the proposal. In particular, the Agencies seek comment on whether a fixed dollar amount, a fixed percentage, or some alternate approach[53] should be used to determine an exempt price increase, and what specific price threshold would be appropriate. The Agencies request that commenters support their recommendations with specific data, where possible.

XX(b)(3)(ii) Different Appraisers

Consistent with TILA section 129H(b)(2)(A), proposed § 1026.XX(b)(3)(ii) would require an additional appraisal from a ''different'' certified or licensed appraiser. 15 U.S.C. 1639h(b)(2)(A). Proposed § 1026.XX(b)(3)(ii) provides that the two appraisals that would be required by § 1026.XX(b)(3)(i) may not be performed by the same certified or licensed appraiser. Proposed § 1026.XX(b)(3)(ii) would not impose any additional

[52] Based on county recorder information from select counties licensed to FHFA by DataQuick Information Systems.

[53] The Agencies have considered requiring that creditors use a housing price index as a reference point for normal increases in price due to appreciation in housing values. For example, the rule could require an additional appraisal if the current sale price exceeds the prior sale price by a percentage greater than a percentage change in value of a housing price index for the relevant residential housing market since the date the seller acquired the property. While using a price index would account for natural price fluctuations in a particular market better than the fixed dollar or percentage approaches described above, the Agencies believe such a requirement could be burdensome for industry and provide little benefit to consumers. The movement of an index covering all property sales in a particular market area may not provide accurate or useful information about the proper valuation of a single property, especially if that property is atypical in any significant aspect.

conditions regarding the identity of the appraisers. During informal outreach conducted by the Agencies, some participants suggested that the Agencies impose additional requirements regarding the appraiser performing the second valuation for the higher-risk mortgage loan, such as a requirement that the second appraiser not have knowledge of the first appraisal. Outreach participants indicated that this requirement would minimize undue pressure to value the property at a price similar to the first appraiser. The Agencies have not proposed any additional conditions on what it means to obtain an appraisal from a different certified or licensed appraiser because the Agencies expect that the valuation independence requirements in Regulation Z will be sufficient to ensure that the second appraiser performs an independent valuation.

In 2010 the Board implemented TILA section 129E through an interim final rule, which established new requirements for valuation independence for consumer credit transactions secured by the consumer's principal dwelling. *See* 12 CFR 1026.42; 75 FR 66554 (Oct. 28, 2010). The Board explained that the new requirements in TILA were designed to ensure that real estate appraisals used to support creditors' underwriting decisions are based on the appraiser's independent professional judgment, free of any influence or pressure that may be exerted by parties that have an interest in the transaction. Among other things, the valuation independence requirements generally prohibit:

- Creditors and providers of settlement services from attempting directly or indirectly to cause the value assigned to a consumer's principal dwelling to be based on any factor other than the independent judgment of the person preparing the valuation through coercion, extortion, inducement, bribery, or intimidation of, compensation or instruction to, or collusion with a person that prepares valuations (§ 1026.42(c)(1));
- Persons preparing valuations from materially misrepresenting the value of the consumer's principal dwelling (§ 1026.42(c)(2)(i));
- Persons preparing a valuation or performing valuation management functions for a covered transaction from having a direct or indirect interest, financial or otherwise, in the property or transaction for which the valuation is or will be performed (§ 1026.42(d)(1)(i)); and
- Creditors from extending credit if the creditor knows, at or before consummation, of a violation of § 1026.42(c) or 1026.42(d), unless the creditor documents that it has acted with reasonable diligence to determine that the valuation does not materially misstate or misrepresent the value of the consumer's principal dwelling (§ 1026.42(e)).

Question 30: The Agencies seek comment on whether the rule should include additional conditions on how the creditor must obtain the additional appraisal under § 1026.XX(b)(3)(i). For example, should the rule prohibit the creditor from obtaining the two appraisals from appraisers employed by the same appraisal firm, or from two appraisers who receive the assignments for the two required appraisals from the same appraisal management company?

XX(b)(3)(iii) Relationship to Paragraph (b)(1)

Proposed § 1026.XX(b)(3)(ii) would require that the additional appraisal meet the requirements of the first appraisal, which includes the requirements that the appraisal be performed by a certified or licensed appraiser who conducts a physical visit of the interior of the mortgaged property. The Agencies believe that this approach best effectuates the purposes of the statute. TILA section 129H(b)(1) provides that, ''Subject to the rules prescribed under paragraph (4), an appraisal of property to be secured by a higher-risk mortgage does not meet the requirements of this section unless it is performed by a certified or licensed appraiser who conducts a physical property visit of the interior of the mortgaged property''. 15 U.S.C. 1639h(b)(1). The ''second appraisal'' required under TILA section 129H(b)(2)(A) is ''an appraisal of property to be secured by a higher-risk mortgage'' under TILA section 129H(b)(1). 15 U.S.C. 1639h(b)(1), (b)(2)(A). Therefore, to meet the requirements of TILA section 129H, the additional appraisal would be required to be ''performed by a certified or licensed appraiser who conducts a physical visit of the interior of the property that will secure the transaction.'' TILA section 129H(b)(1), 15 U.S.C. 1639h(b)(1). In addition, under TILA section 129H(b)(2)(A), the additional appraisal must analyze several elements, including ''any improvements made to the property between the date of the previous sale and the current sale.'' 15 U.S.C. 1639h(b)(2)(A). The Agencies believe that the purposes of the statute would be best implemented by requiring the second appraiser to perform a physical interior property visit to analyze any improvements made to the property. Without an on-site visit, the second appraiser would have difficulty confirming that any improvements identified by the seller or the first appraiser were made. Thus, proposed § 1026.XX(b)(3)(iii) provides that if the conditions in proposed § 1026.XX(b)(3)(i) are present, the creditor must obtain an additional appraisal that meets the requirements of the first appraisal, as provided in proposed § 1026.XX(b)(1).

XX(b)(3)(iv) Requirements for the Additional Appraisal

TILA section 129H(b)(2)(A) would require that the additional appraisal ''include an analysis of the difference in sale prices, changes in market conditions, and any improvements made to the property between the date of the previous sale and the current sale.'' 15 U.S.C. 1639h(b)(2)(A). Proposed § 1026.XX(b)(3)(iv)(A) would require that the additional appraisal include an analysis of the difference between the price at which the seller acquired the property and the price the consumer is obligated to pay to acquire the property, as specified in the consumer's acquisition agreement. In addition, proposed § 1026.XX(b)(3)(iv)(B)–(C) would require that the additional appraisal include an analysis of changes in market conditions and improvements made to the property between the date of the seller's acquisition of the property and the date of the consumer's agreement to acquire the property. For consistency with the statute, the Agencies have listed the requirement to analyze the difference in sale prices as an element distinct from the analysis of changes in market conditions and any improvements made to the property.

Question 31: The Agencies invite comment on this interpretation and whether the rule should adopt an alternate approach.

For consistency throughout the proposal, proposed § 1026.XX(b)(3)(iv)(A) uses the terms ''the price at which the seller acquired the property'' and the ''price the consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller'' as the prices that the additional appraisal must analyze. These are the same criteria that a creditor would analyze to determine whether the seller acquired the property at a price lower than the current sale price in proposed § 1026.XX(b)(3)(i)(B). Similarly, paragraphs (b)(3)(iv)(B) and (b)(3)(iv)(C) of proposed § 1026.XX(b)(3)(iv) use the terms ''date the seller acquired the property'' and

the ''date of the consumer's agreement to acquire the property'' as the dates the additional appraisal must analyze in considering changes in market conditions and any improvements made to the property. These are the same dates that a creditor would analyze to determine whether the property is being resold within the 180-day period in proposed § 1026.XX(b)(3)(i)(B). Proposed comment XX(b)(3)(iv)–1 contains cross-references to other proposed comments that clarify how a creditor would identify the relevant dates and prices.

Question 32: The Agencies invite comment on this terminology and whether additional clarification of these requirements is necessary.

XX(b)(3)(v) No Charge for the Additional Appraisal

TILA section 129H(b)(2)(B) provides that ''[t]he cost of the second appraisal required under subparagraph (A) may not be charged to the applicant.'' 15 U.S.C. 1639h(b)(2)(B). Proposed § 1026.XX(b)(3)(v) provides that ''[i]f the creditor must obtain two appraisals under paragraph (b)(3)(i) of this section, the creditor may charge the consumer for only one of the appraisals.'' As clarified in proposed comment XX(b)(3)(v)–1, the creditor would be prohibited from imposing a fee specifically for that appraisal or by marking up the interest rate or any other fees payable by the consumer in connection with the higher-risk mortgage loan.

The proposed comment also explains that the creditor would be prohibited from charging the consumer for the ''performance of one of the two appraisals required under § 1026.XX(b)(3)(i).'' This comment is intended to clarify that the prohibition on charging the consumer under § 1026.XX(b)(3)(v) applies to charges for the cost of performing the appraisal, not the cost of providing the consumer with a copy of the appraisal. As implemented by proposed § 1026.XX(d)(4), TILA section 129H(c) would prohibit the creditor from charging the consumer for one copy of each appraisal conducted pursuant to the higher-risk mortgage rule. 15 U.S.C. 1639h(c); *see also* section-by-section analysis of proposed § 1026.XX(d)(4), below. As discussed above, the Agencies have not used the phrase ''second appraisal'' in the proposed rule because, in practice, a creditor ordering two appraisals at the same time may not know which of the two appraisals would be the ''second'' appraisal. The Agencies understand that the additional appraisal could be separately identified because it must contain an analysis of elements in proposed § 1026.XX(b)(3)(iv), but the Agencies also understand that some appraisers may perform such an analysis as a matter of routine, and that it may be difficult to distinguish the two appraisals on that basis.

Question 33: The Agencies invite comment on the proposed approach of permitting the creditor to charge for only one appraisal, and whether other ways to identify the ''second appraisal'' as the one that cannot be charged to the consumer may exist.

In addition, proposed § 1026.XX(b)(3)(ii) prohibits the creditor from charging ''the consumer'' in place of the statutory term, ''applicant.'' The Agencies believe that use of the broader term ''consumer'' is necessary to clarify that the creditor may not charge the consumer for the cost of the additional appraisal after consummation of the loan.

XX(b)(3)(vi) Creditor's Determinations Under Paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this Section

XX(b)(3)(vi)(A) Reasonable Diligence

Proposed § 1026.XX(b)(3)(vi)(A) would require the creditor to exercise reasonable diligence to determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of proposed § 1026.XX and are met—namely, whether the seller acquired the property 180 or fewer days prior to the date of the consumer's agreement to acquire the property from the seller, at a price that was lower than the price the consumer is obligated to pay, as specified in the consumer's agreement to acquire the property from the seller. Although TILA section 129H does not include a diligence standard, the Agencies are proposing one to implement the statute's requirement that the creditor obtain an additional appraisal. To determine whether an additional appraisal is required, the creditor would be required to know whether the criteria regarding the property's sale prices and dates of acquisition are met. The Agencies believe it may be difficult in some cases for a creditor to know with absolute certainty whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of proposed § 1026.XX are met. Similarly, a creditor may have difficulty knowing whether it had relied on the ''best information'' available in making such a determination, which could require that creditors perform an exhaustive review of every document that might contain information about a property's sales history and unduly limit the availability of credit to higher-risk mortgage consumers.

To meet the proposed reasonable diligence standard, the Agencies believe that creditors should be able to rely on written source documents that are generally available in the normal course of business. Accordingly, proposed comment XX(b)(3)(vi)(A)–1 clarifies that a creditor has acted with reasonable diligence to determine when the seller acquired the property and whether the price at which the seller acquired the property is lower than the price reflected in the consumer's acquisition agreement if, for example, the creditor bases its determination on information contained in written source documents, as discussed below.

The proposed comment provides a list of written source documents that the creditor could use to perform reasonable diligence as follows: a copy of the recorded deed from the seller; a copy of a property tax bill; a copy of any owner's title insurance policy obtained by the seller; a copy of the RESPA settlement statement from the seller's acquisition (*i.e.,* the HUD–1 or any successor form [54]); a property sales history report or title report from a third-party reporting service; sales price data recorded in multiple listing services; tax assessment records or transfer tax records obtained from local governments; a written appraisal, including a signed appraiser's certification stating that the appraisal was performed in conformity with USPAP, that shows any prior transactions for the subject property; a copy of a title commitment report; or a property abstract.

Question 34: The Agencies specifically invite comment on whether these or other source documents would provide reliable information about a property's sales history.[55] The Agencies also request comment on whether these or other source documents could be relied on in making the additional appraisal determination, provided they indicate the seller's acquisition date or the seller's acquisition price.

The proposed comment contains a footnote explaining that a ''title commitment report'' is a document from a title insurance company describing the property interest and status of its title, parties with interests in the title and the nature of their claims, issues with the

[54] As explained in a footnote in the proposed comment, the Bureau's 2012 TILA–RESPA Proposal contains a proposed successor form to the RESPA settlement statement. See § 1026.38 (Closing Disclosure Form) of the Bureau's 2012 TILA–RESPA Proposal, available at *http://www.consumerfinance.gov/regulations/.*

[55] *See also* HUD Mortgagee Letter 2003–07 (May 22, 2003) (providing examples of documents a creditor could use to comply with the time-period restrictions in the FHA Anti-Flipping Rule).

title that must be resolved prior to closing of the transaction between the parties to the transfer, amount and disposition of the premiums, and endorsements on the title policy. The footnote also explains that the document is issued by the title insurance company prior to the company's issuance of an actual title insurance policy to the property's transferee and/or creditor financing the transaction. In different jurisdictions, this instrument may be referred to by different terms, such as a title commitment, title binder, title opinion, or title report.

Regarding the list of source documents described above, the Agencies note that the first four listed items would be voluntarily provided directly or indirectly by the seller, rather than collected from publicly available sources. Permitting the use of these documents presents the risk that the creditor would be presented with altered copies. Balanced against this risk is the concern that no information sources are publicly available in non-disclosure jurisdictions and jurisdictions with significant lag times before public land records are updated to reflect new transactions.[56] The Agencies are concerned that, unless the creditor can rely on other sources, such as sources provided by the seller, the higher-risk mortgage transaction may not proceed at all, or could proceed only with an additional appraisal containing a limited form of the analysis that would be required by TILA section 129H(b)(2)(A). 15 U.S.C. 1639h(b)(2)(A). (For a discussion of how a higher-risk mortgage transaction could proceed with limited information about the seller's acquisition, see the section-by-section analysis of proposed § 1026.XX(b)(3)(vi)(B), below).

Question 35: The Agencies are particularly interested in whether a creditor should be permitted to rely on a signed USPAP-compliant written appraisal prepared for the higher-risk mortgage transaction to determine the seller's acquisition date and price.

The Agencies understand that USPAP Standards Rule 1–5 requires appraisers to ''analyze all sales of the subject property that occurred within the three (3) years prior to the effective date of the appraisal'' if that information is available to the appraiser ''in the normal course of business.''[57] Thus, the Agencies expect that, in most cases, a creditor could rely on the first appraisal prepared for the higher-risk mortgage transaction to reveal information relevant to determining whether an additional appraisal would be required under § 1026.XX(b)(3)(i). However, the Agencies are concerned that a written appraisal may not be trustworthy if the appraiser were a party to a fraudulent flipping scheme.

Question 36: In light of the abuses sought to be prevented by the statute, the Agencies invite comment on whether allowing a creditor to rely on the appraisal for the requisite information is appropriate and whether a creditor could take any specific measures to ensure the appraiser is reporting prior sales accurately. The Agencies are particularly interested in receiving comment on whether, for creditors that are required to select an independent appraiser, such as creditors subject to the Federal banking agencies' FIRREA title XI rules, the creditor's selection of an independent appraiser is sufficient to address the concern that the appraiser may be colluding with a seller in perpetrating a fraudulent flipping scheme.

The Agencies also note that some of the listed documents may not necessarily be publicly available. Even in jurisdictions that, at the time of the particular loan application, make up-to-date sales information publicly available, the Agencies are reluctant to suggest that the creditor should have to look further than publicly available information that is commonly obtained as part of creditors' current loan underwriting processes.

Question 37: The Agencies question whether other information sources are likely to be more easily available or more accurate, and request commenters' views on this point.

Oral statements. Proposed comment XX(b)(3)(vi)(A)-2 explains that reliance on oral statements of interested parties, such as the consumer, seller, or mortgage broker does not constitute reasonable diligence for determining whether an additional appraisal is required under § 1026.XX(b)(3)(i). The Agencies do not believe that creditors should be permitted to rely on oral statements offered by parties to the transaction because they may be engaged in the type of fraud the statutory provision was designed to prevent.

Question 38: However, the Agencies request comment on whether circumstances exist in which oral statements offered by parties to the transaction could be considered reliable if documented appropriately, and how such statements should be documented to ensure greater reliability.

XX(b)(3)(vi)(B) Inability To Make the Determination Under Paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this Section

In general, the Agencies believe that, based on recent data provided by FHFA, most property resales would not trigger the proposal's conditions requiring an additional appraisal.[58] However, the Agencies understand that, in some cases, a creditor performing typical underwriting and documentation procedures may be unable to ascertain through information derived from public records whether the conditions in the additional appraisal requirement have been triggered. For example, a creditor may be unable to determine information about the seller's acquisition because of lag times in recording public records. The Agencies also understand that some source documents often report only nominal amounts of consideration when describing the consideration paid by the current titleholder for the property. Moreover, as noted, several ''non-disclosure'' jurisdictions do not make the price at which a seller acquired a property publicly available. In addition, the creditor may obtain conflicting information from written source documents. In these cases, a creditor may be unable to determine, based on its reasonable diligence, whether the criteria in proposed paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) have been met.

For the reasons discussed below, the Agencies believe that a higher-risk mortgage loan creditor should be required to obtain an additional appraisal if the creditor cannot determine the seller's acquisition price or date based on written source documents. Accordingly, proposed § 1026.XX(b)(3)(vi)(B) would require a higher-risk mortgage loan creditor that cannot determine the seller's acquisition date or price to obtain an additional appraisal.

Proposed comment XX(b)(3)(vi)(B)-1 provides two examples of how this rule would apply: one in which a creditor is

[56] During informal outreach conducted by the Agencies, representatives of large, small, and regional lenders expressed concern that in some cases, a creditor may be unable to determine the seller's date and price due to information gaps in the public record. The Agencies also understand that a creditor may not be able to determine prior transaction data because of delays in the recording of public records. The Agencies also understand that certain ''non-disclosure'' jurisdictions do not make the price at which a seller acquired a property available in the public records.

[57] Appraisal Standards Bd., Appraisal Fdn., Standards Rule 1–5, USPAP (2012–2013 ed.).

[58] Based on county recorder information from select counties licensed to FHFA by DataQuick Information Systems.

unable to obtain information on the seller's acquisition price or date and the other in which a creditor obtains conflicting information about the seller's acquisition price or date. In the first example, proposed comment XX(b)(3)(vi)(B)-1.i assumes that a creditor orders and reviews the results of a title search showing the seller's acquisition date is within the 180-day window, but the seller's acquisition price was not included. In this case, the creditor would not be able to determine whether the price paid by the seller to acquire the property was lower than the price the consumer is obligated to pay under the consumer's acquisition agreement, pursuant to § 1026.XX(b)(3)(i)(B). Before extending a higher-risk mortgage loan, the creditor must either: (1) perform additional diligence to obtain information showing the seller's acquisition price and determine whether two written appraisals in compliance with § 1026.XX(b)(3) would be required based on that information; or (2) obtain two written appraisals in compliance with § 1026.XX(b)(3). *See also* proposed comment XX(b)(3)(vi)(B)-2.

In the second example, proposed comment XX(b)(3)(vi)(B)-1.ii assumes that a creditor reviews the results of a title search indicating that the last recorded purchase was more than 180 days before the consumer's agreement to acquire the property. This proposed comment also assumes that the creditor subsequently receives a written appraisal indicating that the seller acquired the property less than 180 days before the consumer's agreement to acquire the property. In this case, the creditor would not be able to determine whether the seller acquired the property within 180 days of the date of the consumer's agreement to acquire the property from the seller, pursuant to § 1026.XX(b)(3)(i)(A). Before extending a higher-risk mortgage loan, the creditor must either: (1) perform additional diligence to obtain information confirming the seller's acquisition date (and price, if within 180 days) and determine whether two written appraisals in compliance with § 1026.XX(b)(3) would be required based on that information; or (2) obtain two written appraisals in compliance with § 1026.XX(b)(3). *See also* comment XX(b)(3)(vi)(B)-3.

Under this proposal, when information about a property is not available from written source documents, creditors extending higher-risk mortgage loans will routinely incur increased costs associated with obtaining the additional appraisal. One risk of the proposal is that, because TILA section 129H(b)(2)(B) prohibits creditors from charging their customers for the additional appraisal, 15 U.S.C. 1639h(b)(2)(B), creditors will simply refrain from engaging in any higher-risk mortgage loan transaction where sales history data cannot be obtained. *See also* proposed § 1026.XX(b)(3)(v). In ''non-disclosure'' jurisdictions, where property sales price information is routinely unavailable through public records, this requirement could limit the availability of higher-risk mortgage loans.

The Agencies believe, however, that requiring an additional appraisal where creditors are unable to obtain the seller's acquisition price and date is necessary to prevent circumvention of the statute. In particular, the Agencies are concerned that not requiring an additional appraisal in cases of limited information may encourage the concentration of fraudulent property flipping in ''non-disclosure'' jurisdictions. Similarly, the Agencies are concerned that sellers that acquire and sell properties within a short timeframe could take advantage of delays in the public recording of property sales to engage in fraudulent flipping transactions. The Agencies believe that, where the seller's acquisition date in particular is not in the public record due to recording delays, it is more reasonable to assume that the seller's transaction was sufficiently recent to be covered by the rule than not.

Question 39: The Agencies request comment on whether the enhanced protections for consumers afforded by requiring an additional appraisal whenever the seller's acquisition date or price cannot be determined merit the potential restraint on the availability of higher-risk mortgage loans. The Agencies also request comment on whether concerns about these potential restraints on credit availability make it particularly important to include the first four source documents listed in the proposed commentary, even though they would be seller-provided, and whether these concerns warrant further expanding the sources of information creditors may rely on to satisfy the reasonable diligence standard under the proposed rule.

Modified requirements for content of additional appraisal. As discussed above, proposed § 1026.XX(b)(3)(vi)(B) would require a higher-risk mortgage loan creditor that cannot determine the seller's acquisition date or price to obtain an additional appraisal. However, proposed § 1026.XX(b)(3)(vi)(B) also provides that the additional appraisal in this situation would not have to contain the full analysis required for additional appraisals of flipping transactions under proposed § 1026.XX(b)(3)(iv)(A)-(C). *See* TILA section 129H(b)(2)(A), 15 U.S.C. 1639h(b)(2)(A). Specifically, under proposed § 1026.XX(b)(vi)(B), the additional appraisal must include an analysis of the elements that would be required in proposed § 1026.XX(b)(3)(iv)(A)-(C) only to the extent that the creditor knows the seller's purchase price and acquisition date. As discussed in the section-by-section analysis of proposed § 1026.XX(b)(3)(ii), TILA section 129H(b)(2)(A) requires that the additional appraisal analyze changes in market conditions, improvements to the property, and the difference in sales prices. 15 U.S.C. 1639h(b)(2)(A). An appraiser could not perform this analysis if efforts to obtain the seller's acquisition date and price were not successful.

Proposed comment XX(b)(3)(vi)(B)–2 confirms that, in general, the additional appraisal required under § 1026.XX(b)(3)(i) should include an analysis of the factors listed in § 1026.XX(b)(3)(iv)(A)–(C). However, the proposed comment also confirms that if, following reasonable diligence, a creditor cannot determine whether the criteria in § 1026.XX(b)(3)(i)(A) and (B) are met due to a lack of information or conflicting information, the required additional appraisal must include the analyses required under § 1026.XX(b)(3)(iv)(A), (B), and (C) only to the extent that the information necessary to perform the analysis is known. *See* section-by-section analysis of paragraphs (b)(3)(i) and (b)(3)(iv) of proposed § 1026.XX. The proposed comment provides two examples. First, proposed comment XX(b)(3)(vi)(B)–2.i states that, if a creditor is unable, following reasonable diligence, to determine the price at which the seller acquired the property, the second written appraisal obtained by the creditor is not required to include the analysis under § 1026.XX(b)(3)(iv)(A) of the difference between the price at which the seller acquired the property and the price that the consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller. The proposed comment also explains that the second written appraisal would be required to include the analysis under paragraphs (b)(3)(iv)(B) and (b)(3)(iv)(C) of proposed § 1026.XX of the changes in market conditions and any improvements made to the property between the date the

seller acquired the property and the date of the consumer's agreement to acquire the property.

In addition, the Agencies note that the proposed rule does not provide commentary explaining how the creditor would obtain an additional appraisal if the creditor is unable to determine the date the seller acquired the property but is able to determine the price at which the seller acquired the property. Proposed § 1026.XX(b)(3)(iv)(A) would require creditors to perform ''an analysis of the difference between the price at which the seller acquired the property and the price that the consumer is obligated to pay to acquire the property.''

Question 40: The Agencies request comment on whether an appraiser would be unable to analyze the difference in the price the consumer is obligated to pay to acquire the property and the price at which the seller acquired the property without knowing when the seller acquired the property. If such an analysis is not possible without information about when the seller acquired the property, the Agencies invite comment on whether the rule should assume the seller acquired the property 180 days prior to the date of the consumer's agreement to acquire the property.

The Agencies believe that allowing creditors to comply with a modified form of the full analysis where a creditor cannot determine information about a property based on its reasonable diligence is a reasonable interpretation of the statute. It would be impossible for a creditor to obtain an appraisal that complies with the full analysis requirement of TILA section 129H(b)(2)(A) concerning the change in price, market conditions, and improvements to the property if a creditor could not determine when or for how much the prior sale occurred.

In sum, the Agencies' proposed approach to situations in which the creditor cannot obtain the necessary information, either due to a lack of information or conflicting information, is to require an additional appraisal, but, to account for missing or conflicting information, require a modified version of the full additional analysis required under TILA section 129H(b)(2)(A) and proposed § 1026.XX(b)(3)(iv). 15 U.S.C. 1639h(b)(2)(A). Among alternative approaches not chosen by the Agencies is to prohibit creditors from extending the higher-risk mortgage loan altogether under these circumstances. The Agencies believe, however, that a flat prohibition would unduly limit the availability of higher-risk mortgage loans to consumers.

Question 41: The Agencies request comment on the proposed approach to situations in which the creditor cannot obtain the necessary information and whether the rule should address information gaps about the flipping transaction in other ways.

XX(c) Required Disclosure

XX(c)(1) In General

Title XIV of the Dodd-Frank Act added two new appraisal-related notification requirements for consumers. First, TILA section 129H(d) requires that, at the time of the initial mortgage application for a higher-risk mortgage loan, the applicant must be ''provided with a statement by the creditor that any appraisal prepared for the mortgage is for the sole use of the creditor, and that the applicant may choose to have a separate appraisal conducted at the expense of the applicant.'' 15 U.S.C. 1639h(d). Proposed § 1026.XX(c) implements the new disclosure requirement added by TILA section 129H(d).

In addition, new section 701(e)(5) of the Equal Credit Opportunity Act (ECOA) similarly requires a creditor to notify an applicant in writing, at the time of application, of the ''right to receive a copy of each written appraisal and valuation'' subject to ECOA section 701(e). 15 U.S.C. 1691(e)(5). Read together, the revisions to TILA and ECOA will require creditors to provide two appraisal disclosures to consumers applying for a higher-risk mortgage loan secured by a first lien on a consumer's principal dwelling. The Bureau intends to implement ECOA section 701(e) separately, using its authority to promulgate rules pursuant to section 703(a) of ECOA; however, in developing this proposal jointly with the Agencies, the Bureau has been cognizant of the need to promote consistency for consumers and reduce operational burden for creditors in implementing both the new TILA and ECOA appraisal-related disclosure requirements.

Consumer Testing. In developing this proposal to implement the disclosure requirements in TILA section 129H(d), the Agencies have relied on consumer testing conducted on behalf of the Bureau as part of its development of integrated disclosures under the Real Estate Settlement Procedures Act (RESPA) and TILA. While a short summary is included below, a more comprehensive discussion of the Bureau's consumer testing protocol and procedures has been published in the **Federal Register** as part of the Bureau's 2012 TILA–RESPA Proposal.

Testing the Appraisal Disclosures. As part of its broader testing of integrated mortgage disclosures, the Bureau tested versions of the new appraisal-related disclosures required by both TILA and ECOA. The Bureau believed that testing both appraisal-related disclosures together was important to determine how best to provide these two overlapping but separate disclosures in a manner that would minimize consumer confusion and improve consumer comprehension. Testing showed that consumers tended to find the two notifications confusing when they were given together using, in both cases, the language in the statute. Consumer comprehension of both appraisal-related disclosures significantly improved when a slightly longer plain language version of the notifications was provided. The Agencies believe that Congress intended the ECOA and TILA notices to work together to provide consumers a better understanding of collateral valuations used by the creditor in determining whether to extend secured credit to the consumer. Based on the results of the consumer testing performed by the Bureau, the Agencies are proposing to implement the appraisal disclosure required in TILA with a new § 1026.XX(c)(1) that would require the following disclosure: ''We may order an appraisal to determine the property's value and charge you for this appraisal. We will promptly give you a copy of any appraisal, even if your loan does not close. You can pay for an additional appraisal for your own use at your own cost.''

While the proposed disclosure is longer than the express statutory language provided in section 129H(d), the Agencies believe that the additional explanatory text is necessary to promote consumer comprehension and to reduce any confusion associated with the ECOA appraisal notification that will also have to be given to applicants for most higher-risk mortgage loans. The proposed notification is accurate because, like the ECOA section 701(e) appraisal requirement, TILA section 129H(c) also requires creditors to provide consumers with a copy of the appraisals at least three days prior to consummation.

The proposed disclosure does not include the express language in TILA section 129H(d) that ''the appraisal prepared for the mortgage is for the sole use of the creditor.'' 15 U.S.C. 1639h(d). The Agencies are proposing not to include this express language in the disclosure language because, in testing performed by the Bureau, it confused consumers. Requirements to disclose

appraisal information to residential mortgage consumers, such as under TILA section 129H(c), are intended to help consumers understand the collateral valuation information on which creditors rely in reaching decisions on consumers' mortgage applications. 15 U.S.C. 1639h(c). TILA section 129H(d) seeks to convey that the valuation conclusions in the appraisal are prepared for the benefit of the creditor, not the consumer. 15 U.S.C. 1639h(d). The disclosure language proposed by the Agencies addresses this point by advising consumers they may obtain an additional appraisal at their own cost for their own use. In formulating this language without ''sole use'' terminology, the Agencies are not suggesting that TILA section 129H should be construed to confer upon consumers a status equivalent to an intended third-party beneficiary with respect to the valuation conclusion in written appraisals obtained by creditors. 15 U.S.C. 1639h.

Question 42: The Agencies request comment on the proposed language and whether additional changes should be made to the text of the notification to further enhance consumer comprehension.

Proposed comment XX(c)(1)–1 clarifies that when two or more consumers apply for a loan subject to this section, the creditor is required to give the disclosure to only one of the consumers. This interpretation is for consistency with comment 14(a)(2)(i)–1 in Regulation B, which interprets the requirement in § 1002.14(a)(2)(i) that creditors notify applicants of the right to receive copies of appraisals. 12 CFR 1002.14(a)(2) and comment 14(a)(2)(i)–1.

XX(c)(2) Timing of Disclosure

TILA section 129H(c) requires that the disclosure be provided at the time of the initial mortgage application. 15 U.S.C. 1639h(c). To be consistent with other similar TILA and RESPA notifications provided to consumers [59] and to allow creditors sufficient time to deliver written disclosures to applicants, when an application is submitted over the phone, by fax, or by mail, proposed § 1026.XX(c)(2) requires that the disclosure be delivered not later than the third business day after the creditor receives the consumer's application. In addition, providing the notification to consumers at the same time as other similar notifications allows consumers to read the notification in context with other important information that must be delivered not later than the third business day after the creditor receives the consumer's application. The Agencies believe this interpretation is consistent with the requirements of TILA section 129H(d). 15 U.S.C. 1639h(d).

Question 43: The Agencies request comment on whether providing the notification at some other time would be more beneficial to consumers, and how the notification should be provided when an application is submitted by telephone, facsimile or electronically. For example, the Agencies solicit comment on whether it would be appropriate to require that creditors provide the disclosure at the same time the application is received, or even as part of the application.

Question 44: The Agencies also solicit comment on whether creditors who have a reasonable belief that the transaction will not be a higher-risk mortgage loan at the time of application, but later determine that the applicant only qualifies for a higher-risk mortgage loan, should be allowed an opportunity to cure and give the required disclosure at some later time in the application process.

XX(d) Copy of Appraisals

XX(d)(1) In General

Consistent with TILA section 129H(c), proposed § 1026.XX(d) requires that a creditor must provide a copy of any written appraisal performed in connection with a higher-risk mortgage loan to the applicant. 15 U.S.C. 1639h(c).

Similar to proposed comment XX(c)(1)–1, proposed comment XX(d)(1)–1 clarifies that when two or more consumers apply for a loan subject to this section, the creditor is required to give the copy of required appraisals to only one of the consumers.

XX(d)(2) Timing

TILA section 129H(c) requires that the appraisal copy must be provided to the consumer at least three (3) days prior to the transaction closing date. 15 U.S.C. 1639h(c). Proposed § 1026.XX(d)(2) requires creditors to provide copies of written appraisals pursuant to § 1026.XX(d)(1) no later than ''three business days'' prior to consummation of the higher-risk mortgage loan. The Agencies believe that requiring that the appraisal be provided three (3) business days in advance of consummation is a reasonable interpretation of the statute and is consistent with the Agencies' interpretation of the statutory term ''days'' used in the Bureau's proposed rule amending 12 CFR 1002.14, which implements the appraisal requirements of new ECOA section 701(e)(1). *See* 15 U.S.C. 1691(e)(1); and the Bureau's 2012 ECOA Proposal.[60] In addition, the Agencies' interpretation of the term ''days'' to mean ''business days'' is consistent with other similar regulatory requirements being proposed under the TILA and RESPA. *See* Bureau's 2012 TILA–RESPA Proposal.

For consistency with the other provisions of Regulation Z, proposed § 1026.XX also uses the term ''consummation'' instead of the statutory term ''closing'' that is used in TILA section 129H(c). 15 U.S.C. 1639h(c). The term ''consummation'' is defined in § 1026.2(a)(13) as the time that a consumer becomes contractually obligated on a credit transaction. The Agencies have interpreted the two terms as having the same meaning for the purpose of implementing TILA section 129H. 15 U.S.C. 1639h.

XX(d)(3) Form of Copy

Section 1026.31(b) currently provides that the disclosures required under subpart E of Regulation Z may be provided to the consumer in electronic form, subject to compliance with the consumer-consent and other applicable provisions of the Electronic Signatures in Global and National Commerce Act (E-Sign Act) (15 U.S.C. 7001 et seq.). The Agencies believe that it is also appropriate to allow creditors to provide applicants with copies of written appraisals in electronic form if the applicant consents to receiving the copies in such form. Accordingly, proposed § 1026.XX(d)(3) provides that any copy of a written appraisal required by § 1026.XX(d)(1) may be provided to the applicant in electronic form, subject to compliance with the consumer consent and other applicable provisions of the E-Sign Act.

XX(d)(4) No Charge for Copy of Appraisal

TILA section 129H(c) provides that a creditor shall provide one (1) copy of each appraisal conducted in accordance with this section in connection with a higher-risk mortgage to the applicant without charge. 15 U.S.C. 1639h(c). The Agencies have interpreted this section to prohibit creditors from charging consumers for providing a copy of

[59] *See, e.g.,* 12 CFR 1026.19(a)(1)(i) (''In a mortgage transaction subject to the Real Estate Settlement Procedures Act (12 U.S.C. 2601 *et seq.*) that is secured by the consumer's dwelling * * * the creditor shall make good-faith estimates of the disclosures required by section 1026.18 and shall deliver or place them in the mail not later than the third business day after the creditor receives the consumer's written application.'').

[60] The Bureau's 2012 ECOA Proposal is available at *http://www.consumerfinance.gov/regulations/.*

written appraisals required for higher-risk mortgage loans. Accordingly, proposed § 1026.XX(d)(4) provides that a creditor must not charge the applicant for a copy of a written appraisal required to be provided to the consumer pursuant to § 1026.XX(d)(1).

Proposed comment XX(d)(4)–1 clarifies that the creditor is prohibited from charging the consumer for any copy of an appraisal required to be provided under § 1026.X(d)(1), including by imposing a fee specifically for a required copy of an appraisal or by marking up the interest rate or any other fees payable by the consumer in connection with the higher-risk mortgage loan.

XX(e) Relation to Other Rules

Proposed paragraph (e) would clarify that the proposed rules were developed jointly by the Agencies. The Board proposes to codify its higher-risk mortgage appraisal rules at 12 CFR 226.XX *et seq.;* the Bureau proposes to codify its higher-risk mortgage appraisal rules at 12 CFR 1026.XX *et seq.;* and the OCC proposes to codify its higher-risk mortgage appraisal rules at 12 CFR Part 34 and 12 CFR Part 164. There is, however, no substantive difference among the three sets of rules. The NCUA and FHFA propose to adopt the rules as published in the Bureau's Regulation Z at 12 CFR 1026.XX, by cross-referencing these rules in 12 CFR 722.3 and 12 CFR Part 1222, respectively. The FDIC proposes to not cross-reference the Bureau's Regulation Z at 12 CFR 1026.XX.

V. Section 1022(b)(2) of the Dodd-Frank Act

Overview

In developing the proposed rule, the Bureau has considered potential benefits, costs, and impacts to consumers and covered persons.[61] The Bureau is issuing this proposal jointly with the Federal banking agencies and FHFA, and has consulted with these agencies, the Department of Housing and Urban Development, and the Federal Trade Commission, including regarding consistency with any prudential, market, or systemic objectives administered by such agencies.

As discussed above, the proposed rule would implement section 1471 of the Dodd-Frank Act, which establishes appraisal requirements for higher-risk mortgage loans. Consistent with the statute, the proposal would allow a creditor to make a higher-risk mortgage loan only if the following conditions are met:

- The creditor obtains a written appraisal;
- The appraisal is performed by a certified or licensed appraiser;
- The appraiser conducts a physical property visit of the interior of the property;
- At application, the applicant is provided with a statement regarding the purpose of the appraisal, that the creditor will provide the applicant a copy of any written appraisal, and that the applicant may choose to have a separate appraisal conducted at the expense of the applicant; and
- The creditor provides the consumer with a free copy of any written appraisals obtained for the transaction at least three (3) business days before closing.

In addition, as required by the Act, the proposal would require a higher-risk mortgage loan creditor to obtain an additional written appraisal, at no cost to the borrower, under the following circumstances:

- The higher-risk mortgage loan will finance the acquisition of the consumer's principal dwelling;
- The seller selling what will become the consumer's principal dwelling acquired the home within 180 days prior to the consumer's purchase agreement (measured from the date of the consumer's purchase agreement); and
- The consumer is acquiring the home for a higher price than the seller paid, although comment is requested on whether a threshold price increase would be appropriate.

The additional written appraisal, from a different licensed or certified appraiser, generally must include the following information: an analysis of the difference in sale prices (*i.e.,* the sale price paid by the seller and the acquisition price of the property as set forth in the consumer's purchase agreement), changes in market conditions, and any improvements made to the property between the date of the previous sale and the current sale.

The proposal also includes a request for comments to address a proposed amendment to the method of calculation of the APR that is being proposed as part of another mortgage-related proposal issued for comment by the Bureau. In the Bureau's proposal to integrate mortgage disclosures (2012 TILA–RESPA Proposal), the Bureau is proposing to adopt a more simple and inclusive finance charge calculation for closed-end credit secured by real property or a dwelling.[62] As the finance charge is integral to the calculation of the APR, the Bureau believes it is possible that a more inclusive finance charge could increase the number of loans covered by this rule. The Bureau currently is seeking data to assist in assessing potential impacts of a more inclusive finance charge in connection with the 2012 TILA–RESPA and its proposal to implement Dodd-Frank Act provision related to ''high-cost'' loans (2012 HOEPA Proposal).[63]

In many respects, the proposed rule would codify mortgage lenders' current practices. In outreach calls to industry, all respondents reported requiring the use of full-interior appraisals in 95% or more of first-lien transactions[64] and providing copies of appraisals to borrowers as a matter of course if a loan is originated.[65] The convention of using full-interior appraisals on first-liens may have developed to improve underwriting quality, and the implementation of this proposed rule would assure that the practice would continue under different market conditions.

The Bureau notes that many of the proposed provisions implement self-effectuating amendments to TILA. The costs and benefits of these proposed provisions would arise largely or in some cases entirely from the statute and not from the proposed rule that implements them. Such proposed provisions would provide benefits compared to allowing these TILA amendments to take effect alone, however, by clarifying parts of the statute that are ambiguous. Greater clarity on these issues should reduce the compliance burdens on covered persons by reducing costs for attorneys and compliance officers as well as potential costs of over-compliance and unnecessary litigation. Moreover, the costs that these provisions would

[61] Specifically, Section 1022(b)(2)(A) calls for the Bureau to consider the potential benefits and costs of a regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Act; and the impact on consumers in rural areas.

[62] *See* 2012 TILA–RESPA Proposal, pp. 101–127, 725–28, 905–11 (published July 9, 2012), available at *http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_integrated-mortgage-disclosures.pdf.*

[63] *See* 2012 HOEPA Proposal, pp. 44, 149–211 (published July 9, 2012), available at *http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_high-cost-mortgage-protections.pdf.*

[64] Respondents include a large bank, a trade group of smaller depository institutions, a credit union, and an independent mortgage bank.

[65] Respondents include a large bank, a trade group of smaller depository institutions, and an independent mortgage bank.

impose beyond those imposed by the statute itself are likely to be minimal.

Section 1022 permits the Bureau to consider the benefits, costs and impacts of the proposed rule solely compared to the state of the world in which the statute takes effect without an implementing regulation. To provide the public better information about the benefits and costs of the statute, however, the Bureau has chosen to consider the benefits, costs, and impacts of these major provisions of the proposed rule against a pre-statutory baseline (*i.e.,* the benefits, costs, and impacts of the relevant provisions of the Dodd-Frank Act and the regulation combined).[66]

The Bureau has relied on a variety of data sources to analyze the potential benefits, costs, and impacts of the proposed rule. However, in some instances, the requisite data are not available or are quite limited. Data with which to quantify the benefits of the rule are particularly limited. As a result, portions of this analysis rely in part on general economic principles to provide a qualitative discussion of the benefits, costs, and impacts of the proposal.

The primary source of data used in this analysis is data collected under the Home Mortgage Disclosure Act (HMDA).[67] Because the latest wave of complete data available is for loans made in calendar year 2010, the empirical analysis generally uses the 2010 market as the baseline. Data from fourth quarter 2010 bank and thrift Call Reports,[68] fourth quarter 2010 credit union call reports from the National Credit Union Administration (NCUA), and de-identified data from the National Mortgage Licensing System (NMLS) Mortgage Call Reports (MCR)[69] for the first and second quarter of 2011were also used to identify financial institutions and their characteristics. Most of the analysis relies on a dataset that merges this depository institution financial data from Call Reports to the data from HMDA including higher-risk mortgage loan counts that are created from the loan-level HMDA dataset. The unit of observation in this analysis is the entity: If there are multiple subsidiaries of a parent company then their originations are summed and revenues are total revenues for all subsidiaries.

Other portions of the analysis rely on property-level data regarding parcels and their related financing from DataQuick;[70] data on the location of certified appraisers from the Appraisal Subcommittee Registry;[71] and, demographic data from the 2010 American Community Survey (ACS).[72] Tabulations of the DataQuick data are used for estimation of the frequency of properties being sold within 180 days of a previous sale. The Appraisal Subcommittee's Registry is used to describe the availability of appraisers and the ACS is used to characterize the frequency of first and subordinate liens in rural and urban areas. The Bureau seeks comment on the use of these data sources, the appropriateness to this purpose, and alternative or additional sources of information.

The Bureau requests comment and data on the potential benefits, costs, and impacts of this proposal.

Potential Benefits of the Proposed Rule for Covered Persons and Consumers

In a mortgage transaction, the primary beneficiary of an appraisal is the creditor, as the appraisal helps the creditor avoid lending based on an inflated valuation of the property. Consumers, however, can also benefit from an accurate appraisal. Assuming that full-interior appraisals conducted by a certified or licensed appraiser are more accurate than other valuation methods, the proposal would improve the quality of home price estimates for those transactions where such an appraisal would not be performed currently. The requirement that a second appraisal be conducted in certain circumstances would further reduce the likelihood of an inflated sales price for those transactions.

Benefits to covered persons. Transactions where the collateral is overvalued expose the creditor to higher default risk. Research has shown that lower appraisal quality, defined as the difference between price estimates derived via statistical models and the appraised value, is associated with higher default rates.[73] By tightening appraisal standards for a class of transactions, the proposed rule may reduce default risk for creditors. Furthermore, by requiring the use of full interior appraisals in transactions involving high-risk mortgage loans, the statute prevents creditors from using less costly and possibly less accurate valuation methods in underwriting in order to compete on price. Eliminating the ability to use lower cost valuation methods, and thereby eliminating price competition on this component of the transaction, may benefit firms that prefer to employ more thorough valuation methods.

Benefits to consumers. Individual consumers engage in real estate transactions infrequently, so developing the expertise to value real estate is costly and consumers often rely on experts, such as real estate agents, and list prices to make price determinations. These methods may not lead a consumer to an accurate valuation of a property. For example, there is evidence that real estate agents sell their own homes for significantly more than other houses, which suggests that sellers may not be able to accurately price the homes that they are selling.[74] Other

[66] The Bureau has discretion in any rulemaking to choose an appropriate scope of analysis with respect to potential benefits and costs and an appropriate baseline. The Bureau, as a matter of discretion, has chosen to describe a broader range of potential effects to more fully inform the rulemaking.

[67] The Home Mortgage Disclosure Act (HMDA), enacted by Congress in 1975, as implemented by the Bureau's Regulation C requires lending institutions annually to report public loan-level data regarding mortgage originations. For more information, see *http://www.ffiec.gov/hmda.* It should be noted that not all mortgage lenders report HMDA data. The HMDA data capture roughly 90–95 percent of lending by the Federal Housing Administration and 75–85 percent of other first-lien home loans. Depository institutions, including credit unions, with assets less than $39 million (in 2010), for example, and those with branches exclusively in non-metropolitan areas and those that make no purchase money mortgage loans are not required to report to HMDA. Reporting requirements for non-depository institutions depend on several factors, including whether the company made fewer than 100 purchase money or refinance loans, the dollar volume of mortgage lending as share of total lending, and whether the institution had at least five applications, originations, or purchased loans from metropolitan areas. Robert B. Avery, Neil Bhutta, Kenneth P. Brevoort & Glenn B. Canner, *The Mortgage Market in 2010: Highlights from the Data Reported under the Home Mortgage Disclosure Act,* 97 Fed. Res. Bull., December 2011, at 1, 1 n.2.

[68] Every national bank, State member bank, and insured nonmember bank is required by its primary Federal regulator to file consolidated Reports of Condition and Income, also known as Call Report data, for each quarter as of the close of business on the last day of each calendar quarter (the report date). The specific reporting requirements depend upon the size of the bank and whether it has any foreign offices. For more information, see *http://www2.fdic.gov/call_tfr_rpts/.*

[69] The Nationwide Mortgage Licensing System is a national registry of non-depository financial institutions including mortgage loan originators. Portions of the registration information are public. The Mortgage Call Report data are reported at the institution level and include information on the number and dollar amount of loans originated, the number and dollar amount of loans brokered.

[70] DataQuick is database of property characteristics on more than 120 million properties and 250 million property transactions.

[71] The National Registry is a database containing selected information about State certified and licensed real estate appraisers. Downloaded February 28, 2012.

[72] The American Community Survey is an ongoing survey conducted by the United States Census Bureau.

[73] *See* Michael Lacour-Little and Stephen Malpezzi, *Appraisal Quality and Residential Mortgage Default: Evidence from Alaska,* 27:2 Journal of Real Estate Finance Economics 211–33 (2003).

[74] Levitt, Steven and Chad Syverson. ''Market Distortions When Agents are Better Informed: The

research, this time in a laboratory setting, provides evidence that individuals are sensitive to anchor values when estimating home prices.[75] In such cases, an independent signal of the value of the home should benefit the consumer. Having a professional valuation as a point of reference may help consumers gain a more accurate understanding of the home's value and improve overall market efficiency, relative to the case where the knowledge of true valuations is more limited.[76]

If a borrower is prepared to pay an inflated price for a property then an appraisal that reflects its value more accurately may prevent the transaction from being completed at the inflated price. In addition to the direct costs of paying more than the true value for a property, buying an overvalue property is associated with higher risk of default. If a property that is sold shortly after its previous sale is more likely to have an inflated price, since it may have been purchased the first time with the intention to improve the property quickly and resell it for a profit, the additional appraisal requirement would help ensure an accurate estimate of the value of the property. This might be especially valuable to a consumer. In the case of subordinate-lien transactions, the full-interior appraisal requirement may prevent borrowers from extracting too much equity if their property is overvalued by other valuation methods.

Codifying appraisal standards across the industry would likely simplify the shopping process for consumers who receive HRM offers. First, it may improve their understanding of the determinants of the value of the property that they intend to purchase. In cases where a loan is denied due to an appraiser valuing the property at less than the contract price, the appraisal may provide an itemized explanation of why the property was overvalued, which may help the consumer in future negotiations or property searches. Second, codifying appraisal standards across the industry would simplify the shopping process for consumers by making the process of applying for HRM loans more consistent between lenders. Full-interior appraisals typically cost more than other valuation methods, and appraisal costs are often passed on to consumers. Consumers may not understand the differences between different appraisal methods or know that different creditors will use different methods, and therefore may benefit from the standardization the proposal, if adopted, would cause.

Potential Costs of the Proposed Rule for Covered Persons

The costs of the proposed rule, which are predominantly related to compliance, are more readily quantifiable than the benefits and can be calculated based on the mix of loans originated by an entity and the number of employees at that entity. These compliance costs may be considered as the discrete tasks that would be required by the proposed rule. These can be separated into costs that are associated with the origination of a single higher-risk mortgage loan and the costs of reviewing the regulation and training costs calculated per loan officer and per institution.

Costs per higher-risk mortgage loan. The costs of the proposal for covered persons that derive from additional appraisals depend on the number of appraisals that would be conducted, above and beyond current practice, and the degree to which those costs are passed to consumers. For HMDA reporters, counts of higher-risk mortgage loans that are purchase loans, first-lien refinance loans, or closed-end second loans are computed from the loan-level HMDA data. Accepted statistical methods are used to project loan counts for non-HMDA reporting depository institutions.[77] Estimates of loan officers can be calculated from similar projections of applications per institution.

The calculation of costs for independent mortgage banks (IMBs) uses a slightly different approach.[78] Consistent with the results from HMDA reporting IMBs, the Bureau estimates the costs to IMBs by multiplying a cost per loan by the total number of loans originated by IMBs.[79] To obtain a count of full-time equivalent employees, this number is imputed for HMDA reporting IMBs based on the number of applications (assuming 1.38 days per loan application).[80]

Based on these data sources, the Bureau estimates that there were approximately 280,000 HRMs in 2010. Of these, the Bureau estimates that 117,000 were purchase money mortgages, 136,000 were first-lien refinancings, and 27,000 were closed-end subordinate lien mortgages that were not part of a purchase transaction.[81] The Bureau estimates that the probability that full-interior appraisals are conducted as part of current practice is 95% for purchase-money transactions, 90% for refinance transactions, and 5% for second mortgages. The Bureau therefore estimates that the proposal would lead to 45,100 full-interior appraisals for originations that would not otherwise have a full-interior appraisal.[82]

There would also be additional appraisals from the proposed requirement that lenders obtain a second full-interior appraisal in situations where the home that would secure the higher-risk mortgage is being resold within 180 days at a higher price than the previous transaction involving the property. Based on estimates from DataQuick, the Bureau estimates that the proportion of sales that are resales within 180 days is 5%. For the purposes of this calculation the Bureau conservatively assumes that all of these

Value of Information In Real Estate Transactions.'' The Review of Economics and Statistics 90 no.4 (2008): 599–611.

[75] Scott, Peter and Colin Lizieri. ''Consumer House Price Judgments: New Evidence of Anchoring and Arbitrary Coherence.'' Journal of Property Research 29 no. 1 (2012): 49–68.

[76] For example, in Quan and Quigley's theoretical model where buyers and seller have incomplete information, trades are decentralized, and prices are the result of pairwise bargaining, ''[t]he role of the appraiser is to provide information so that the variance of the price distribution is reduced.'' Quan, Daniel and John Quigley. ''Price Formation and the Appraisal Function in Real Estate Markets.'' Journal of Real Estate Finance and Economics 4 (1991): 127–146.

[77] Poisson regressions are run, projecting loan volumes in these categories on the natural log of characteristics available in the Call reports (total 1–4 family residential loan volume outstanding, full-time equivalent employees, and assets), separately for each category of depository institutions.

[78] ''Independent Mortgage Bank'' refers to non-depository mortgage lenders.

[79] Loan counts and loan amounts were swapped for the one institution that reported originating 130,000 loans with total loan amounts of $8. Institutions with loan amounts above the maximum number of loans reported by an independent mortgage bank in HMDA (134,640) had their loan counts replaced by 134,640. This assumes that the largest independent mortgage bank in terms of loan counts would be a HMDA reporter, which is likely if the firm adheres to the originate-to-distribute model, which implies that most loans would be home purchase (either purchase or refinance) loans, it would originate more than 100 loans, and make at least 5 loans in an MSA or have an office in an MSA, which would require it to report to HMDA. Federal Financial Institutions Examination Council, *A Guide to HMDA Reporting: Getting it Right!* (June 2010), available at *http://www.ffiec.gov/hmda/pdf/2010guide.pdf.* (accessed June 11, 2012).

[80] Sumit Agarwal and Faye Wang, *Perverse Incentives at the Banks? Evidence from Loan Officers* (Federal Reserve Bank of Chicago Working Paper 2009–08).

[81] Purchase money mortgages includes second-lien higher-risk mortgage loans that were part of a purchase transaction. The Bureau assumes that these loans were part of a transaction where the first-lien mortgage was not a higher-risk mortgage loan; to the extent that any of these second-lien purchase money HRMs were part of a transaction where the first lien mortgage was a higher-risk mortgage loan the costs imposed by the proposal would be double-counted. First-lien refinancings includes loans classified as first-lien ''home improvement'' loans in HMDA.

[82] (5%*117,000) + (10%*136,000)+(95%*27,000) = 45,100

are at a price higher than the initial sale and therefore subject to the second appraisal requirement. The Bureau therefore estimates that this provision of the proposal would lead to 5,850 additional full-interior appraisals.[83]

The total effect of the proposal on the number of full-interior appraisals is therefore 50,950.[84]

The following discussion considers estimated compliance costs in the order in which they arise in the mortgage origination process. First, the proposed rule would require that the creditor furnish the applicant with the disclosure in proposed § 1026.xx(c)(1)(I).[85] The cost of this disclosure—at most, delivery of a single piece of paper with a standardized disclosure that could be delivered with other documents or disclosures—would be very low. In addition, the disclosure is included in the 2012 TILA–RESPA Loan Estimate integrated disclosure form proposal;[86] if that proposal were adopted, the cost of providing the disclosure would be part of the overall costs of implementing the integrated disclosure.

Second, the loan officer would be required to verify whether a loan is a higher-risk mortgage. However, this activity is assumed not to introduce any significant costs beyond the regular cost of business because creditors already must compare APRs to APOR for a variety of compliance purposes, such as determining whether a loan qualifies as a ''higher-priced mortgage loan'' for purposes of Regulation Z[87] or to determine if a loan is subject to the protections of the Home Ownership and Equity Protection Act of 1994 (HOEPA).[88]

The third step is that, in order to satisfy the proposed safe harbor provided for at § 1026.XX(b)(2), the creditor would likely order and review full-interior appraisals as prescribed by the proposed rule. The review process is described in the appendix N of the proposed rule, and is assumed to be performed by a loan officer and to take 15 minutes. Assuming an average total hourly labor cost of loan officers of $45.80, the cost of review per additional appraisal is $11.45.[89] With an estimated total number of additional appraisals conducted per year of 50,950, the total cost of reviewing those appraisals is $583,000 (rounded to the nearest thousand).[90]

Creditors would also need to determine whether a second appraisal would be required for the higher-risk mortgage loan based on prior sales involving the property that would secure the loan. This would require labor costs to determine, through reasonable diligence, whether a sale of the property has occurred in the past 180 days at a price lower than the current sale price. The proposal provides that reasonable diligence could be performed through reliance on sources such as property sales history reports, sales price data from Multiple Listing Services or other records, a signed appraisal report that includes prior transactions, title abstracts or reports, copies of the recorded deed from the seller, or other documentation such as a copy of the HUD–1, previous tax bills, or title commitments or binders demonstrating the seller's ownership of the property and the date it was acquired. Since many of these diligence activities are expected to already be carried out for other purposes during the process of closing the loan, and would often be curtailed if the loan is not related to a purchase, the Bureau estimates that reasonable diligence would take, on average, 15 minutes of staff time. The dollar cost per higher-risk mortgage loan is therefore $11.45.[91] With total annual higher-risk mortgage loans of 280,000, the total cost per year is estimated to be $3,205,000 (rounded to the nearest thousand).[92]

The Bureau assumes based on outreach that the direct costs of conducting appraisals would be passed through to consumers, except in the case of an additional appraisal that would be required by proposed § 1026.XX(b)(3) (requiring an additional appraisal for properties that are the subject of certain 180-day resales).[93]. The Bureau conservatively assumes that the cost of each full-interior appraisal is $600.[94] As noted above, the Bureau estimates that 5,850 second full-interior appraisals would be required each year under the proposal, for a total cost of $3,510,000.[95]

Finally, the proposed rule would also require that free copies of appraisals be distributed to borrowers three days before the loan is closed. Market participants, including a large bank, representatives from the Independent Community Bankers of America (ICBA), and a large independent mortgage bank[96] told the Bureau that, in cases where loans are closed, copies of the appraisal are sent out 100% of the time, so it is assumed that this imposes no incremental cost on creditors.

As noted above, the costs of many of the additional appraisals would be born by the consumers. This costs increase may lead to a reduction in the number of HRMs that are originated. The total losses to creditors of this reduction in HRM originations cannot exceed the costs of the appraisals, which are estimated below to be roughly $27,000,000 per year, as creditors could choose to pay for the appraisals, rather than forgo the transactions.

Costs per institution or loan officer. Aside from the per loan costs just described, the Bureau has estimated that each institution would incur the one-time cost of reviewing the regulation and one-time training costs for all loan officers to become familiar with the provisions of the rule.[97] Since the procedures that would be required by the proposed rule such as ordering appraisals and comparing an APR to APOR are already familiar to creditor employees, one-time training costs are assumed to be 30 minutes. The Bureau estimates that there are 83,000 loan officers in the United States, of which 62,000 are employed at depository institutions and 21,000 are employed at IMBs. Using an average hourly labor cost of $45.85, total one-time training costs are estimated to be $1,903,000 (rounded to the nearest thousand).[98]

It is assumed that the regulation is reviewed by lawyers and compliance officers. Each person reviewing the

[83] (117,000 * 5%) = 5,850

[84] (45,100) + (5,850) = 50,950

[85] Creditors must disclose the following statement, in writing, to a consumer who applies for a higher-risk mortgage loan: ''We may order an appraisal to determine the property's value and charge you for this appraisal. We will promptly give you a copy of any appraisal, even if your loan does not close. You can also pay for an additional appraisal for your own use at your own cost.''

[86] *See* 2012 TILA–RESPA Proposal, (published July 9, 2012), *available at http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_integrated-mortgage-disclosures.pdf.*

[87] 12 CFR 1026.35.

[88] 15 U.S.C. 1639.

[89] (.25 * $45.80) = $11.45 The hourly wage rate is based on a weighted average of loan officer wages at depository institutions of $30.66 and at non-depository institution of $31.81, weighted by the share of HRMs that the Bureau are originated by each type of creditor, and inflated to total labor costs. Wages comprised 67.5% of compensation for employees in credit intermediation and related fields in Q4 2010, according to the Bureau of Labor Statistics Series ID CMU2025220000000D,CMU2025220000000P. *http://www.bls.gov/ncs/ect/#tables.*

[90] ($11.45 * 50,950) = $583,000 (rounded to the nearest thousand).

[91] (.25 * $45.80) = $11.45.

[92] ($11.45 * 280,000) = $3,205,000 (rounded to the nearest thousand).

[93] Proposed § 1026.XX(b)(3)(v) would prohibit the creditor from charging the consumer the cost of the additional appraisal.

[94] Industry appraisal fee information shows median fees ranging from $300 to $600.

[95] (600 * 5,850) = $3,510,000.

[96] Interviews conducted on May 15, 2012 and May 24, 2012.

[98] (83,000 * $45.85 * .5) = $1,903,000 (rounded to the nearest thousand)The averages hourly labor cost here is calculated using employment share, rather than share of HRM originations.

regulation would need to review 18 pages of text. At three minutes per page, this is roughly one hour of review. At all firms, one lawyer is assumed to review the regulation. Compliance officer review is assumed to vary by size and type of the institutions, and it is assumed that in some cases there is no compliance officer review: one compliance officer at each independent mortgage bank, two compliance officers at each depository institution larger than $10 billion in assets; and half a compliance officer (on average) at each depository institution smaller than $10 billion in assets. Total hourly labor costs are estimated to be: $114.06 for attorneys at depository institutions, $43.67 for compliance officers at depository institutions, $113.47 for attorneys at IMBs, and $49.48 for compliance officers and IMBs. The Bureau estimates therefore that the review cost at depository institutions larger than $10 billion in assets is $201.41; at depository institutions smaller than $10 billion in assets the cost is $135.90; and at IMBs is $162.95.[99] The Bureau estimates that there were 128 depository institutions larger than $10 billion in assets that originated mortgages in 2010; 6,825 depository institutions smaller than $10 billion in assets, and 2,515 IMBs, so total one-time costs of review are $1,363,000 (rounded to the nearest thousand).[100]

Potential Costs of the Proposed Rule to Consumers

The direct pecuniary costs to consumers that would be imposed by the proposed rule can be calculated as the incremental cost of having a full interior appraisal instead of using another valuation method for those loans where the cost of the appraisal is not born by the creditor. As described above, the Bureau assumes that consumers would pay directly for all appraisals other than the additional appraisals that would be required because of a recent sale of the property, for a total of 45,100 additional appraisals per year. Assuming, conservatively, the consumer pays $600 for an appraisal that would not otherwise have been conducted, versus $5 for an alternative valuation, gives a total direct costs to consumers of [45,100 * ($600-$5)] = $26,835,000 (rounded to the nearest thousand).[101]

Potential Reduction in Access by Consumers to Consumer Financial Products or Services

Some of the costs that would be imposed by the proposed rule are likely to be passed on to consumers of HRMs, particularly those who would not otherwise have a full-interior appraisal or who would have an additional appraisal. This cost increase could be considered a reduction in consumers' access to mortgages. However, the impact on access to credit is probably negligible. Any costs that derive from the additional underwriting requirements incurred under the proposal are likely to be very small. More important, for both first and subordinate lien loans, are the incremental costs from the difference between the full-interior appraisal and alternative valuation method costs.

However, these are only incremental costs for the fraction of loans where this is not already accepted practice. For first liens, full interior inspections are common industry practice: passing the cost of appraisals on to consumers is current industry practice, and consumers appear to accept the appraisal fee so there is unlikely to be a significant adverse effect on consumers' access to credit. Furthermore, these costs may also be rolled into the loan, up to loan-to-value ratio limits, so buyers are unlikely to face short-term liquidity constraints that prevent purchasing the home. The impact of the proposed rule on higher-risk mortgage loan volumes may be greater for subordinate liens because this is where, in practice, the proposed rule would impose a change from the status quo, and also because the cost of a full interior appraisal is a larger proportion of the loan amount. However, changes in loan volume may be mitigated by consumers rolling the appraisal costs into the loan or the consumer and the creditor splitting the incremental cost of the full-interior appraisal if it is profitable for the creditor to do so.

Impact of the Proposed Rule on Depository Institutions and Credit Unions With $10 Billion or Less in Total Assets, As Described in Section 1026[102]

Depository institutions and credit unions with $10 billion or less in assets would experience the same types of impacts as those described above. The impact on individual institutions would depend on the mix of mortgages that these institutions originate, the number of loan officers that would need to be trained, and the cost of reviewing the regulation. The Bureau estimates that these institutions originated 160,000 higher-risk mortgage loans in 2010. Assuming the mix of purchase money, refinancings, and subordinate lien mortgages was the same at these institutions as for the industry as a whole, the Bureau estimates that the proposal would require these institutions to have 25,400 full interior appraisals conducted for transactions that would otherwise not have a full-interior appraisal, and 3,350 additional full-interior appraisal (as would be required by proposed § 1026.XX(b)(3)), for a total of 28,750 appraisals).

The Bureau estimates that the cost to depository institutions and credit unions with $10 billion or less in assets of reviewing the additional appraisals would be $326,000 (rounded to the nearest thousand). This would be $48 per institution per year.[103]

The Bureau estimates that the cost to depository institutions and credit unions with $10 Billion or less in assets of determining whether to order a second full-interior appraisal would also be $326,000 (rounded to the nearest thousand), or $48 per institution per year.[104]

The Bureau estimates that the cost to depository institutions and credit unions with $10 billion or less in assets of conducting second full interior appraisals for recent sold properties would be $2,010,000, or $295 per institution, per year.[105]

The Bureau estimates that the one-time training costs to depository institutions and credit unions with $10 billion or less would be $636,000, or $93 per institution.[106]

The Bureau estimates that the one-time costs of reviewing the regulation to depository institutions and credit unions with $10 billion or less are described above, and would be $135.90

[99] ($114.06) + (2 * 43.67) = $201.41; ($114.06) + (.5 * $43.67) = $135.90; ($113.47 + $49.48) = $162.95.

[100] (128 * $201.41) + (6,825 * $135.90) + (2,515 * 162.95) = $1,363,000 (rounded to the nearest thousand).

[101] [45,100 * ($600-$5)] = $26,835,000 (rounded to the nearest thousand). Industry appraisal fee information shows median fees ranging from $300 to $600.

[102] Approximately 50 banks with under $10 billion in assets are affiliates of large banks with over $10 billion in assets and subject to Bureau supervisory authority under Section 1025. However, these banks are included in this discussion for convenience.

[103] (28,750 * $45.42 * .25) = $326,000 (rounded to the nearest thousand). ($326,000/6,825) = $48.

[104] (28,750 * $45.42 * .25) = $326,000 (rounded to the nearest thousand).

[105] (3,350 * $600) = $2,010,000; ($2,010,000/6,825) = $ 295.

[106] (28,000 * $45.42 * .5) = $636,000.

per institution, or $927,000 (rounded to the nearest thousand) in total.[107]

Significant Alternatives Considered

In determining what level of review creditors should be required of full interior appraisals related to HRMs, two alternatives were considered. One alternative considered was to require a full technical review of the appraisal that would comply with USPAP3. Such a requirement, however, would add substantially to the cost of each appraisal, as a USPAP3 compliant review can costs nearly as much as a full interior appraisal. Another alternative was to require creditors to have USPAP3 compliant reviews conducts on a sample of the appraisals carried out on properties related to an HRM loan. Reviewing a sample of appraisals, however, would be most useful for creditors making a large number of HRMs and employing the same appraisers for a large number of those loans. Given the small number of HRMs made each year, the value of sampling appraisals for full USPAP3 review is likely to be small.

Impact of the Proposed Rule on Consumers in Rural Areas

The Bureau does not anticipate that the proposed rule would have a unique impact on consumers in rural areas. Table 1 presents some basic statistics on rural households' tenure and mortgage behavior from the 2010 American Community Survey. While the proportion of households that own their dwellings (the alternatives are renting or occupying without paying rent) differs between rural (29%) and non-rural households (43%), conditional on living in an owner occupied property, there is not a large difference in the proportion of households with first mortgages or contracts (70% in rural areas and 67% in non-rural areas) and subordinate liens (5% in rural areas and 4% in non-rural areas). Also, conditional on living in owner occupied property, the proportion of households that have moved in the past year and own their homes is 5% for both groups and the proportion of individuals who have moved into their own homes conditional on having a mortgage is 5% for both groups. This suggests that, conditional on owning a home, rural and non-rural households use first and subordinate liens and move at similar rates.

TABLE 1—OWNERSHIP AND MORTGAGE CHARACTERISTICS OF RURAL AND NON-RURAL HOUSEHOLDS, ACS 2010

	Rural [a]	Not rural [a]
Number of Households	19,052,528	103,502,244
Dwelling Owned or Being Bought	42.92%	64.51%
Has a First Mortgage or a Contract	29.92%	43.14%
Has a First Mortgage or a Contract, Conditional on Ownership	69.72%	66.87%
Has a Closed-End Second Mortgage or a Contract	1.99%	2.80%
Has a Closed-End Second Mortgage or a Contract, Conditional on Ownership	4.65%	4.35%
Moved in in the Past Year, Conditional on Ownership	5.17%	4.86%
Moved in in the Past Year, Conditional on Ownership and Having a First Mortgage or Contract	6.14%	5.71%

Source: American Community Survey, 2010.
Weighted using household weights (HHWT). Tabulations based on responses by person 1.
[a] Rural defined as households reported to not be in a metro area in the METRO variable. Households are considered not rural if they are coded: in a metro area, central city; in a metro area, outside central city; central city status unknown; not identifiable.

As mentioned earlier, many small and rural lenders are excluded from HMDA reporting. Because of this, the Bureau does not attempt to project the number of rural loans in a particular category, such as first-lien HRM, subordinate-lien HRM, etc. However, tabulations of rural loans [108] by HMDA reporters may be informative about patterns of rural HRM usage. As is shown in table 2, the proportion of both first lien purchase and first lien refinance loans are higher among loans secured by properties in rural counties than for properties that are not in rural counties—10% of rural first lien purchase loans are higher-risk mortgage loans while 3% of non-rural first-lien purchase loans are higher-risk mortgage loans. This suggests that rural borrowers may be more likely to incur the cost of the proposed rule than non-rural consumers. This assumes, however, that full-interior appraisal probabilities in the absence of the proposed rule are the same for rural and non-rural originations.

TABLE 2—PROPORTION OF HIGHER-RISK-MORTGAGE LOANS (HRMS) BY RURAL AND NON-RURAL STATUS, HMDA REPORTERS

	Rural		Non-Rural	
	% HRM	Total loans	% HRM	Total loans
First Lien Purchase Loans	9.88	285,762	3.19	2,224,001
First Lien Refinance Loans	5.09	563,210	1.67	4,321,446
Subordinate Liens	12.69	32,958	12.71	185,458
Total	7.17	941,590	2.57	6,934,172

Source: HMDA 2010.
Rural is defined as a loan made outside of a micropolitan or metropolitan statistical area.
HMDA reporters only.

One concern that has been raised is that rural creditors may face challenges in being able to hire appraisers for full interior appraisals, particularly when the second appraisal requirement applies. In order to investigate this

[107] ($114.06) + (.5 * $43.67) = $135.90; ($135.90 * 6,825) = $927,000.

[108] Rural is defined as a loan made outside of a micropolitan or metropolitan statistical area.

further, the current Appraisal Subcommittee Registry is used and the zip code provided by each registered appraiser is geocoded. These results are presented in table 3. Assuming that a county has access to an appraiser if he or she is registered in that or an adjacent county, then the median rural county has access to 107 appraisers. In order to obtain two independent appraisals a county must have access to at least two appraisers. Only 13 counties fail to meet this requirement; all of these counties are in Alaska. When attention is restricted to active appraisers, this number of counties increases to 22.

Although requiring the use of licensed and certified appraisers who adhere to the requisite standards may slow down the origination process, available data suggest the requirement is unlikely to result in widespread inability to originate loans.

TABLE 3—AVAILABILITY OF APPRAISERS BY URBAN/RURAL STATUS OF COUNTY

	Rural counties	Urban counties
Mean Number of Appraisers in County	11	155
Median Number of Appraisers in Own County	6	39
Mean Number of Appraisers in Own and Adjacent County	188	662
Median Number of Appraisers in Own and Adjacent County	107	959
Number with Less than 2 Appraisers in Own or Adjacent Counties	13 [a]	0
N	1355	1788

Source: Appraisal Subcommittee National Registry, downloaded Feb 23, 2012.
Appraisers include all appraisers registered in the National Registry.
Appraisers were assigned to counties based on the zip code provided to the National Registry.
[a] All counties that do not have 2 or more appraisers in the county or adjacent counties are in Alaska.

A number of industry representatives asserted that they believed that creditors making higher-risk mortgage loans in rural areas would find it particularly difficult to comply with the second appraisal requirements. The Agencies, in the section-by-section analysis under the heading ''Potential Exemptions from the Additional Appraisal Requirement,'' are requesting comment on whether the final rule, relying on the exemption authority provided in TILA section 129C(b)(4)(B), should provide an exemption from the second appraisal requirement for loans made in ''rural'' areas. In addition, the Agencies are requesting comment on whether the final rule should use the same definition of ''rural'' that is provided in the ability to repay and qualified mortgage rulemaking implementing new TILA section 129C. Accordingly, the Bureau requests that commenters provide data or other information to help demonstrate how such an exemption would serve the public interest and the promote safety and soundness of creditors.

Potential Use of Transaction Coverage Rate

As noted in the section-by-section analysis above, the Bureau is proposing in its 2012 TILA–RESPA Proposal a simpler, more inclusive definition of the finance charge. The broader definition of finance charge would likely increase the number of mortgage loans that meet the higher-risk mortgage loan trigger.

As discussed in the Bureau's 2012 TILA–RESPA Proposal, in the section-by-section analysis above, and below, the Bureau does not currently have sufficient data to model the impact of the more expansive definition of finance charge on other affected regulatory regimes or the impact of potential modifications to the triggers to more closely approximate existing coverage levels. The Bureau is working to obtain additional data prior to issuing a final rule and is seeking comment on plans for data analysis, and also seeks public comment and data submissions on these topics. The 2012 TILA–RESPA Proposal provides a qualitative assessment of the benefits and costs of expanding the finance charge definition, if the agencies made no modifications to the triggers for HRM or other regimes. In order to facilitate rule-by-rule consideration of potential modifications, this notice provides a qualitative assessment of the impact of potential changes to the APR for higher-risk mortgage loans.

The Bureau's separate proposal to expand the definition of finance charge would be expected to increase the number of loans classified as higher-risk mortgage loans, as discussed in the section-by-section analysis above and in the 2012 TILA–RESPA Proposal. The Agencies are seeking comment on whether to adopt a transaction coverage rate (TCR) to approximately offset this increase. Were the Agencies to adopt the proposed changes, the additional benefits and costs to consumers from further increasing the number of loans classified as higher-risk mortgage loans would not occur. The benefits and costs to consumers with such loans would be the inverse of those described above. In addition, because the TCR excludes fees to non-affiliated third-parties, the TCR might result in some loans not being classified as higher-risk mortgage loans that would qualify under an APR threshold using the current definition of finance charge.[109]

Using different metrics for purposes of disclosures and determining coverage of various regulatory regimes may also impose some ongoing complexity and compliance burden. The Bureau believes that any such effects with regard to transaction coverage rate would be mitigated by the fact that both TCR and APR would be easier to compute under the expanded definition of finance charge than the APR today using the current definition. If the Bureau adopts both the more inclusive finance charge and the TCR adjustment in a final rule pursuant to the 2012 HOEPA Proposal and escrow rule, adopting the TCR adjustment in the higher-risk mortgage rule could ensure consistency across rules. In addition, the Agencies are seeking comment on whether use of the TCR or other trigger modifications should be optional, so that creditors could use the broader definition of finance charge to calculate APR and points and fees triggers if they would prefer. The Bureau believes adoption of the proposed modifications would as a whole reduce the economic impacts on creditors of the more expansive definition of finance charge proposed in the 2012 TILA–RESPA Proposal.

[109] The Bureau believes that the margin of differences between the TCR and current APR is significantly smaller than the margin between the current APR and the APR calculated using the expanded finance charge definition because relatively few third-party fees would be excluded by the TCR that are not already excluded under current rules. The agencies are considering ways to supplement the data analysis described above to better assess this issue.

Additional Analysis Being Considered and Request for Information

The Bureau will further consider the benefits, costs and impacts of the proposed provisions and additional proposed modifications before finalizing the proposal. As noted above, there are a number of areas where additional information would allow the Bureau to better estimate the benefits, costs, and impacts of this proposal and more fully inform the rulemaking. The Bureau asks interested parties to provide comment or data on various aspects of the proposed rule, as detailed in the section-by-section analysis. The most significant of these include information or data addressing:

- Data on lending activity of creditors that are not required to report HMDA data, particularly small or rural institutions and non-reporting IMBs.
- Nationally representative data on the usage of different valuation methods or costs
- Measures to account for potential adoption of a broader definition of finance charge, as separately proposed in the Bureau's 2012 TILA–RESPA Proposal;

To supplement the information discussed in in this preamble and any information that the Bureau may receive from commenters, the Bureau is currently working to gather additional data that may be relevant to this and other mortgage related rulemakings. These data may include additional data from the NMLS and the NMLS MCR, loan file extracts from various lenders, and data from the pilot phases of the National Mortgage Database. The Bureau expects that each of these datasets will be confidential. This section now describes each dataset in turn.

First, as the sole system supporting licensure/registration of mortgage companies for 53 agencies for states and territories and mortgage loan originators under the SAFE Act, NMLS contains basic identifying information for non-depository mortgage loan origination companies. Firms that hold a State license or State registration through NMLS are required to complete either a standard or expanded Mortgage Call Report (MCR). The Standard MCR includes data on each firm's residential mortgage loan activity including applications, closed loans, individual mortgage loan originator activity, line of credit and other data repurchase information by state. It also includes financial information at the company level. The expanded report collects more detailed information in each of these areas for those firms that sell to Fannie Mae or Freddie Mac.[110] To date, the Bureau has received basic data on the firms in the NMLS and de-identified data and tabulations of data from the Mortgage Call Report. These data were used, along with data from HMDA, to help estimate the number and characteristics of IMBs active in various mortgage activities. In the near future, the Bureau may receive additional data on loan activity and financial information from the NMLS including loan activity and financial information for identified lenders. The Bureau anticipates that these data will provide additional information about the number, size, type, and level of activity for non-depository lenders engaging in various mortgage origination and servicing activities. As such, it supplements the Bureau's current data for IMBs reported in HMDA and the data already received from NMLS. For example, these new data will include information about the number and size of closed-end first and second loans originated, fees earned from origination activity, levels of servicing, revenue estimates for each firm and other information. The Bureau may compile some simple counts and tabulations and conduct some basic statistical modeling to better model the levels of various activities at various types of firms, such as the frequency of HRM loans.

Second, the Bureau is working to obtain a random selection of loan-level data from a handful of lenders. The Bureau intends to request loan file data from lenders of various sizes and geographic locations to construct a representative dataset. In particular, the Bureau will request a random sample of ''GFEs'' and ''HUD–1'' forms from loan files for closed-end mortgage loans. These forms include data on some or all loan characteristics including settlement charges, origination charges, appraisal fees, flood certifications, mortgage insurance premiums, homeowner's insurance, title charges, balloon payment, prepayment penalties, origination charges, and credit charges or points. Through conversations with industry, the Bureau believes that such loan files exist in standard electronic formats allowing for the creation of a representative sample for analysis. The Bureau may use these data to further measure the impacts of certain proposed changes. Calculations of various categories of settlement and origination charges may help the Bureau calculate the various impacts of proposed changes to the definitions of finance charges and other aspects of the proposal, including loans that would meet the high rate or high risk definitions mandating additional consumer protections.

Third, the Bureau may also use data from the pilot phases of the National Mortgage Database (NMDB) to refine its proposals and/or its assessments of the benefits costs and impacts of these proposals. The NMDB is a comprehensive database, currently under development, of loan-level information on first lien single-family mortgages. It is designed to be a nationally representative sample (1 percent) and contains data derived from credit reporting agency data and other administrative sources along with data from surveys of mortgage borrowers. The first two pilot phases, conducted over the past two years, vetted the data development process, successfully pretested the survey component and produced a prototype dataset. The initial pilot phases validated that credit repository data are both accurate and comprehensive and that the survey component yields a representative sample and a sufficient response rate. A third pilot is currently being conducted with the survey being mailed to holders of five thousand newly originated mortgages sampled from the prototype NMDB. Based on the 2011 pilot, a response rate of fifty percent or higher is expected. These survey data will be combined with the credit repository information of non-respondents, and then deidentified. Credit repository data will be used to minimize non-response bias, and attempts will be made to impute missing values. The data from the third pilot will not be made public. However, to the extent possible, the data may be analyzed to assist the CFPB in its regulatory activities and these analyses will be made publically available.

The survey data from the pilots may be used by the Bureau to analyze consumers' shopping behavior regarding mortgages. Questions may also assess borrowers' understanding of their loan terms and the various charges involved with origination. Tabulations of the survey data for various populations and simple regression techniques may be used to help the Bureau with its analysis.

In addition to the comment solicited elsewhere in this proposed rule, the Bureau requests commenters to submit data and to provide suggestions for additional data to assess the issues discussed above and other potential benefits, costs, and impacts of the proposed rule. The Bureau also requests comment on the use of the data

[110] More information about the Mortgage Call Report can be found at *http://mortgage.nationwidelicensingsystem.org/slr/common/mcr/Pages/default.aspx.*

described above. Further, the Bureau seeks information or data on the proposed rule's potential impact on consumers in rural areas as compared to consumers in urban areas. The Bureau also seeks information or data on the potential impact of the proposed rule on depository institutions and credit unions with total assets of $10 billion or less as described in Dodd-Frank Act section 1026 as compared to depository institutions and credit unions with assets that exceed this threshold and their affiliates.

VI. Regulatory Flexibility Act

Board

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires an agency either to provide an initial regulatory flexibility analysis with a proposed rule or certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. The proposed regulations cover certain banks, other depository institutions, and non-bank entities that extend higher-risk mortgage loans to consumers. The Small Business Administration (SBA) establishes size standards that define which entities are small businesses for purposes of the RFA.[111] The size standard to be considered a small business is: $175 million or less in assets for banks and other depository institutions; and $7 million or less in annual revenues for the majority of nonbank entities that are likely to be subject to the proposed regulations. Based on its analysis, and for the reasons stated below, the Board believes that the rule will not have a significant economic impact on a substantial number of small entities. Nevertheless, the Board is publishing an initial regulatory flexibility analysis. The Board will, if necessary, conduct a final regulatory flexibility analysis after consideration of comments received during the public comment period.

The Board requests public comment on all aspects of this analysis.

A. Reasons for the Proposed Rule

Section 1471 of the Dodd-Frank Act establishes a new TILA section 129H, which sets forth appraisal requirements applicable to higher-risk mortgages. The Act generally defines ''higher-risk mortgage'' as a closed-end consumer loan secured by a principal dwelling with an APR that exceeds the APOR by 1.5 percent for first-lien loans, 2.5 percent for first-lien jumbo loans, or 3.5 percent for subordinate-liens. The definition of higher-risk mortgage expressly excludes qualified mortgages, as defined in TILA section 129C, as well as reverse mortgage loans that are qualified mortgages as defined in TILA section 129C.

Specifically, new TILA section 129H does not permit a creditor to extend credit in the form of a higher-risk mortgage loan to any consumer without first:

- Obtaining a written appraisal performed by a certified or licensed appraiser who conducts a physical property visit of the interior of the property.
- Obtaining an additional appraisal from a different certified or licensed appraiser if the purpose of the higher-risk mortgage loan is to finance the purchase or acquisition of a mortgaged property from a seller within 180 days of the purchase or acquisition of the property by that seller at a price that was lower than the current sale price of the property. The additional appraisal must include an analysis of the difference in sale prices, changes in market conditions, and any improvements made to the property between the date of the previous sale and the current sale.
- Providing the applicant, at the time of the initial mortgage application, with a statement that any appraisal prepared for the mortgage is for the sole use of the creditor, and that the applicant may choose to have a separate appraisal conducted at the applicant's expense.
- Providing the applicant with one copy of each appraisal conducted in accordance with TILA section 129H without charge, at least three (3) days prior to the transaction closing date.

Section 1400 of the Dodd-Frank Act requires that final regulations to implement these provisions be issued by January 21, 2013.

B. Statement of Objectives and Legal Basis

The **SUPPLEMENTARY INFORMATION** above contains this information. As discussed above, the legal basis for the proposed regulations is new TILA sections 129H(b)(4). 15 U.S.C. 1639h(b)(4). New TILA section 129H was established by section 1471 of the Dodd-Frank Act.

C. Description of Small Entities to Which the Regulation Applies

The proposed regulations apply to creditors that make higher-risk mortgage loans, as defined above. To estimate the number of small entities that will be subject to the requirements of the proposed rule, the Board is relying primarily on data from Reports of Condition and Income (''Call Reports'') to identify asset size of depository institutions and certain subsidiaries of banks and bank companies, as well as home lending data reported by respondents subject to the reporting requirements of the Home Mortgage Disclosure Act (HMDA). The exact number of small entities likely to be affected by the proposal, however, is unknown because the Board lacks reliable sources for certain information. For example, reliable information is not available regarding the extent of mortgage loan origination activity by institutions not subject to the reporting requirements of HMDA; such institutions are predominantly those that have offices only in rural areas or that are very small entities (assets under $40 million as of the end of 2010). Moreover, for the majority of HMDA respondents that are not depository institutions, neither annual revenue information nor exact asset size information is available.

The Board can, however, provide an estimate of a portion of the number of small depository institutions that would be subject to the proposed rule. According to the 2011 HMDA data, there are approximately 1,569 commercial banks, 283 savings and loans, and 1,179 credit unions that could be considered small entities and that extend mortgages, and therefore are potentially subject to the proposed rule. HMDA data indicates that the majority of these institutions extended at least one higher-risk mortgage loan in 2011. As noted above, the available data are insufficient to estimate the number of non-bank entities that would be subject to the proposed rule and that are small as defined by the SBA. However, using the size standard set forth by the SBA for depository institutions ($175 million or less in assets), the Board can estimate based on 2011 HMDA data that about 250 small mortgage companies extended mortgages in 2011.

The number of these small entities that would make higher-risk mortgage loans in the future is unknown. The Board believes that of the small entities identified, however, the majority would make at least one higher-risk mortgage loan, and thus be subject to the proposed rule, because the majority have made such loans in the past.

The Board invites comment regarding the number and type of small entities that would be affected by the proposed rule.

[111] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, available at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

D. Projected Reporting, Recordkeeping and Other Compliance Requirements

The compliance requirements of the proposed regulations are described in detail in the **SUPPLEMENTARY INFORMATION** above.

The proposed regulations generally apply to creditors that make higher-risk mortgage loans, which are generally mortgages with an annual percentage rate that exceeds the average prime offer rate by a specified percentage, subject to certain exceptions. The proposed rule would generally require creditors to obtain an appraisal or appraisals meeting certain specified standards, provide applicants with a notification regarding the use of the appraisals, and give applicants a copy of the written appraisals used.

A creditor would be required to determine if it extends higher-risk mortgage loans and, if so, would need to analyze the regulations. The creditor would need to establish procedures for identifying mortgages subject to the additional appraisal requirements. A creditor making a higher-risk mortgage loan would need to obtain a written appraisal performed by a certified or licensed appraiser who conducts a physical property visit of the interior of the property. Creditors seeking a safe harbor for compliance with this requirement would need to

- Order that the appraiser perform the written appraisal in conformity with the USPAP and title XI of the FIRREA, and any implementing regulations, in effect at the time the appraiser signs the appraiser's certification;
- Verify through the National Registry that the appraiser who signed the appraiser's certification was a certified or licensed appraiser in the State in which the appraised property is located as of the date the appraiser signed the appraiser's certification;
- Confirm that the elements set forth in appendix N to this part are addressed in the written appraisal; and
- Confirm that it has no actual knowledge to the contrary of facts or certifications contained in the written appraisal.

A creditor would also need to determine whether it is financing the purchase or acquisition of a mortgaged property from a seller within 180 days of the purchase or acquisition of the property by that seller, who purchased the property for less than the current sale price. If so, the creditor would need to obtain an additional appraisal of the property and confirm that the appraisal meets the requirements of the first appraisal. The creditor would also need to ensure that the additional appraisal included an analysis of the difference in sale prices, changes in market conditions, and any improvements made to the property between the date of the previous sale and the current sale.

Creditors extending higher-risk mortgages also would need to design, generate, and provide a new notice to applicants. Specifically, they would provide at the time of the initial application the statement that the appraisal is for the sole use of the creditor. In addition, higher-risk mortgage creditors would have to provide the applicant with a copy of each appraisal conducted at least three days prior to closing and develop systems for that purpose.

The Board believes that certain factors might mitigate the economic impact of the proposed rule. The Board believes only a small number of loans would be affected by the proposed rule. For example, according to HMDA data, less than four percent of first-lien mortgage loans in 2010 or 2011 would be classified as ''higher-risk'' and thus subject to any appraisal requirement. Moreover, information collected by the CFPB indicates that fewer than five percent of mortgage loans involve a property that was previously purchased within 180 days. Thus, significantly less than one percent of mortgage loans would be subject to the provisions requiring second appraisals.

In addition, based on outreach, the Board believes that many creditors are already obtaining written appraisals performed by certified or licensed appraisers who conduct a physical property visit of the interior of the property. Creditors may be obtaining such appraisals pursuant to other requirements, such as of FIRREA title XI or the FHA Anti-Flipping Rule, or they may be obtaining the appraisals voluntarily.

Because of the small number of transactions affected, the Board believes the proposed rule is unlikely to have a significant economic impact on a substantial number of small entities. The Board seeks information and comment on any costs, compliance requirements, or changes in operating procedures arising from the application of the proposed rule to small institutions.

E. Identification of Duplicative, Overlapping, or Conflicting Federal Regulations

The Board has not identified any Federal statutes or regulations that would duplicate, overlap, or conflict with the proposed regulations. The proposed rule will work in conjunction with the existing requirements of FIRREA title XI and its implementing regulations.

F. Discussion of Significant Alternatives

As noted in the **SUPPLEMENTARY INFORMATION**, the Board is proposing an alternative definition of ''higher-risk mortgage loan'' that would allow creditors to exclude some fees from the ''rate'' used to determine if a loan is a ''higher-risk mortgage loan.'' By excluding these fees, it is possible that fewer loans would be covered by the rule, and thus burden on creditors could be reduced. In addition, as described in the **SUPPLEMENTARY INFORMATION**, adopting the alternative definition could ensure uniformity and consistency across rules. The proposed rule also exempts reverse mortgages and loans secured only by a residential structure from the rule's coverage. In addition, the proposed rule seeks to establish a less burdensome means for creditors to determine that an appraiser has met certain requirements by providing creditors with a safe harbor. Lastly, the proposed rule seeks to reduce burden by allowing a creditor subject to the additional appraisal requirement under TILA section 129H(b)(2) to obtain an appraisal that contains the analysis required in TILA section 129H(b)(2)(A) only to the extent needed information is known. 15 U.S.C. 1639h(b)(2).

The Board welcomes comments on any other significant alternatives to the proposed rule that accomplish the objectives of section 1471 of the Dodd-Frank Act, which establishes new TILA section 129H, and that minimize any significant economic impact of the proposed rule on small entities.

Bureau

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) 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.[112] The Bureau

[112] For purposes of assessing the impacts of the proposed rule on small entities, ''small entities'' is defined in the RFA to include small businesses, small not-for-profit organizations, and small government jurisdictions. 5 U.S.C. 601(6). A ''small business'' is determined by application of Small Business Administration regulations and reference to the North American Industry Classification System (''NAICS'') classifications and size standards. 5 U.S.C. 601(3). A ''small organization'' is any ''not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' 5 U.S.C. 601(4). A ''small governmental jurisdiction'' is the government of a city, county, town, township, village, school

also is subject to certain additional procedures under the RFA involving the convening of a panel to consult with small business representatives prior to proposing a rule for which an IRFA is required.[113] An IRFA is not required for this proposal because the proposal, if adopted, would not have a significant economic impact on a substantial number of small entities.

A. Summary of Proposed Rule

The empirical approach to calculating the impact that the proposed regulation has on small entities subject to the proposed rule follows the methodology, and uses the same data, as the analysis conducted under Section 1022(a) of the Dodd-Frank Act. The impact analysis focuses on the economic impact of the proposed rule, relative to a pre-statute baseline, for small depository institutions (DIs) and non-depository independent mortgage banks (IMBs). The Small Business Administration classifies DIs (commercial banks, savings institutions, credit unions, and other depository institutions) as small if they have assets less than $175 million, and classifies other real estate credit firms as small if they have less than $7 million in annual revenues.[114]

The proposed rule would implement section 1471 of the Dodd-Frank Act, which establishes appraisal requirements for higher-risk mortgage loans.[115] Consistent with the statute, the proposal would allow a creditor to make a higher-risk mortgage loan only if the following conditions are met:

- The creditor obtains a written appraisal;
- The appraisal is performed by a certified or licensed appraiser;
- The appraiser conducts a physical property visit of the interior of the property;
- At application, the applicant is provided with a statement regarding the purpose of the appraisal, that the creditor will provide the applicant a copy of that any written appraisal, and that the applicant may choose to have a separate appraisal conducted at the expense of the applicant; and
- The creditor provides the consumer with a free copy of any written appraisals obtained for the transaction at least three (3) business days before closing.

In addition, as required by the Act, the proposal would require a higher-risk mortgage loan creditor to obtain an additional written appraisal, at no cost to the borrower, under the following circumstances:

- The higher-risk mortgage loan will finance the acquisition of the consumer's principal dwelling;
- The seller selling what will become the consumer's principal dwelling acquired the home within 180 days prior to the consumer's purchase agreement (measured from the date of the consumer's purchase agreement); and
- The consumer is acquiring the home for a higher price than the seller paid, although comment is requested on whether a threshold price increase would be appropriate.

The additional written appraisal, from a different licensed or certified appraiser, generally must include the following information: an analysis of the difference in sale prices (*i.e.,* the sale price paid by the seller and the acquisition price of the property as set forth in the consumer's purchase agreement), changes in market conditions, and any improvements made to the property between the date of the previous sale and the current sale.

The proposal also includes a request for comments to address a proposed amendment to the method of calculation of the APR that is being proposed as part of other mortgage-related proposals issued for comment by the Bureau. In the Bureau's proposal to integrate mortgage disclosures (2012 TILA–RESPA Proposal), the Bureau is proposing to adopt a more simple and inclusive finance charge calculation for closed-end credit secured by real property or a dwelling.[116] As the finance charge is integral to the calculation of the APR, the Agencies believe it is possible that a more inclusive finance charge could increase the number of loans covered by this rule. The Agencies note that the Bureau currently is seeking data to assist in assessing potential impacts of a more inclusive finance charge in connection with the 2012 TILA–RESPA and its proposal to implement Dodd-Frank Act provision related to ''high-cost'' loans (2012 HOEPA Proposal).[117]

B. Number and Classes of Affected Entities

Of the roughly 17,747 depository institutions (including credit unions) and IMBs, 13,106 are below the relevant small entity thresholds. Of the small institutions, 9,807 are estimated to have originated mortgage loans in 2010. While loan counts exist for credit unions and HMDA-reporting DIs and IMBs, they must be projected for non-HMDA reporters. For IMBs, data on revenues exists for 560 of 2,515 institutions. An accepted statistical method (''nearest neighbor matching'') is used to estimate the number of these institutions that have less than $7 million in revenues from the MCR.

TABLE 4—COUNTS AND ORIGINATIONS OF CREDITORS BY TYPE

Category	NAICS code	Total entities	Small entity threshold	Small entities	Entities that originate any mortgage loans [c]	Small entities that originate any mortgage loans [c]
Commercial Banking [a]	522110	6596	$175 million in assets	3764	6362	3597
Savings Institutions [a]	522120	1145	$175 million in assets	491	1138	487
Credit Unions [b]	522130	7491	$175 million in assets	6569	4359	3441

district, or special district with a population of less than 50,000. 5 U.S.C. 601(5).

[113] 5 U.S.C. 609.

[114] 13 CFR Ch. 1.

[115] The Bureau has proposed separately in the 2012 TILA–RESPA Proposal to expand the definition of the finance charge. If that change is adopted, it would be expected to increase the number of loans classified as higher-risk mortgage loans. The Bureau notes that it has accounted for the impacts of this potential change in the 2012 TILA–RESPA Proposal, including in that Proposal's Initial Regulatory Flexibility Analysis and Small Business Review Panel Process. In connection with the proposed definition change, the Agencies are seeking comment in this proposal on whether to modify the triggers, including by using the transaction coverage rate in place of the APR, to offset the impact of a broader definition of finance charge on higher-risk mortgage loan coverage levels. As discussed in the Dodd-Frank Act section 1022 analysis, adoption of those adjustments might impose some one-time implementation costs and compliance complexity, but the Bureau believes adoption of the proposed modifications would as a whole reduce the economic impacts on creditors of the more expansive definition of finance charge proposed in the 2012 TILA–RESPA Proposal.

[116] See 2012 TILA–RESPA Proposal, pp. 101–127, 725–28, 905–11 (published July 9, 2012), available at *http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_integrated-mortgage-disclosures.pdf.*

[117] See 2012 HOEPA Proposal, pp. 44, 149–211 (published July 9, 2012), available at *http://files.consumerfinance.gov/f/201207_cfpb_proposed-rule_high-cost-mortgage-protections.pdf.*

TABLE 4—COUNTS AND ORIGINATIONS OF CREDITORS BY TYPE—Continued

Category	NAICS code	Total entities	Small entity threshold	Small entities	Entities that originate any mortgage loans [c]	Small entities that originate any mortgage loans [c]
Real Estate Credit [d,e]	522292	2515	$7 million in revenues.	2282	2515	2282
Total		17,747		13106	14374	9807

[a] Asset size obtained from December 2010 Call Report Data downloaded from SNL. The institutions in the category savings institutions are all thrifts.
[b] Asset size obtained from December 2010 NCUA Call Reports.
[c] For HMDA reporters, loan counts from HMDA 2010. For institutions that do not report to HMDA, loan counts projected based on call report data fields and counts for HMDA reporters.
[d] NMLS Mortgage Call Report (MCR) for Q1 and Q2 of 2011. All MCR reporters who originate at least one loan or have positive loan amounts are considered to be engaged in real estate credit (instead of purely mortgage brokers).
[e] Revenues were not missing for 560 of the 2499 institutions. For institutions with missing revenue values revenues were imputed using nearest neighbor matching of the count of originations and the count of brokered loans.

C. Analysis

Although most depository institutions and IMBs are affected by the proposed rule, the proposed rule does not have a significant impact on a substantial number of small entities, as is demonstrated by the burden estimates for small institutions calculated below. For each institution the cost of compliance is calculated and then divided by a measure of revenue.[118] For depository institutions, revenue is obtained from the appropriate call report. For non-depository institutions, the frequency of HRM is not available in the MCR. However, data available in HMDA shows that the proportion of HRM in a non-DI's originations does not vary by origination volume. As such, HMDA data is used in lieu of the MCR data to calculate costs of compliance with the proposed rule.

For small depository institutions, Table 5 reports various statistics for the estimated cost of compliance with the proposed rule as a percentage of revenues using conservative assumptions. The assumptions underlying the Bureau's estimates are explained in the table and are generally discussed in more detail in the Section 1022(b)(2) section. The third column shows that for all small DIs and for each category of small DI, the median cost of compliance is between 0.0% and 0.8% of revenues, and for each category the mean cost of compliance is 0.10% or less of revenues. No small thrifts or small credit unions, and 0.1% of small banks have cost-to-revenue ratios that exceed 1% of revenues.

TABLE 5—COST OF COMPLIANCE FOR DEPOSITORY INSTITUTION AS A PERCENTAGE OF REVENUES, INSTITUTIONS LESS THAN $175 MILLION IN ASSETS

	N	Mean	Median	99th Percentile	Count >1%	Count >3%
All Institutions	7672	0.04%	0.02%	0.26%	9	7
Banks	3764	0.08%	0.06%	0.33%	9	7
Thrifts	491	0.10%	0.08%	0.45%	0	0
Credit Unions	3417	0.01%	0.00%	0.07%	0	0

Sources: HMDA 2010, bank and thrift Q4 2010 call report (obtained from SNL Financial) and credit union call report, and Bureau calculations. Originations drawn from HMDA 2010 for HMDA reporters and imputed for HMDA non-reporters using call report information.
Assumptions: The cost of providing the initial disclosure is $.10. Full-interior appraisals cost $600, alternative valuations cost $5. The probability of full-interior appraisals for a transaction is 95% for purchase-money transactions, 90% for refinance transactions, and 5% for second mortgages. The proportion of resales within 180 days is 5%. Costs of the first full interior appraisal are passed on completely to consumers. The review of the appraisal upon receipt takes 15 minutes of loan officer time. Loan officers are trained for 1 hour on the regulation beyond what considered customary training. Every 3 years the regulation is reviewed for 45 minutes by a lawyer and 0.5 compliance officers. Wages are $29.48 per hour for compliance officers, $30.66 for loan officers, and $76.99 for lawyers, and wages are assumed to be 67.5% of total compensation.[119]

The source of information on the number of HRMs is HMDA, but because HMDA does not provide revenue information it is not possible to determine which IMBs in HMDA have revenue less than $7 million. While most IMBs are small, in order to provide a very conservative estimate we evaluate the compliance costs of the smallest IMBs, as measured by originations. For IMBs that report HMDA data, Table 6 presents estimates of the cost of compliance.[120] Panel A presents estimates of the cost of compliance with the proposed rule for institutions in the first quartile (the smallest 25%) of IMBs by number of originations and Panel B presents estimates of the cost of compliance for all IMBs. As noted above, revenue information is not available for all IMBs so two proxies for revenue are employed: (1) 3% of origination dollar volume, and (2) the median revenue per origination for MCR reporters that report revenue.[121] Using either proxy, the mean cost of

[118] Revenue has been used in other analyses of economic impacts under the RFA. For purposes of this analysis, the Bureau uses revenue as a measure of economic impact. In the future, the Bureau will consider whether an alternative quantifiable or numerical measure may be available that would be more appropriate for financial firms.

[119] Wages comprised 67.5% of compensation for employees in credit intermediation and related fields in Q4 2010, according to the Bureau of Labor Statistics Series ID CMU2025220000000D,CMU2025220000000P. *http://www.bls.gov/ncs/ect/#tables.*

[120] Since IMBs tend to originate-to-distribute regardless of size or urban/rural status, we believe that revenues per origination do not differ substantially between HMDA reporters and non-reporters. Thus, we believe it reasonable to extrapolate the results to HMDA non-reporters.

[121] Industry experts estimate that gross revenues per loan are approximately 3%.

compliance is less than 2 percent of total revenues for first quartile IMBs and median cost of compliance is below 0.3% of revenues. Using the 3% of origination dollar volume measure, 9.3% of institutions in the first quartile have compliance costs that exceed 1% of revenues and 4.4% have compliance costs that exceed 3% of revenues. Similarly, using the median revenue per loan measure, 11.0% have compliance costs that exceed 1% of revenues and 4.4% of have revenues that exceed 3% of revenues. Thus, the Bureau believes that, using the more conservative proxy, no more than approximately 11% of small IMBs would have compliance costs that exceed 1% of revenues, and no more than approximately 4.4% would have costs that exceed 3% of revenues.

TABLE 6—COST OF COMPLIANCE FOR IMB, HMDA REPORTERS ONLY

	N[a]	Mean	Median	99th Percentile	Count >1%	Count >3%
Panel A: 1st Quartile of HMDA Reporting IMBs						
Cost Per Origination	181	$53.28	$9.50	$695.96		
Cost Per Application	211	$7.97	$5.10	$91.89		
Total Cost/(3% of Origination Volume)[b]	181	1.17%	0.21%	13.98%	17	8
(Cost Per Origination)/(Median Revenues Per Loan)[c]	181	1.60%	0.29%	20.91%	20	8
Panel B: All IMBs						
Cost Per Origination	819	$17.82	$6.23	$91.89		
Cost Per Application	849	$5.30	$4.30	$21.60		
Total Cost/(3% of Origination Volume)	819	0.38%	0.11%	3.97%	26	11
(Cost Per Origination)/(Median Revenues Per Loan)	819	0.54%	0.19%	2.76%	32	8

Source: HMDA 2010.

Number of employees at IMBs imputed by application count divided by 1.38 loan-officer days per application for full time loan officers who work 2080 hours per year.

Assumptions: Full-interior appraisal costs $600, alternative valuations cost $5. The probability of full-interior appraisals for a transaction are 95% is purchase-money transactions, 90% for refinance transactions, and 5% for second mortgages. The proportion of resales within 180 days is 5%. Costs of the first full interior appraisal are passed on completely to consumers. The review of the appraisal upon receipt takes 15 minutes of loan officer time. Loan officers are trained for 1 hour on the regulation beyond what is considered customary training. Every 3 years the regulation is reviewed for 45 minutes by a lawyer and a compliance officer. Wages are $33.40 per hour for compliance officers, $31.81 for loan officers, and $76.59 for lawyers, and wages are assumed to be 67.5% of total compensation.

[a] Cost per origination restricted to institutions with positive origination values, cost per application restricted to institutions with positive application values, total cost divided by 3% of origination volume restricted to institutions with positive origination volume.

[b] Industry experts estimate that gross revenues per loan are approximately 3% of origination amount. The MBA's Mortgage Bankers Performance Report reports that in the 4th quarter of 2010 IMBs and subsidiaries reported that total production operating expenses were $4930 per loan, average profits were $1082 per loan, and average loan balance was $208,319.

[c] Median revenue per origination ($3328) calculated using NMLS MCR data from Q1 and Q2 of 2011.

Because many of the costs imposed by the proposed rule are likely to be passed on to consumers, this may result in a decrease in demand for mortgage loans. However, any possible decrease in loan amounts is likely to be negligible. For both first and subordinate lien loans, the incremental costs to consumers are the difference in costs between the full-interior appraisal and alternative valuation method costs and perhaps some additional underwriting charges to reflect additional labor costs. These charges are unlikely to exceed $600. For first liens, full interior inspections are common industry practice so for the typical transaction additional costs passed on to consumers would be small. Furthermore, these costs may also be rolled into the loan, up to loan-to-value ratio limits, so short-term liquidity constraints for buyers are unlikely to bind. Passing the cost of appraisals on to consumers is current industry practice, and consumers appear to accept the appraisal fee, so there is unlikely to be an adverse effect on demand.

A more likely impact would be on the volume of higher-risk mortgage subordinate liens because this is where, in practice, the proposed rule would impose a change from the status quo, and also because the cost of a full interior appraisal is a larger proportion of the loan amount. However, changes in loan volume may be mitigated by consumers rolling the appraisal costs into the loan or the consumer and the creditor splitting the incremental cost of the full-interior appraisal if it is profitable for the creditor to do so. Similarly, the costs imposed on creditors are sufficiently small that they are unlikely to result in a decrease in the supply of credit.

D. Certification

Accordingly, the Director of the Consumer Financial Protection Bureau certifies that this proposal, if adopted, would not have a significant economic impact on a substantial number of small entities. The Bureau requests comment on the analysis above and requests any relevant data.

FDIC

The RFA generally requires that, in connection with a notice of proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities.[122] A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined in regulations promulgated by the Small Business Administration to include banking organizations with total assets of less than or equal to $175 million) and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule.

[122] *See* 5 U.S.C. 601 *et seq.*

As of March 31, 2012, there were approximately 2,571 small FDIC-supervised banks, which include 2,410 state nonmember banks and 161 state-chartered savings banks. The FDIC analyzed the 2010 Home Mortgage Disclosure Act [123] (HMDA) dataset to determine how many loans by FDIC-supervised banks might qualify as HRMs under section 129H of the TILA as added by section 1471 of the Dodd-Frank Act. This analysis reflects that only 70 FDIC-supervised banks originated at least 100 HRMs, with only four banks originating more than 500 HRMs. Further, the FDIC-supervised banks that met the definition of a small entity originated on average less than 8 HRM loans each in 2010.

The proposed rule could impact small FDIC-supervised institutions by:

1. Requiring an appraisal on real estate financial transactions that previously did not require an appraisal,
2. Mandating that the appraiser conduct a physical visit to the interior of the property, and
3. Requiring a second appraisal at the lender's expense in certain situations.

As for the first potential impact, the FDIC noted that Part 323 of the FDIC Rules and Regulations [124] (Part 323) requires financial institutions to obtain an appraisal for federally related transactions unless an exemption applies. Part 323 grants an exemption to the appraisal requirement for real estate-related financial transactions of $250,000 or less. However, Part 323 requires financial institutions to obtain an appropriate evaluation that is consistent with safe and sound banking practices for such transactions. The proposed NPR will supersede this exemption, resulting in creditors having to obtain an appraisal for a HRM transaction regardless of the transaction amount. The requirement to obtain an appraisal rather than an evaluation does not pose a new burden to financial institutions, as they are required by Part 323 to obtain some type of valuation of the mortgaged property. The proposed NPR merely limits the type of permissible valuation to an appraisal for HRMs.

As for the second potential impact, the proposed NPR's requirement affects a lender to the extent that a lender must instruct the appraiser to conduct a physical visit of the interior of the mortgaged property. The USPAP and title XI of FIRREA and the regulations prescribed thereunder do not require appraisers to perform on-site visits. Instead, USPAP requires appraisers to include a certification which clearly states whether the appraiser has or has not personally inspected the subject property. During informal outreach conducted by the Agencies, outreach participants indicated that many creditors require appraisers to perform a physical inspection of the mortgaged property. This requirement is documented in the *Uniform Residential Appraisal Report* form used as a matter of practice in the industry, which includes a certification that the appraiser performed a complete visual inspection of the interior and exterior areas of the subject property. Outreach participants indicated that requiring a physical visit of the interior of the mortgaged property added on average an additional cost of about $50 to the appraisal fee, which is paid by the applicant.

As for the third potential impact, the proposed NPR's requirement to conduct a second appraisal for certain transactions should not affect many FDIC-supervised banks. As previously indicated, FDIC-supervised banks that met the definition of a small entity originated an average of less than 8 HRM loans each in 2010. According to estimates provided by FHFA, about five (5) percent of single-family property sales in 2010 reflected situations in which the same property had been sold within a 180-day period. This information reflects that most small FDIC-supervised banks will have to obtain a second appraisal for a nominal amount of transactions at the banks' expense. The estimated cost of a second appraisal is between $350 to $600.

It is the opinion of the FDIC that the proposed rule will not have a significant economic impact on a substantial number of small entities that it regulates in light of the fact that: (1) Part 323 already requires FDIC-supervised depository institutions to obtain some type of valuation for real estate-related financial transactions; (2) the requirement of conducting a physical visit of the interior of the mortgaged property creates a potential burden for an appraiser, rather than the lender, with the cost being born by the applicant; and (3) the second appraisal requirement should affect a nominal amount of transactions. Accordingly, a regulatory flexibility analysis is not required.

The FDIC seeks comment on whether the proposed rule, if adopted in final form, would impose undue burdens, or have unintended consequences for, small FDIC-supervised institutions and whether there are ways such potential burdens or consequences could be minimized in a manner consistent with section 129H of TILA.

FHFA

The proposed rule applies only to institutions in the primary mortgage market that originate mortgage loans. FHFA's regulated entities—Fannie Mae, Freddie Mac, and the Federal Home Loan Banks—operate in the secondary mortgage markets. In addition, these entities do not come within the meaning of small entities as defined in the Regulatory Flexibility Act (See 5 U.S.C. 601(6)).

NCUA

The RFA generally requires that, in connection with a notice of proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities.[125] A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule. NCUA defines small entities as small credit unions having less than ten million dollars in assets [126] in contrast to the definition of small entities in the rules issued by the Small Business Administration (SBA), which include banking organizations with total assets of less than or equal to $175 million.

NCUA staff analyzed the 2010 Home Mortgage Disclosure Act (HMDA) dataset to determine how many loans by federally insured credit unions (FICUs) might qualify as HRMs under section 129H of the TILA.[127] As of March 31, 2012, there were 2,475 FICUs that met NCUA's small entity definition but none of these institutions reported data to HMDA in 2010. For purposes of this rulemaking and for consistency with the Agencies, NCUA reviewed the dataset for FICUs that met the small entity standard for banking organizations

[123] The FDIC based its analysis on the HMDA data, as it provided a proxy for the characteristics of HRMs. While the FDIC recognizes that fewer higher-price loans were generated in 2010, a more historical review is not possible because the average offer price (a key data element for this review) was not added until the fourth quarter of 2009. The FDIC also recognizes that the HMDA data provides information relative to mortgage lending in metropolitan statistical areas, but not in rural areas.

[124] 12 CFR part 323.

[125] *See* 5 U.S.C. 601 *et seq.*

[126] 68 FR 31949 (May 29, 2003).

[127] NCUA based its analysis on the HMDA data, as it provided a proxy for the characteristics of HRMs. The analysis is restricted to 2010 HMDA data because the average offer price (a key data element for this review) was not added in the HMDA data until the fourth quarter of 2009.

under the SBA's regulations. As of March 31, 2012, there were approximately 6,060, FICUs with total assets of $175 million or less. Of the FICUs which reported 2010 HMDA data, 452 reported at least one HRM. The data reflects that only three FICUs originated at least 100 HRMs, with no FICUs originating more than 500 HRMs, and eighty-eight percent of reporting FICUs originating 10 HRMs or less. Further, FICUs that met the SBA's definition of a small entity originated an average 4 HRM loans each in 2010.[128] For the reasons provided below, NCUA certifies that the proposed rule, if adopted in final form, would not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required.

As previously discussed, section 1471 of the Dodd-Frank Act[129] generally requires the Agencies to jointly prescribe regulations that require a creditor to:

(i) Obtain a written appraisal for a higher-risk mortgage that is prepared by a state licensed or certified appraiser who:

a. Conducted a physical visit of the interior of the property to be mortgage, and

b. Performed the appraisal in compliance with USPAP and title XI of FIRREA, and the regulations prescribed under such title;

(ii) Obtain, at not cost to the applicant, a second appraisal that includes certain analyses from a different certified or licensed appraiser if the purpose of a higher-risk mortgage is to finance the acquisition of the mortgaged property from a seller within 180 days of the seller's acquisition and at a price lower than the current sale price of the property;

(iii) Provide, at the time of the initial mortgage application, the applicant a statement that any appraisal prepared for the mortgage is for the sole use of the creditor, and that the applicant may choose to have a separate appraisal conducted by an appraiser of the applicant's choosing at the applicant's expense; and

(iv) Provide the applicant with one (1) copy of each appraisal without charge and at least three (3) business days prior to the transaction closing date.

The proposed rule implements the appraisal requirements of section 1471 of the Dodd-Frank Act. Part 722 of NCUA's Rules and Regulations[130] requires FICUs to obtain an appraisal for federally related transactions unless an exemption applies. Part 722 grants an exemption to the appraisal requirement for real estate-related financial transactions of $250,000 or less. However, part 722 requires FICUs to obtain an appropriate evaluation that is consistent with safe and sound banking practices for such transactions.

The proposed NPR will supersede this exemption, resulting in FICUs having to obtain an appraisal for a HRM transaction regardless of the transaction amount. The requirement to obtain an appraisal rather than an evaluation does not pose a new burden to financial institutions, as they are required by part 722 to obtain some type of valuation of the mortgaged property. The proposed NPR merely limits the type of permissible valuation to an appraisal for HRMs.

The proposed NPR's requirement to conduct a physical visit of the interior of the mortgaged property potentially adds an additional burden to the appraiser. The USPAP and title XI of FIRREA and the regulations prescribed thereunder do not require appraisers to perform on-site visits. Instead, USPAP requires appraisers to include a certification which clearly states whether the appraiser has or has not personally inspected the subject property. During informal outreach conducted by the Agencies, outreach participants indicated that many creditors require appraisers to perform a physical inspection of the mortgaged property. This requirement is documented in the *Uniform Residential Appraisal Report* form used as a matter of practice in the industry, which includes a certification that the appraiser performed a complete visual inspection of the interior and exterior areas of the subject property. Outreach participants indicated that requiring a physical visit of the interior of the mortgaged property added on average an additional cost of about $50 to the appraisal fee, which is paid by the applicant.

In light of the fact that few loans made by FICUs would qualify as HRMs, the fact that many creditors already require that an appraiser conduct an interior inspection of mortgage collateral property in connection with an appraisal; and the fact that requiring an interior inspection would add a relatively small amount to the cost of an appraisal, the proposed rule will not have a significant economic impact on a substantial number of small FICUs, and therefore, no regulatory flexibility analysis is required.

OCC

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b) (RFA), the regulatory flexibility analysis otherwise required under section 603 of the RFA is not required if the agency certifies that the proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include commercial banks, savings institutions and other depository credit intermediation with assets less than or equal to $175 million[131] and trust companies with total assets of $7 million or less) and publishes its certification and a short, explanatory statement in the **Federal Register** along with its proposed rule.

Section 1471 of the Dodd-Frank Act establishes a new TILA section 129H, which sets forth appraisal requirements applicable to higher-risk mortgage loans. A ''higher-risk mortgage'' generally is a closed-end consumer loan secured by a principal dwelling with an APR that exceeds the APOR by 1.5 percent for first-lien loans with a principal amount below the conforming loan limit, 2.5 percent for first-lien jumbo loans, or 3.5 percent for subordinate-liens. The definition of higher-risk mortgage loan expressly excludes qualified mortgages, as defined in TILA section 129C, as well as reverse mortgage loans that are qualified mortgages as defined in TILA section 129C.

Specifically, new TILA section 129H does not permit a creditor to extend credit in the form of a higher-risk mortgage loan to any consumer without first:

- Obtaining a written appraisal performed by a certified or licensed appraiser who conducts a physical property visit of the interior of the property.
- Obtaining an additional written appraisal from a different certified or licensed appraiser if the purpose of the higher-risk mortgage loan is to finance the purchase or acquisition of a mortgaged property from a seller within 180 days of the purchase or acquisition of the property by that seller at a price

[128] With only a fraction of small FICUs reporting data to HMDA, NCUA also analyzed FICUs not observed in the HMDA data. Using the total number of real estate loans originated by FICUs with less than $175M in total assets, NCUA estimated the average number of HRMs per real estate loan originated. Using this ratio to interpolate the likely number of HRM originations, the analysis suggests that small FICUs originate on average less than 2 HRM loans each year.

[129] *Codified at* section 129H of the Truth-in-Lending Act, 15 U.S.C. 1631 *et seq.*

[130] 12 CFR part 722.

[131] ''A financial institution's assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.'' See footnote 8 of the U.S. Small Business Administration's Table of Size Standards.

that was lower than the current sale price of the property. The additional written appraisal must include an analysis of the difference in sale prices, changes in market conditions, and any improvements made to the property between the date of the previous sale and the current sale.

• Providing the applicant, at the time of the initial mortgage application, with a statement that any written appraisal prepared for the mortgage is for the sole use of the creditor, and that the applicant may choose to have a separate appraisal conducted at the applicant's expense.

• Providing the applicant with one copy of each appraisal conducted in accordance with TILA section 129H without charge, at least three (3) days prior to the transaction closing date.

The OCC currently supervises 1,970 banks (1,281 commercial banks, 66 trust companies, 576 Federal savings associations and 47 branches or agencies of foreign banks). We estimate that less than 1,400 of the banks supervised by the OCC are currently originating one- to four-family residential mortgage loans. Approximately 772 OCC supervised banks are small entities based on the SBA's definition of small entities for RFA purposes. Of these, the OCC estimates that 465 originate mortgages and therefore maybe impacted by the proposed rule.

The OCC classifies the economic impact of total costs on a bank as significant if the total costs in a single year are greater than 5 percent of total salaries and benefits, or greater than 2.5 percent of total non-interest expense. The OCC estimates that the average cost per small bank will range from a lower bound of approximately $10 thousand to an upper bound of approximately $18 thousand. Using the upper bound cost estimate, we believe the proposed rule will have a significant economic impact on three small banks, which is not a substantial number.

Therefore, we believe the proposed rule will not have a significant economic impact on a substantial number of small entities. The OCC certifies that the Proposed Rule would not, if promulgated, have a significant economic impact on a substantial number of small entities.

VII. Paperwork Reduction Act

Certain provisions of this proposed rule contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (Paperwork Reduction Act or PRA). Under the PRA, the Agencies may not conduct or sponsor, and a person is not required to respond to, an information collection unless the information collection displays a valid Office of Management and Budget (OMB) control number. The information collection requirements contained in this joint notice of proposed rulemaking have been submitted to OMB for review and approval by the Bureau, FDIC, NCUA, and OCC under section 3506 of the PRA and section 1320.11 of the OMB's implementing regulations (5 CFR part 1320). The Board reviewed the proposed rule under the authority delegated to the Board by OMB.

Title of Information Collection: Higher-Risk Mortgage Appraisals.

Frequency of Response: Event generated.

Affected Public: Businesses or other for-profit and not-for-profit organizations.[132]

Bureau: Insured depository institutions with more than $10 billion in assets, their depository institution affiliates, and certain non-depository mortgage institutions.[133]

FDIC: Insured state non-member banks, insured state branches of foreign banks, and certain subsidiaries of these entities.

OCC: National banks, Federal savings associations, Federal branches or agencies of foreign banks, or any operating subsidiary thereof.

Board: State member banks, uninsured state branches and agencies of foreign banks.

NCUA: Federally insured credit unions.

Abstract: The collection of information requirements in this proposed rule are found in proposed paragraphs (b)(1), (b)(2), (b)(3), (c), and (d) of 12 CFR 1026.XX. This information is required to protect consumers and promotes the safety and soundness of creditors making higher-risk mortgage loans. This information will be used by creditors to evaluate real estate collateral in higher-risk mortgage loan transactions and by consumers entering these transactions. The collections of information are mandatory for creditors making higher-risk mortgage loans.

The proposed rule would require that, within three days of application, a creditor provide a disclosure that informs consumers regarding the purpose of the appraisal, that the creditor will provide the consumer a copy of any appraisal, and that the consumer may choose to have a separate appraisal conducted at the expense of the consumer (Initial Appraisal Disclosure). *See* proposed 12 CFR 1026.XX(c). If a loan meets the definition of a higher-risk mortgage loan, then the creditor would be required to obtain a written appraisal prepared by a certified or licensed appraiser who conducts a physical visit of the interior of the property that will secure the transaction, and send a copy of the written appraisal to the consumer (Written Appraisal). *See* proposed 12 CFR 1026.XX(b)(1) and (d). To qualify for the safe harbor provided under the proposed rule, a creditor would be required to review the written appraisal as specified in the text of the rule and appendix N. *See* proposed 12 CFR 1026.XX(b)(2). If a loan is classified as a higher-risk mortgage loan that will finance the acquisition of the property to be mortgaged, and the property was acquired within the previous 180 days by the seller at a price that was lower than the current sale price, then the creditor would be required to obtain an additional appraisal that meets the requirements described above (Additional Written Appraisal). *See* proposed 12 CFR 1026.XX(b)(3). The Additional Written Appraisal must also analyze: (1) the difference between the price at which the seller acquired the property and the price the consumer agreed to pay, (2) changes in market conditions between the date the seller acquired the property and the date the consumer agreed to acquire the property, and (3) any improvements made to the property between the date the seller acquired the property and the consumer agreed to acquire the property. *See* proposed 12 CFR 1026.XX(b)(3)(iv). A creditor would also be required to send a copy of the additional written appraisal to the consumer. 12 CFR 1026.XX(d).

Calculation of Estimated Burden

Under the proposed Initial Appraisal Disclosure, the creditor would be required to provide a short, written disclosure within three days of application. Because the disclosure may be classified as a warning label supplied by the Federal government, the Agencies are assigning it no burden for purposes of this PRA analysis.[134] In

[132] The burdens on the affected public generally are divided in accordance with the Agencies' respective administrative enforcement authority under TILA section 108, 15 U.S.C. 1607.

[133] The Bureau and the Federal Trade Commission (FTC) generally both have enforcement authority over non-depository institutions for Regulation Z. Accordingly, for purposes of this PRA analysis, the Bureau has allocated to itself half of the Bureau's estimated burden to non-depository mortgage institutions. The FTC is responsible for estimating and reporting to OMB its share of burden under this proposal.

[134] ''The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the

addition, the Agencies contemplate that once the TILA–RESPA integrated disclosure forms are finalized, the appraisal-related disclosure will be given as part of those forms. As such, this disclosure should not impose additional costs on creditors.

The estimated burden for the proposed Written Appraisal requirements includes the burden the creditor bears to review for completeness the written appraisal in order to satisfy the safe harbor criteria set forth in the proposed rule and to send a copy of the written appraisal to the consumer.

Under the Additional Written Appraisal requirement, if a loan is classified as a higher-risk mortgage loan that will finance the acquisition of the property to be mortgaged, and that property was acquired within the previous 180 days by the seller at a price that was lower than the current sale price, then the creditor would be required to obtain an additional written appraisal containing additional analyses. The additional written appraisal would have to be prepared by a certified or licensed appraiser different from the appraiser performing the other written appraisal for the higher-risk mortgage loan, and a copy of the additional appraisal must be sent to the consumer. The additional appraisal would be required to meet the standards of the other written appraisal for the higher-risk mortgage loan. Thus, in order to qualify for the safe harbor provided in the proposed rule, the written appraisal would also have to be reviewed for completeness.

The agencies estimate that respondents would take, on average, 15 minutes per appraisal to comply with the proposed disclosure requirements under the Written Appraisal requirement. The agencies estimate further that respondents would take, on average, 15 minutes per HRM to investigate and verify the need for a second appraisal; and then an additional 15 minutes to comply, where necessary, with the proposed disclosure requirements of the Second Written Appraisal. For the small fraction of loans requiring a second appraisal, the burden is similar to the prior information collection. The following table summarizes these burdens.

Estimated Paperwork Burden

TABLE 7—SUMMARY OF BURDEN HOURS FOR INFORMATION COLLECTIONS IN PROPOSED RULE

	Estimated number of respondents [a]	Estimated number of appraisals per respondent [b]	Estimated burden hours per appraisal [c]	Estimated total annual burden hours [d] = (a*b*c)
Review and Provide a Copy of a Full Interior Appraisal				
Bureau: [135]				
Depository Inst. > $10 B in total assets + Depository Inst. Affiliates	128	472	0.25	15,104
Non-Depository Inst.	2,515	24	0.25	15,090
FDIC	2,571	8	0.25	5,142
Board [136]	418	24	0.25	2,508
OCC	1,399	69	0.25	24,133
NCUA	2,437	6	0.25	3,656
Total	9,468			65,632
Investigate and Verify Requirement for Second Appraisal				
Bureau:				
Depository Inst. > $10 B in total assets + Depository Inst. Affiliates	128	472	0.25	15,104
Non-Depository Inst.	2,515	24	0.25	15,090
FDIC	2,571	15	0.25	9,641
Board	418	24	0.25	2,508
OCC	1,399	69	0.25	24,133
NCUA	2,437	6	0.25	3,656
Total	9,468			70,132
Conduct and Provide Second Appraisal				
Bureau:				
Depository Inst. > $10 B in total assets + Depository Inst. Affiliates	128	24	0.25	768
Non-Depository Inst.	2,515	1	0.25	629
FDIC	2,571	1	0.25	643
Board	418	1	0.25	105
OCC	1,399	3	0.25	1,049
NCUA	2,437	0.3	0.25	183
Total	9,468			3,376

Notes: (1) Respondents include all institutions estimated to originate HRMs.
(2) There may be an additional ongoing burden of roughly 75 hours for privately insured credit unions estimated to originate HRMs. The Bureau will assume half of the burden for non-depository institutions and the privately insured credit unions.

public is not included within'' the definition of ''collection of information.'' 5 CFR 1320.3(c)(2).

Respondents will also have to review the instructions and legal guidance associated with the proposed rule and train loan officers regarding the proposed rule. The Agencies estimate that these one-time costs are as follows: Bureau 32,754 hours; FDIC: 10,284 hours; Board 3,344 hours; OCC: 19,586 hours; NCUA: 7,311 hours.[137]

Request for Comments on Proposed Information Collection

Comments are specifically requested concerning: (i) Whether the proposed collections of information are necessary for the proper performance of the functions of the Agencies, including whether the information will have practical utility; (ii) the accuracy of the estimated burden associated with the proposed collections of information; (iii) how to enhance the quality, utility, and clarity of the information to be collected; and (iv) how to minimize the burden of complying with the proposed collections of information, including the application of automated collection techniques or other forms of information technology. All comments will become a matter of public record. Comments on the collection of information requirements should be sent to the OMB desk officers for the agencies (*i.e.* ''Desk Officer for the Bureau of Consumer Financial Protection''): by mail to U.S. Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, or by the internet to *http://oira_submission@omb.eop.gov,* with copies to the Agencies at the addresses listed in the **ADDRESSES** section of this **SUPPLEMENTARY INFORMATION.**

FHFA

The proposed rule does not contain any collections of information requiring review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). Therefore, FHFA has not submitted any materials to OMB for review.

List of Subjects

12 CFR Part 34

Appraisal, Appraiser, Banks, Banking, Consumer protection, Credit, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in Lending.

12 CFR Part 164

Appraisals, Mortgages, Reporting and recordkeeping requirements, Savings associations, Truth in Lending.

12 CFR Part 226

Advertising, Appraisal, Appraiser, Consumer protection, Credit, Federal Reserve System, Mortgages, Reporting and recordkeeping requirements, Truth in lending.

12 CFR Part 722

Appraisal, Credit, Credit unions, Mortgages, Reporting and recordkeeping requirements.

12 CFR Part 1026

Advertising, Appraisal, Appraiser, Banking, Banks, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

12 CFR Part 1222

Government sponsored enterprises, Mortgages, Appraisals.

Text of Proposed Revisions

Department of the Treasury

Office of the Comptroller of the Currency

Authority and Issuance

For the reasons set forth in the preamble, the OCC proposes to amend 12 CFR parts 34 and 164, as follows:

PART 34—REAL ESTATE LENDING AND APPRAISALS

1. The authority citation for part 34 is revised to read as follows:

Authority: 12 U.S.C. 1 *et seq.,* 25b, 29, 93a, 371, 1463, 1464, 1465, 1701j-3, 1828(o), 3331 *et seq.,* 5101 *et seq.,* 5412(b)(2)(B) and 15 U.S.C. 1639h.

2. Subpart G to part 34 is added to read as follows:

Subpart G—Appraisals for Higher Risk Mortgage Loans

Sec.
34.201 Authority, purpose and scope.
34.202 Definitions applicable to higher risk mortgage loans.
34.203 Appraisals for higher risk mortgage loans.
Appendix A to Subpart G—Appraisal Safe Harbor Review
Appendix B to Subpart G—OCC Interpretations

Subpart G—Appraisals for Higher Risk Mortgage Loans

§ 34.201 Authority, purpose and scope.

(a) *Authority.* This subpart is issued by the Office of the Comptroller of the Currency under 12 U.S.C. 93a, 12 U.S.C. 1463, 1464 and 15 U.S.C. 1639h.

(b) *Purpose.* The OCC adopts this subpart pursuant to the requirements of section 129H of the Truth in Lending Act (15 U.S.C. 1639h) which provides that a creditor, including a national bank or operating subsidiary, a Federal branch or agency or a Federal savings association or operating subsidiary, may not extend credit in the form of a higher risk mortgage loan without complying with the requirements of section 129H of the Truth in Lending Act (15 U.S.C. 1639h) and this subpart G.

(c) *Scope.* This subpart applies to higher risk mortgage loan transactions entered into by national banks and their operating subsidiaries, Federal branches and agencies and Federal savings associations and operating subsidiaries of savings associations.

§ 34.202 Definitions applicable to higher risk mortgage loans.

For purposes of this subpart:

(a) Annual percentage rate has the same meaning as determined under 12 CFR 1026.22.

(b) Average prime offer rate has the same meaning as in 12 CFR 1026.35(a)(2)(ii).

(c) Creditor has the same meaning as in 12 CFR 1026.2(17).

(d) Reverse mortgage has the same meaning as in 12 CFR 1026.33(a).

(e) Qualified mortgage has the same meaning as in 12 CFR 1026.43(e).

(f) Transaction coverage rate has the same meaning as in 12 CFR 1026.35(a)(2)(i).

§ 34.203 Appraisals for higher risk mortgage loans.

(a) *Definitions.* For purposes of this subpart:

(1) *Certified or licensed appraiser* means a person who is certified or licensed by the State agency in the State in which the property that secures the transaction is located, and who performs the appraisal in conformity with the Uniform Standards of Professional Appraisal Practice and the requirements applicable to appraisers in title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (12 U.S.C. 3331 *et seq.*), and any implementing regulations

[135] The information collection requirements (ICs) in this proposed rule will be incorporated with the Bureau's existing collection associated with Truth in Lending Act (Regulation Z) 12 CFR 1026 (OMB No. 3170–0015).

[136] The ICs in this rule will be incorporated with the Board's Reporting, Recordkeeping, and Disclosure Requirements associated with Regulation Z (Truth in Lending), 12 CFR part 226, and Regulation AA (Unfair or Deceptive Acts or Practices), 12 CFR part 227 (OMB No. 7100–0199). The burden estimates provided in this rule pertain only to the ICs associated with this proposed rulemaking.

[137] Estimated one-time burden is calculated assuming a fixed burden per institution to review the regulations and fixed burden per estimated loan officer in training costs. As a result of the different size and mortgage activities across institutions, the average per-institution one-time burdens vary across the Agencies.

in effect at the time the appraiser signs the appraiser's certification.

(2) Except as provided in paragraph (a)(2)(ii) of this section, *higher-risk mortgage loan* means:

Alternative 1: Annual Percentage Rate—Paragraph (a)(2)(i)

(i) A closed-end consumer credit transaction secured by the consumer's principal dwelling with an annual percentage rate, as determined under 12 CFR 1026.22, that exceeds the average prime offer rate, as defined in 12 CFR 1026.35(a)(2)(ii), for a comparable transaction as of the date the interest rate is set:

(A) By 1.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that does not exceed the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac;

(B) By 2.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that exceeds the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac; and

(C) By 3.5 or more percentage points, for a loan secured by a subordinate lien.

Alternative 2: Transaction Coverage Rate—Paragraph (a)(2)(i)

(i) A closed-end consumer credit transaction secured by the consumer's principal dwelling with a transaction coverage rate, as defined in 12 CFR 1026.35(a)(2)(i), that exceeds the average prime offer rate, as defined in 12 CFR 1026.35(a)(2)(ii), for a comparable transaction as of the date the interest rate is set:

(A) By 1.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that does not exceed the limit in effect as of the date the transaction's interest rate is set for the principal obligation eligible for purchase by Freddie Mac;

(B) By 2.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that exceeds the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac; and

(C) By 3.5 or more percentage points, for a loan secured by a subordinate lien.

(ii) Notwithstanding paragraph (a)(2)(i) of this section, a *higher-risk mortgage loan* does not include:

(A) A qualified mortgage.

(B) A reverse-mortgage transaction.

(C) A loan secured solely by a residential structure.

(3) *National Registry* means the database of information about State certified and licensed appraisers maintained by the Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

(4) *State agency* means a ''State appraiser certifying and licensing agency'' recognized in accordance with section 1118(b) of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (12 U.S.C. 3347(b)) and any implementing regulations.

(b) *Appraisals required for higher-risk mortgage loans.* (1) *In general.* A creditor shall not extend a higher-risk mortgage loan to a consumer without obtaining, prior to consummation, a written appraisal of the property to be mortgaged. The appraisal must be performed by a certified or licensed appraiser who conducts a physical visit of the interior of the property that will secure the transaction.

(2) *Safe harbor.* A creditor is deemed to have obtained a written appraisal that meets the requirements of paragraph (b)(1) of this section if the creditor:

(i) Orders that the appraiser perform the appraisal in conformity with the Uniform Standards of Professional Appraisal Practice and title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (12 U.S.C. 3331 *et seq.*), and any implementing regulations, in effect at the time the appraiser signs the appraiser's certification;

(ii) Verifies through the National Registry that the appraiser who signed the appraiser's certification was a certified or licensed appraiser in the State in which the appraised property is located as of the date the appraiser signed the appraiser's certification;

(iii) Confirms that the elements set forth in Appendix A to this subpart are addressed in the written appraisal; and

(iv) Has no actual knowledge to the contrary of facts or certifications contained in the written appraisal.

(3) *Additional appraisal for certain higher-risk mortgage loans.* (i) *In general.* A creditor shall not extend a higher-risk mortgage loan to a consumer to finance the acquisition of the consumer's principal dwelling without obtaining, prior to consummation, two written appraisals, if:

(A) The seller acquired the property 180 or fewer days prior to the date of the consumer's agreement to acquire the property from the seller; and

(B) The price at which the seller acquired the property was lower than the price that the consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller, by an amount equal to or greater than *XX.*

(ii) *Different appraisers.* The two appraisals required under paragraph (b)(3)(i) of this section may not be performed by the same certified or licensed appraiser.

(iii) *Relationship to paragraph (b)(1) of this section.* If two appraisals must be obtained under paragraph (b)(3)(i) of this section, each appraisal shall meet the requirements of paragraph (b)(1) of this section.

(iv) *Requirements for the additional appraisal.* In addition to meeting the requirements for an appraisal under paragraph (b)(1) of this section, the additional appraisal must include an analysis of:

(A) The difference between the price at which the seller acquired the property and the price that the consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller;

(B) Changes in market conditions between the date the seller acquired the property and the date of the consumer's agreement to acquire the property; and

(C) Any improvements made to the property between the date the seller acquired the property and the date of the consumer's agreement to acquire the property.

(v) *No charge for the additional appraisal.* If the creditor must obtain two appraisals under paragraph (b)(3)(i) of this section, the creditor may charge the consumer for only one of the appraisals.

(vi) *Creditor's determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.*

(A) *Reasonable diligence.* A creditor shall exercise reasonable diligence to determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section are met.

(B) *Inability to make the determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.* If, after exercising reasonable diligence, a creditor cannot determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section are met, the creditor shall not extend a higher-risk mortgage loan without obtaining, prior to consummation, two written appraisals in accordance with paragraphs (b)(3)(ii) through (v) of this section. However, the additional appraisal shall include an analysis of the factors in paragraph (b)(3)(iv) of this section only to the extent that the information necessary for the appraiser

to perform the analysis can be determined.

(c) *Required disclosure.* (1) *In general.* A creditor shall disclose the following statement, in writing, to a consumer who applies for a higher-risk mortgage loan: ''We may order an appraisal to determine the property's value and charge you for this appraisal. We will promptly give you a copy of any appraisal, even if your loan does not close. You can pay for an additional appraisal for your own use at your own cost.''

(2) *Timing of disclosure.* The disclosure required by paragraph (c)(1) of this section shall be mailed or delivered not later than the third business day after the creditor receives the consumer's application. If the disclosure is not provided to the consumer in person, the consumer is presumed to have received the disclosures three business days after they are mailed or delivered.

(d) *Copy of appraisals.* (1) *In general.* A creditor shall provide to the consumer a copy of any written appraisal performed in connection with a higher-risk mortgage loan pursuant to the requirements of paragraph (b) of this section.

(2) *Timing.* A creditor shall provide a copy of each written appraisal pursuant to paragraph (d)(1) of this section no later than three business days prior to consummation of the higher-risk mortgage loan.

(3) *Form of copy.* Any copy of a written appraisal required by paragraph (d)(1) of this section may be provided to the applicant in electronic form, subject to compliance with the consumer consent and other applicable provisions of the Electronic Signatures in Global and National Commerce Act (E-Sign Act) (15 U.S.C. 7001 *et seq.*).

(4) *No charge for copy of appraisal.* A creditor shall not charge the applicant for a copy of a written appraisal required to be provided to the consumer pursuant to paragraph (d)(1) of this section.

(e) *Relation to other rules.* These rules were developed jointly by the Federal Reserve Board (Board), the OCC, the Federal Deposit Insurance Corporation, the National Credit Union Administration, the Federal Housing Finance Agency, and the Consumer Financial Protection Bureau (Bureau). These rules are substantively identical to the Board's and the Bureau's higher-risk mortgage appraisal rules published separately in 12 CFR 226.43 and 12 CFR 1026.XX.

Appendix A to Subpart G—Appraisal Safe Harbor Review

To qualify for the safe harbor provided in § 34.203(b)(2) a creditor must check the appraisal report to confirm that the written appraisal:

1. Identifies the creditor who ordered the appraisal and the property and the interest being appraised.
2. Indicates whether the contract price was analyzed.
3. Addresses conditions in the property's neighborhood.
4. Addresses the condition of the property and any improvements to the property.
5. Indicates which valuation approaches were used, and includes a reconciliation if more than one valuation approach was used.
6. Provides an opinion of the property's market value and an effective date for the opinion.
7. Indicates that a physical property visit of the interior of the property was performed.
8. Includes a certification signed by the appraiser that the appraisal was prepared in accordance with the requirements of the Uniform Standards of Professional Appraisal Practice.
9. Includes a certification signed by the appraiser that the appraisal was prepared in accordance with the requirements of title XI of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, as amended (12 U.S.C. 3331 *et seq.*), and any implementing regulations.

Appendix B to Subpart G—OCC Interpretations

Commentary to § 34.203—Appraisals for Higher-Risk Mortgage Loans

34.203(a) Definitions.

34.203(a)(1) Certified or licensed appraiser.

1. *USPAP.* The Uniform Standards of Professional Appraisal Practice (USPAP) are established by the Appraisal Standards Board of the Appraisal Foundation (as defined in 12 U.S.C. 3350(9)). Under § 34.203(a)(1), the relevant USPAP standards are those found in the edition of USPAP in effect at the time the appraiser signs the appraiser's certification.

2. *Appraiser's certification.* The appraiser's certification refers to the certification that must be signed by the appraiser for each appraisal assignment. This requirement is specified in USPAP Standards Rule 2–3.

3. *FIRREA title XI and implementing regulations.* The relevant regulations are those prescribed under section 1110 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA), as amended (12 U.S.C. 3339), that relate to an appraiser's development and reporting of the appraisal in effect at the time the appraiser signs the appraiser's certification. Paragraph (3) of FIRREA section 1110 (12 U.S.C. 3339(3)), which relates to the review of appraisals, is not relevant for determining whether an appraiser is a certified or licensed appraiser under § 34.203(a)(1).

34.203(a)(2) Higher-risk mortgage loan.

Paragraph 34.203(a)(2)(i).

1. *Principal dwelling.* The term ''principal dwelling'' has the same meaning under § 34.203(a)(2) as under 12 CFR 1026.2(a)(24). *See* the Official Staff Interpretations to the Bureau's Regulation Z (Supplement I to Part 1026), comment 2(a)(24)-3.

2. *Average prime offer rate.* For guidance on average prime offer rates, *see* the Official Staff Interpretations to the Bureau's Regulation Z, comment 35(a)(2)-1.

3. *Comparable transaction.* For guidance on determining the average prime offer rate for comparable transactions, *see* the Official Staff Interpretations to the Bureau's Regulation Z, comments 35(a)(2)-2 and -4.

4. *Rate set.* For guidance on the date the annual percentage rate is set, *see* the Official Staff Interpretations to the Bureau's Regulation Z, comment 35(a)(2)-3.

Paragraph 34.203(a)(2)(ii)(C).

1. *Secured solely by a residential structure.* Loans secured solely by a residential structure cannot be ''higher-risk mortgage loans.'' Thus, for example, a loan secured by a manufactured home and the land on which it is sited could be a ''higher-risk mortgage loan.'' By contrast, a loan secured solely by a manufactured home cannot be a ''higher-risk mortgage loan.''

34.203(b) Appraisals required for higher-risk mortgage loans.

34.302(b)(1) In general.

1. *Written appraisal—electronic transmission.* To satisfy the requirement that the appraisal be ''written,'' a creditor may obtain the appraisal in paper form or via electronic transmission.

34.203(b)(2) Safe harbor.

1. *Safe harbor.* A creditor that satisfies the conditions in § 34.203(b)(2)(i) through (iv) will be deemed to have complied with the appraisal requirements of § 34.203(b)(1). A creditor that does not satisfy the conditions in § 34.203(b)(2)(i) through (iv) does not necessarily violate the appraisal requirements of § 34.203(b)(1).

Paragraph 34.203(b)(2)(iii).

1. *Confirming elements in the appraisal.* To confirm that the elements in Appendix A to this subpart are included in the written appraisal, a creditor need not look beyond the face of the written appraisal and the appraiser's certification.

34.203(b)(3) Additional appraisal for certain higher-risk mortgage loans.

1. *Acquisition.* For purposes of § 34.203(b)(3), the terms ''acquisition'' and ''acquire'' refer to the acquisition of legal title to the property pursuant to applicable State law, including by purchase.

34.203(b)(3)(i) In general.

1. *Two appraisals.* An appraisal that was previously obtained in connection with the seller's acquisition or the financing of the seller's acquisition of the property does not satisfy the requirements of § 34.203 (b)(3).

Paragraph 34.203(b)(3)(i)(A).

1. *180-day calculation.* The time period described in § 34.203(b)(3)(i)(A) is calculated by counting the day after the date on which the seller acquired the property, up to and including the date of the consumer's agreement to acquire the property that secures the transaction. *See also* comments 34.203(b)(3)(i)(A)-2 and -3 in this Appendix B. For example, assume that the creditor determines that date of the consumer's acquisition agreement is October 15, 2012, and that the seller acquired the property on April 17, 2012. The first day to be counted

in the 180-day calculation would be April 18, 2012, and the last day would be October 15, 2012. In this case, the number of days would be 181, so an additional appraisal is not required.

2. *Date of the consumer's agreement to acquire the property.* For the date of the consumer's agreement to acquire the property under § 34.203(b)(3)(i)(A), the creditor should use the date on which the consumer and the seller signed the agreement provided to the creditor by the consumer. The date on which the consumer and the seller signed the agreement might not be the date on which the consumer became contractually obligated under State law to acquire the property. For purposes of § 34.203(b)(3)(i)(A), a creditor is not obligated to determine whether and to what extent the agreement is legally binding on both parties. If the dates on which the consumer and the seller signed the agreement differ, the creditor should use the later of the two dates.

3. *Date seller acquired the property.* For purposes of § 34.203(b)(3)(i)(A), the date on which the seller acquired the property is the date on which the seller became the legal owner of the property pursuant to applicable State law. *See also* comments 34.203(b)(3)(vi)(A)-1 and -2 and comment (b)(3)(vi)(B)-1 in this Appendix B.

Paragraph 34.203(b)(3)(i)(B).

1. *Price at which the seller acquired the property.* The price at which the seller acquired the property refers to the amount paid by the seller to acquire the property. The price at which the seller acquired the property does not include the cost of financing the property. *See also* comments 34.203(b)(3)(vi)(A)-1 and (b)(3)(vi)(B)-1 in this Appendix B.

2. *Price the consumer is obligated to pay to acquire the property.* The price the consumer is obligated to pay to acquire the property is the price indicated on the consumer's agreement with the seller to acquire the property. *See* comment 34.203(b)(3)(i)(A)-2 in this Appendix B. The price the consumer is obligated to pay to acquire the property from the seller does not include the cost of financing the property. For purposes of § 34.203(b)(3)(i)(B), a creditor is not obligated to determine whether and to what extent the agreement is legally binding on both parties.

34.203(b)(3)(iv) Requirements for the additional appraisal.

1. *Determining acquisition dates and prices used in the analysis of the additional appraisal.* For guidance on identifying the date the seller acquired the property, see comment 34.203(b)(3)(i)(A)-3 in this Appendix B. For guidance on identifying the date of the consumer's agreement to acquire the property, *see* comment 34.203(b)(3)(i)(A)-2 in this Appendix B. For guidance on identifying the price at which the seller acquired the property, *see* comment 34.203(b)(3)(i)(B)-1 in this Appendix B. For guidance on identifying the price the consumer is obligated to pay to acquire the property, *see* comment 34.203(b)(3)(i)(B)-2 in this Appendix B.

34.203(b)(3)(v) No charge for additional appraisal.

1. *Fees and mark-ups.* The creditor is prohibited from charging the consumer for the performance of one of the two appraisals required under § 34.203(b)(3)(i), including by imposing a fee specifically for that appraisal or by marking up the interest rate or any other fees payable by the consumer in connection with the higher-risk mortgage loan.

Paragraph 34.203(b)(3)(vi) Creditor's determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.

34.203(b)(3)(vi)(A) In general.

1. *Reasonable diligence—documentation required.* A creditor acts with reasonable diligence to determine when the seller acquired the property and whether the price at which the seller acquired the property is lower than the price reflected in the consumer's agreement to acquire the property if, for example, the creditor bases its determination on information contained in written source documents, such as:

i. A copy of the recorded deed from the seller.

ii. A copy of a property tax bill.

iii. A copy of any owner's title insurance policy obtained by the seller.

iv. A copy of the RESPA settlement statement from the seller's acquisition (*i.e.,* the HUD–1 or any successor form [138]).

v. A property sales history report or title report from a third-party reporting service.

vi. Sales price data recorded in multiple listing services.

vii. Tax assessment records or transfer tax records obtained from local governments.

viii. An appraisal report signed by an appraiser who certifies that the appraisal was performed in conformity with USPAP that shows any prior transactions for the subject property.

ix. A copy of a title commitment report [139] detailing the seller's ownership of the property, the date it was acquired, or the price at which the seller acquired the property.

x. A property abstract.

2. *Reasonable diligence—oral statements insufficient.* Reliance on oral statements of interested parties, such as the consumer, seller, or mortgage broker, does not constitute reasonable diligence under § 34.203(b)(3)(vi)(A).

34.203(b)(3)(vi)(B) Inability to make the determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this subpart.

1. *Lack of information and conflicting information—two appraisals required.* Unless a creditor can demonstrate that the requirement to obtain two appraisals under § 34.203(b)(3)(i) does not apply, the creditor must obtain two written appraisals in compliance with § 34.203(b)(3)(vi)(B). *See also* comment 34.203(b)(3)(vi)(B)–2. For example:

i. Assume a creditor orders and reviews the results of a title search and the seller's acquisition price was not included. In this case, the creditor would not be able to determine whether the price at which the seller acquired the property was lower than the price the consumer is obligated to pay under the consumer's acquisition agreement, pursuant to § 34.203(b)(3)(i)(B). Before extending a higher-risk mortgage loan, the creditor must either: perform additional diligence to obtain information showing the seller's acquisition price and determine whether two written appraisals would be required based on that information; or obtain two written appraisals in compliance with § 34.203(b)(3)(vi)(B). *See also* comment 34.203(b)(3)(vi)(B)–2 in this Appendix B.

ii. Assume a creditor reviews the results of a title search indicating that the last recorded purchase was more than 180 days before the consumer's agreement to acquire the property. Assume also that the creditor subsequently receives an appraisal report indicating that the seller acquired the property fewer than 180 days before the consumer's agreement to acquire the property. In this case, the creditor would not be able to determine whether the seller acquired the property within 180 days of the date of the consumer's agreement to acquire the property from the seller, pursuant to § 34.203(b)(3)(i)(A). Before extending a higher-risk mortgage loan, the creditor must either: perform additional diligence to obtain information confirming the seller's acquisition date and determine whether two written appraisals would be required based on that information; or obtain two written appraisals in compliance with § 34.203(b)(3)(vi)(B). *See also* comment 34.203(b)(3)(vi)(B)–2 in this Appendix B.

2. *Lack of information and conflicting information—requirements for the additional appraisal.* In general, the additional appraisal required under § 34.203(b)(3)(i) should include an analysis of the factors listed in § 34.203(b)(3)(iv)(A)–(C). However, if, following reasonable diligence, a creditor cannot determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of § 34.203 are met due to a lack of information or conflicting information, the required additional appraisal must include the analyses required under § 34.203(b)(3)(iv)(A) through (C) only to the extent that the information necessary to perform the analysis is known. For example:

i. Assume that a creditor is able, following reasonable diligence, to determine that the date on which the seller acquired the property occurred 180 or fewer days prior to the date of the consumer's agreement to acquire the property. However, the creditor is unable, following reasonable diligence, to determine the price at which the seller acquired the property. In this case, the creditor is required to obtain an additional written appraisal that includes an analysis

[138] The Bureau has developed a successor form to the RESPA settlement statement as explained in the Bureau's proposal for an integrated TILA–RESPA disclosure form. See the Bureau's 2012 TILA–RESPA Proposal.

[139] The ''title commitment report'' is a document from a title insurance company describing the property interest and status of its title, parties with interests in the title and the nature of their claims, issues with the title that must be resolved prior to closing of the transaction between the parties to the transfer, amount and disposition of the premiums, and endorsements on the title policy. This document is issued by the title insurance company prior to the company's issuance of an actual title insurance policy to the property's transferee and/or creditor financing the transaction. In different jurisdictions, this instrument may be referred to by different terms, such as a title commitment, title binder, title opinion, or title report.

under paragraphs (b)(3)(iv)(B) and (b)(3)(iv)(C) of § 34.203 of the changes in market conditions and any improvements made to the property between the date the seller acquired the property and the date of the consumer's agreement to acquire the property. However, the creditor is not required to obtain an additional written appraisal that includes analysis under § 34.203(b)(3)(iv)(A) of the difference between the price at which the seller acquired the property and the price that the consumer is obligated to pay to acquire the property.

34.203(c) Required disclosure.

34.203(c)(1) In general.

1. *Multiple applicants.* When two or more consumers apply for a loan subject to this section, the creditor is required to give the disclosure to only one of the consumers.

34.203(d) Copy of appraisals.

34.203(d)(1) In general.

1. *Multiple applicants.* When two or more consumers apply for a loan subject to this subpart, the creditor is required to give the copy of each required appraisal to only one of the consumers.

34.203(d)(4) No charge for copy of appraisal.

1. *Fees and mark-ups.* The creditor is prohibited from charging the consumer for any copy of an appraisal required to be provided under § 34.203(d)(1), including by imposing a fee specifically for a required copy of an appraisal or by marking up the interest rate or any other fees payable by the consumer in connection with the higher-risk mortgage loan.

PART 164—APPRAISALS

3. The authority citation for Part 164 is revised to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1828(m), 3331 *et seq.,* 5412(b)(2)(B), 15 U.S.C. 1639h.

§§ 164.1–164.8 [Designated as Subpart A]

4. Sections 164.1 through 164.8 are designated as Subpart A.

Subpart A—Appraisals

4a. The heading of subpart A is added to read as set forth above.

5. Subpart B is added to read as follows:

Subpart B—Appraisals for Higher Risk Mortgage Loans

Sec.
164.20 Authority, purpose and scope.
164.21 Application of requirements for higher risk mortgage loans.

164.20 Authority, purpose and scope.

(a) *Authority.* This subpart is issued under 12 U.S.C. 1463, 1464 and 15 U.S.C. 1639h.

(b) *Purpose.* This subpart implements section 129H of the Truth in Lending Act (15 U.S.C. 1639h), which provides that a creditor, including a Federal savings association or its operating subsidiary, may not extend credit in the form of a higher risk mortgage loan without complying with the requirements of section 129H of the Truth in Lending Act (15 U.S.C. 1639h) and the implementing regulations.

(c) *Scope.* This subpart applies to higher risk mortgage loan transactions entered into by Federal savings associations and operating subsidiaries of savings associations.

§ 164.21 Application of requirements for higher risk mortgage loans.

Federal savings associations and their operating subsidiaries may not extend credit in the form of a higher risk mortgage loan without complying with the requirements of Section 129H of the Truth in Lending Act (15 U.S.C. 1639h) and the implementing regulations adopted by the OCC at 12 CFR Part 34, Subpart G.

Board of Governors of the Federal Reserve System

Authority and Issuance

For the reasons stated above, the Board of Governors of the Federal Reserve System proposes to amend Regulation Z, 12 CFR part 226, as follows:

PART 226—TRUTH IN LENDING ACT (REGULATION Z)

6. The authority citation for part 226 is revised to read as follows:

Authority: 12 U.S.C. 3806; 15 U.S.C. 1604, 1637(c)(5), 1639(l), and 1639h; Pub. L. 111–24 section 2, 123 Stat. 1734; Pub. L. 111–203, 124 Stat. 1376.

7. New § 226.43 is added to read as follows:

§ 226.43—Appraisals for higher-risk mortgage loans

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

(1) *Certified or licensed appraiser* means a person who is certified or licensed by the State agency in the State in which the property that secures the transaction is located, and who performs the appraisal in conformity with the Uniform Standards of Professional Appraisal Practice and the requirements applicable to appraisers in title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (12 U.S.C. 3331 *et seq.*), and any implementing regulations, in effect at the time the appraiser signs the appraiser's certification.

(2) Except as provided in paragraph (a)(2)(ii) of this section, *higher-risk mortgage loan* means:

Alternative 1: Annual Percentage Rate—Paragraph (a)(2)(i)

(i) A closed-end consumer credit transaction secured by the consumer's principal dwelling with an annual percentage rate, as determined under 12 CFR 1026.22, that exceeds the average prime offer rate, as defined in 12 CFR 1026.35(a)(2)(ii), for a comparable transaction as of the date the interest rate is set:

(A) By 1.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that does not exceed the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac;

(B) By 2.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that exceeds the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac; and

(C) By 3.5 or more percentage points, for a loan secured by a subordinate lien.

Alternative 2: Transaction Coverage Rate—Paragraph (a)(2)(i)

(i) A closed-end consumer credit transaction secured by the consumer's principal dwelling with a transaction coverage rate, as defined in 12 CFR 1026.35(a)(2)(i), that exceeds the average prime offer rate, as defined in 12 CFR 1026.35(a)(2)(ii), for a comparable transaction as of the date the interest rate is set:

(A) By 1.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that does not exceed the limit in effect as of the date the transaction's interest rate is set for the principal obligation eligible for purchase by Freddie Mac;

(B) By 2.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that exceeds the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac; and

(C) By 3.5 or more percentage points, for a loan secured by a subordinate lien.

(ii) Notwithstanding paragraph (a)(2)(i) of this section, a *higher-risk mortgage loan* does not include:

(A) A qualified mortgage as defined in 12 CFR 1026.43(e).

(B) A reverse-mortgage transaction as defined in 12 CFR 1026.33(a).

(C) A loan secured solely by a residential structure.

(3) *National Registry* means the database of information about State

certified and licensed appraisers maintained by the Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

(4) *State agency* means a ''State appraiser certifying and licensing agency'' recognized in accordance with section 1118(b) of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (12 U.S.C. 3347(b)) and any implementing regulations.

(b) *Appraisals required for higher-risk mortgage loans.* (1) *In general.* A creditor shall not extend a higher-risk mortgage loan to a consumer without obtaining, prior to consummation, a written appraisal performed by a certified or licensed appraiser who conducts a physical visit of the interior of the property that will secure the transaction.

(2) *Safe harbor.* A creditor is deemed to have obtained a written appraisal that meets the requirements of paragraph (b)(1) of this section if the creditor:

(i) Orders that the appraiser perform the written appraisal in conformity with the Uniform Standards of Professional Appraisal Practice and title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (12 U.S.C. 3331 *et seq.*), and any implementing regulations, in effect at the time the appraiser signs the appraiser's certification;

(ii) Verifies through the National Registry that the appraiser who signed the appraiser's certification was a certified or licensed appraiser in the State in which the appraised property is located as of the date the appraiser signed the appraiser's certification;

(iii) Confirms that the elements set forth in appendix N to this part are addressed in the written appraisal; and

(iv) Has no actual knowledge to the contrary of facts or certifications contained in the written appraisal.

(3) *Additional appraisal for certain higher-risk mortgage loans.* (i) *In general.* A creditor shall not extend a higher-risk mortgage loan to a consumer to finance the acquisition of the consumer's principal dwelling without obtaining, prior to consummation, two written appraisals, if:

(A) The seller acquired the property 180 or fewer days prior to the date of the consumer's agreement to acquire the property from the seller; and

(B) The price at which the seller acquired the property was lower than the price that the consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller, by an amount equal to or greater than *XX.*

(ii) *Different appraisers.* The two appraisals required under paragraph (b)(3)(i) of this section may not be performed by the same certified or licensed appraiser.

(iii) *Relationship to paragraph (b)(1) of this section.* If two appraisals must be obtained under paragraph (b)(3)(i) of this section, each appraisal shall meet the requirements of paragraph (b)(1) of this section.

(iv) *Requirements for the additional appraisal.* In addition to meeting the requirements for an appraisal under paragraph (b)(1) of this section, the additional appraisal must include an analysis of:

(A) The difference between the price at which the seller acquired the property and the price that the consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller;

(B) Changes in market conditions between the date the seller acquired the property and the date of the consumer's agreement to acquire the property; and

(C) Any improvements made to the property between the date the seller acquired the property and the date of the consumer's agreement to acquire the property.

(v) *No charge for the additional appraisal.* If the creditor must obtain two appraisals under paragraph (b)(3)(i) of this section, the creditor may charge the consumer for only one of the appraisals.

(vi) *Creditor's determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.*

(A) *Reasonable diligence.* A creditor shall exercise reasonable diligence to determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section are met.

(B) *Inability to make the determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.* If, after exercising reasonable diligence, a creditor cannot determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section are met, the creditor shall not extend a higher-risk mortgage loan without obtaining, prior to consummation, two written appraisals in accordance with paragraphs (b)(3)(ii) through (v) of this section. However, the additional appraisal shall include an analysis of the factors in paragraph (b)(3)(iv) of this section only to the extent that the information necessary for the appraiser to perform the analysis can be determined.

(c) *Required disclosure.* (1) *In general.* A creditor shall disclose the following statement, in writing, to a consumer who applies for a higher-risk mortgage loan: ''We may order an appraisal to determine the property's value and charge you for this appraisal. We will promptly give you a copy of any appraisal, even if your loan does not close. You can pay for an additional appraisal for your own use at your own cost.''

(2) *Timing of disclosure.* The disclosure required by paragraph (c)(1) of this section shall be mailed or delivered not later than the third business day after the creditor receives the consumer's application. If the disclosure is not provided to the consumer in person, the consumer is presumed to have received the disclosures three business days after they are mailed or delivered.

(d) *Copy of appraisals.* (1) *In general.* A creditor shall provide to the consumer a copy of any written appraisal performed in connection with a higher-risk mortgage loan pursuant to the requirements of paragraph (b) of this section.

(2) *Timing.* A creditor shall provide a copy of each written appraisal pursuant to paragraph (d)(1) of this section no later than three business days prior to consummation of the higher-risk mortgage loan.

(3) *Form of copy.* Any copy of a written appraisal required by paragraph (d)(1) of this section may be provided to the applicant in electronic form, subject to compliance with the consumer consent and other applicable provisions of the Electronic Signatures in Global and National Commerce Act (E-Sign Act) (15 U.S.C. 7001 *et seq.*).

(4) *No charge for copy of appraisal.* A creditor shall not charge the applicant for a copy of a written appraisal required to be provided to the consumer pursuant to paragraph (d)(1) of this section.

(e) *Relation to other rules.* These rules were developed jointly by the Federal Reserve Board (Board), the Office of the Comptroller of the Currency (OCC), the Federal Deposit Insurance Corporation, the National Credit Union Administration, the Federal Housing Finance Agency, and the Consumer Financial Protection Bureau (Bureau). These rules are substantively identical to the OCC's and the Bureau's higher-risk mortgage appraisal rules published separately in 12 CFR part 34, subpart G and 12 CFR 164.20 through 164.21 (for the OCC), and 12 CFR 1026.XX (for the Bureau). The Board's rules apply to all creditors who are State member banks, bank holding companies and their subsidiaries (other than a bank), savings and loan holding companies and their subsidiaries (other than a savings and

loan association), and uninsured state branches and agencies of foreign banks. Compliance with the Board's rules satisfies the requirements of 15 U.S.C. 1639h.

8. Appendix N to Part 226 is added to read as follows:

Appendix N to Part 226—Appraisal Safe Harbor Review

To qualify for the safe harbor provided in § 226.43(b)(2) a creditor must check the appraisal report to confirm that the written appraisal:

1. Identifies the creditor who ordered the appraisal and the property and the interest being appraised.
2. Indicates whether the contract price was analyzed.
3. Addresses conditions in the property's neighborhood.
4. Addresses the condition of the property and any improvements to the property.
5. Indicates which valuation approaches were used, and includes a reconciliation if more than one valuation approach was used.
6. Provides an opinion of the property's market value and an effective date for the opinion.
7. Indicates that a physical property visit of the interior of the property was performed.
8. Includes a certification signed by the appraiser that the appraisal was prepared in accordance with the requirements of the Uniform Standards of Professional Appraisal Practice.
9. Includes a certification signed by the appraiser that the appraisal was prepared in accordance with the requirements of title XI of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, as amended (12 U.S.C. 3331 *et seq.*), and any implementing regulations.

9. In Supplement I to part 226, new *Section 226.43—Appraisals for Higher-Risk Mortgage Loans* is added to read as follows:

Supplement I to Part 226—Official Interpretations

* * * * *

Section 226.43—Appraisals for Higher-Risk Mortgage Loans

43(a) Definitions.

43(a)(1) Certified or licensed appraiser.

1. *USPAP.* The Uniform Standards of Professional Appraisal Practice (USPAP) are established by the Appraisal Standards Board of the Appraisal Foundation (as defined in 12 U.S.C. 3350(9)). Under § 226.43(a)(1), the relevant USPAP standards are those found in the edition of USPAP in effect at the time the appraiser signs the appraiser's certification.

2. *Appraiser's certification.* The appraiser's certification refers to the certification that must be signed by the appraiser for each appraisal assignment. This requirement is specified in USPAP Standards Rule 2–3.

3. *FIRREA title XI and implementing regulations.* The relevant regulations are those prescribed under section 1110 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA), as amended (12 U.S.C. 3339), that relate to an appraiser's development and reporting of the appraisal in effect at the time the appraiser signs the appraiser's certification. Paragraph (3) of FIRREA section 1110 (12 U.S.C. 3339(3)), which relates to the review of appraisals, is not relevant for determining whether an appraiser is a certified or licensed appraiser under § 226.43(a)(1).

43(a)(2) Higher-risk mortgage loan.

Paragraph 43(a)(2)(i).

1. *Principal dwelling.* The term ''principal dwelling'' has the same meaning under § 226.43(a)(2) as under 12 CFR 1026.2(a)(24). *See* the Official Staff Interpretations to the Bureau's Regulation Z (Supplement I to Part 1026), comment 2(a)(24)–3.

2. *Average prime offer rate.* For guidance on average prime offer rates, see the Official Staff Interpretations to the Bureau's Regulation Z, comment 35(a)(2)–1.

3. *Comparable transaction.* For guidance on determining the average prime offer rate for comparable transactions, see the Official Staff Interpretations to the Bureau's Regulation Z, comments 35(a)(2)–2 and –4.

4. *Rate set.* For guidance on the date the annual percentage rate is set, see the Official Staff Interpretations to the Bureau's Regulation Z, comment 35(a)(2)–3.

Paragraph 43(a)(2)(ii)(C).

1. *Secured solely by a residential structure.* Loans secured solely by a residential structure cannot be ''higher-risk mortgage loans.'' Thus, for example, a loan secured by a manufactured home and the land on which it is sited could be a ''higher-risk mortgage loan.'' By contrast, a loan secured solely by a manufactured home cannot be a ''higher-risk mortgage loan.''

43(b) Appraisals required for higher-risk mortgage loans.

43(b)(1) In general.

1. *Written appraisal—electronic transmission.* To satisfy the requirement that the appraisal be ''written,'' a creditor may obtain the appraisal in paper form or via electronic transmission.

43(b)(2) Safe harbor.

1. *Safe harbor.* A creditor that satisfies the conditions in § 226.43(b)(2)(i) through (iv) will be deemed to have complied with the appraisal requirements of § 226.43(b)(1). A creditor that does not satisfy the conditions in § 226.43(b)(2)(i) through (iv) does not necessarily violate the appraisal requirements of § 226.43(b)(1).

Paragraph 43(b)(2)(iii).

1. *Confirming elements in the appraisal.* To confirm that the elements in appendix N to this part are included in the written appraisal, a creditor need not look beyond the face of the written appraisal and the appraiser's certification.

43(b)(3) Additional appraisal for certain higher-risk mortgage loans.

1. *Acquisition.* For purposes of § 226.43(b)(3), the terms ''acquisition'' and ''acquire'' refer to the acquisition of legal title to the property pursuant to applicable State law, including by purchase.

43(b)(3)(i) In general.

1. *Two appraisals.* An appraisal that was previously obtained in connection with the seller's acquisition or the financing of the seller's acquisition of the property does not satisfy the requirements of § 226.43(b)(3).

Paragraph 43(b)(3)(i)(A).

1. *180-day calculation.* The time period described in § 226.43(b)(3)(i)(A) is calculated by counting the day after the date on which the seller acquired the property, up to and including the date of the consumer's agreement to acquire the property that secures the transaction. *See also* comments 43(b)(3)(i)(A)–2 and –3. For example, assume that the creditor determines that date of the consumer's acquisition agreement is October 15, 2012, and that the seller acquired the property on April 17, 2012. The first day to be counted in the 180-day calculation would be April 18, 2012, and the last day would be October 15, 2012. In this case, the number of days would be 181, so an additional appraisal is not required.

2. *Date of the consumer's agreement to acquire the property.* For the date of the consumer's agreement to acquire the property under § 226.43(b)(3)(i)(A), the creditor should use the date on which the consumer and the seller signed the agreement provided to the creditor by the consumer. The date on which the consumer and the seller signed the agreement might not be the date on which the consumer became contractually obligated under State law to acquire the property. For purposes of § 226.43(b)(3)(i)(A), a creditor is not obligated to determine whether and to what extent the agreement is legally binding on both parties. If the dates on which the consumer and the seller signed the agreement differ, the creditor should use the later of the two dates.

3. *Date seller acquired the property.* For purposes of § 226.43(b)(3)(i)(A), the date on which the seller acquired the property is the date on which the seller became the legal owner of the property pursuant to applicable State law. *See also* comments 43(b)(3)(vi)(A)–1 and –2 and comment (b)(3)(vi)(B)–1.

Paragraph 43(b)(3)(i)(B).

1. *Price at which the seller acquired the property.* The price at which the seller acquired the property refers to the amount paid by the seller to acquire the property. The price at which the seller acquired the property does not include the cost of financing the property. *See also* comments 43(b)(3)(vi)(A)–1 and (b)(3)(vi)(B)–1.

2. *Price the consumer is obligated to pay to acquire the property.* The price the consumer is obligated to pay to acquire the property is the price indicated on the consumer's agreement with the seller to acquire the property. *See* comment 43(b)(3)(i)(A)–2. The price the consumer is obligated to pay to acquire the property from the seller does not include the cost of financing the property. For purposes of § 226.43(b)(3)(i)(B), a creditor is not obligated to determine whether and to what extent the agreement is legally binding on both parties.

43(b)(3)(iv) Requirements for the additional appraisal.

1. *Determining acquisition dates and prices used in the analysis of the additional appraisal.* For guidance on identifying the date the seller acquired the property, see comment 43(b)(3)(i)(A)–3. For guidance on identifying the date of the consumer's agreement to acquire the property, see comment 43(b)(3)(i)(A)–2. For guidance on identifying the price at which the seller

acquired the property, see comment 43(b)(3)(i)(B)–1. For guidance on identifying the price the consumer is obligated to pay to acquire the property, see comment 43(b)(3)(i)(B)–2.

43(b)(3)(v) No charge for additional appraisal.

1. *Fees and mark-ups.* The creditor is prohibited from charging the consumer for the performance of one of the two appraisals required under § 226.43(b)(3)(i), including by imposing a fee specifically for that appraisal or by marking up the interest rate or any other fees payable by the consumer in connection with the higher-risk mortgage loan.

Paragraph 43(b)(3)(vi) Creditor's determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.

43(b)(3)(vi)(A) In general.

1. *Reasonable diligence—documentation required.* A creditor acts with reasonable diligence to determine when the seller acquired the property and whether the price at which the seller acquired the property is lower than the price reflected in the consumer's agreement to acquire the property if, for example, the creditor bases its determination on information contained in written source documents, such as:

i. A copy of the recorded deed from the seller.

ii. A copy of a property tax bill.

iii. A copy of any owner's title insurance policy obtained by the seller.

iv. A copy of the RESPA settlement statement from the seller's acquisition (*i.e.,* the HUD–1 or any successor form [140]).

v. A property sales history report or title report from a third-party reporting service.

vi. Sales price data recorded in multiple listing services.

vii. Tax assessment records or transfer tax records obtained from local governments.

viii. An appraisal report signed by an appraiser who certifies that the appraisal was performed in conformity with USPAP that shows any prior transactions for the subject property.

ix. A copy of a title commitment report [141] detailing the seller's ownership of the property, the date it was acquired, or the price at which the seller acquired the property.

x. A property abstract.

2. *Reasonable diligence—oral statements insufficient.* Reliance on oral statements of interested parties, such as the consumer, seller, or mortgage broker, does not constitute reasonable diligence under § 226.43(b)(3)(vi)(A).

43(b)(3)(vi)(B) Inability to make the determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.

1. *Lack of information and conflicting information—two appraisals required.* Unless a creditor can demonstrate that the requirement to obtain two appraisals under § 226.43(b)(3)(i) does not apply, the creditor must obtain two written appraisals in compliance with § 226.43(b)(3)(vi)(B). *See also* comment 43(b)(3)(vi)(B)–2. For example:

i. Assume a creditor orders and reviews the results of a title search and the seller's acquisition price was not included. In this case, the creditor would not be able to determine whether the price at which the seller acquired the property was lower than the price the consumer is obligated to pay under the consumer's acquisition agreement, pursuant to § 226.43(b)(3)(i)(B). Before extending a higher-risk mortgage loan, the creditor must either: Perform additional diligence to obtain information showing the seller's acquisition price and determine whether two written appraisals would be required based on that information; or obtain two written appraisals in compliance with § 226.43(b)(3)(vi)(B). *See* also comment 43(b)(3)(vi)(B)-2.

ii. Assume a creditor reviews the results of a title search indicating that the last recorded purchase was more than 180 days before the consumer's agreement to acquire the property. Assume also that the creditor subsequently receives an appraisal report indicating that the seller acquired the property fewer than 180 days before the consumer's agreement to acquire the property. In this case, the creditor would not be able to determine whether seller acquired the property within 180 days of the date of the consumer's agreement to acquire the property from the seller, pursuant to § 226.43(b)(3)(i)(A). Before extending a higher-risk mortgage loan, the creditor must either: Perform additional diligence to obtain information confirming the seller's acquisition date and determine whether two written appraisals would be required based on that information; or obtain two written appraisals in compliance with § 226.43(b)(3)(vi)(B). *See also* comment 43(b)(3)(vi)(B)-2.

2. *Lack of information and conflicting information—requirements for the additional appraisal.* In general, the additional appraisal required under § 226.43(b)(3)(i) should include an analysis of the factors listed in § 226.43(b)(3)(iv)(A) through (C). However, if, following reasonable diligence, a creditor cannot determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of § 226.43 are met due to a lack of information or conflicting information, the required additional appraisal must include the analyses required under § 226.43(b)(3)(iv)(A) through (C) only to the extent that the information necessary to perform the analysis is known. For example:

i. Assume that a creditor is able, following reasonable diligence, to determine that the date on which the seller acquired the property occurred 180 or fewer days prior to the date of the consumer's agreement to acquire the property. However, the creditor is unable, following reasonable diligence, to determine the price at which the seller acquired the property. In this case, the creditor is required to obtain an additional written appraisal that includes an analysis under paragraphs (b)(3)(iv)(B) and (b)(3)(iv)(C) of § 226.43 of the changes in market conditions and any improvements made to the property between the date the seller acquired the property and the date of the consumer's agreement to acquire the property. However, the creditor is not required to obtain an additional written appraisal that includes analysis under § 226.43(b)(3)(iv)(A) of the difference between the price at which the seller acquired the property and the price that the consumer is obligated to pay to acquire the property.

43(c) Required disclosure.

43(c)(1) In general.

1. *Multiple applicants.* When two or more consumers apply for a loan subject to this section, the creditor is required to give the disclosure to only one of the consumers.

43(d) Copy of appraisals.

43(d)(1) In general.

1. *Multiple applicants.* When two or more consumers apply for a loan subject to this section, the creditor is required to give the copy of each required appraisal to only one of the consumers.

43(d)(4) No charge for copy of appraisal.

1. *Fees and mark-ups.* The creditor is prohibited from charging the consumer for any copy of an appraisal required to be provided under § 226.43(d)(1), including by imposing a fee specifically for a required copy of an appraisal or by marking up the interest rate or any other fees payable by the consumer in connection with the higher-risk mortgage loan.

National Credit Union Administration

Authority and Issuance

For the reasons discussed above, NCUA proposes to amend 12 CFR part 722 as follows:

PART 722—APPRAISALS

10. The authority citation for part 722 is revised to read as follows:

Authority: 12 U.S.C. 1766, 1789 and 3339. Section 722.3(f) is also issued under 15 U.S.C. 1639h.

11. In § 722.3, add paragraph (f) to read as follows:

§ 722.3 Appraisals required; transactions requiring a State certified or licensed appraiser.

* * * * *

(f) *Higher-risk mortgages.* A credit union may not extend credit to a consumer in the form of a higher-risk mortgage as defined in the Truth in Lending Act, 15 U.S.C. 1601 et seq., without meeting the requirements of 15 U.S.C. 1639h and its implementing

[140] The Bureau has developed a successor form to the RESPA settlement statement as explained in the Bureau's proposal for an integrated TILA–RESPA disclosure form. See the Bureau's TILA–RESPA Proposal.

[141] The ''title commitment report'' is a document from a title insurance company describing the property interest and status of its title, parties with interests in the title and the nature of their claims, issues with the title that must be resolved prior to closing of the transaction between the parties to the transfer, amount and disposition of the premiums, and endorsements on the title policy. This document is issued by the title insurance company prior to the company's issuance of an actual title insurance policy to the property's transferee and/or creditor financing the transaction. In different jurisdictions, this instrument may be referred to by different terms, such as a title commitment, title binder, title opinion, or title report.

regulations in Regulation Z, 12 CFR 1026.XX.

Bureau of Consumer Financial Protection

Authority and Issuance

For the reasons set forth in the preamble, the Bureau proposes to amend Regulation Z, 12 CFR part 1026, as follows:

PART 1026—TRUTH IN LENDING ACT (REGULATION Z)

12. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 5512, 5581; 15 U.S.C. 1601 *et seq.*

Subpart C—Closed-End Credit

13. New § 1026.XX is added to read as follows:

§ 1026.XX Appraisals for higher-risk mortgage loans.

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

(1) *Certified or licensed appraiser* means a person who is certified or licensed by the State agency in the State in which the property that secures the transaction is located, and who performs the appraisal in conformity with the Uniform Standards of Professional Appraisal Practice and the requirements applicable to appraisers in title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (12 U.S.C. 3331 *et seq.*), and any implementing regulations in effect at the time the appraiser signs the appraiser's certification.

(2) Except as provided in paragraph (a)(2)(ii) of this section, *higher-risk mortgage loan* means:

Alternative 1: Annual Percentage Rate—Paragraph (a)(2)(i)

(i) A closed-end consumer credit transaction secured by the consumer's principal dwelling with an annual percentage rate, as determined under § 1026.22, that exceeds the average prime offer rate, as defined in § 1026.35(a)(2)(ii), for a comparable transaction as of the date the interest rate is set:

(A) By 1.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that does not exceed the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac;

(B) By 2.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that exceeds the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac; and

(C) By 3.5 or more percentage points, for a loan secured by a subordinate lien.

Alternative 2: Transaction Coverage Rate—Paragraph (a)(2)(i)

(i) A closed-end consumer credit transaction secured by the consumer's principal dwelling with a transaction coverage rate, as defined in § 1026.35(a)(2)(i), that exceeds the average prime offer rate, as defined in § 1026.35(a)(2)(ii), for a comparable transaction as of the date the interest rate is set:

(A) By 1.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that does not exceed the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac;

(B) By 2.5 or more percentage points, for a loan secured by a first lien with a principal obligation at consummation that exceeds the limit in effect as of the date the transaction's interest rate is set for the maximum principal obligation eligible for purchase by Freddie Mac; and

(C) By 3.5 or more percentage points, for a loan secured by a subordinate lien.

(ii) Notwithstanding paragraph (a)(2)(i) of this section, a *higher-risk mortgage loan* does not include:

(A) A qualified mortgage as defined in § 1026.43(e).

(B) A reverse-mortgage transaction as defined in § 1026.33(a).

(C) A loan secured solely by a residential structure.

(3) *National Registry* means the database of information about State certified and licensed appraisers maintained by the Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

(4) *State agency* means a ''State appraiser certifying and licensing agency'' recognized in accordance with section 1118(b) of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (12 U.S.C. 3347(b)) and any implementing regulations.

(b) *Appraisals required for higher-risk mortgage loans.* (1) *In general.* A creditor shall not extend a higher-risk mortgage loan to a consumer without obtaining, prior to consummation, a written appraisal of the property to be mortgaged. The appraisal must be performed by a certified or licensed appraiser who conducts a physical visit of the interior of the property that will secure the transaction.

(2) *Safe harbor.* A creditor is deemed to have obtained a written appraisal that meets the requirements of paragraph (b)(1) of this section if the creditor:

(i) Orders that the appraiser perform the appraisal in conformity with the Uniform Standards of Professional Appraisal Practice and title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (12 U.S.C. 3331 *et seq.*), and any implementing regulations, in effect at the time the appraiser signs the appraiser's certification;

(ii) Verifies through the National Registry that the appraiser who signed the appraiser's certification was a certified or licensed appraiser in the State in which the appraised property is located as of the date the appraiser signed the appraiser's certification;

(iii) Confirms that the elements set forth in appendix N to this part are addressed in the written appraisal; and

(iv) Has no actual knowledge to the contrary of facts or certifications contained in the written appraisal.

(3) *Additional appraisal for certain higher-risk mortgage loans.* (i) *In general.* A creditor shall not extend a higher-risk mortgage loan to a consumer to finance the acquisition of the consumer's principal dwelling without obtaining, prior to consummation, two written appraisals, if:

(A) The seller acquired the property 180 or fewer days prior to the date of the consumer's agreement to acquire the property from the seller; and

(B) The price at which the seller acquired the property was lower than the price that the consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller, by an amount equal to or greater than *XX.*

(ii) *Different appraisers.* The two appraisals required under paragraph (b)(3)(i) of this section may not be performed by the same certified or licensed appraiser.

(iii) *Relationship to paragraph (b)(1) of this section.* If two appraisals must be obtained under paragraph (b)(3)(i) of this section, each appraisal shall meet the requirements of paragraph (b)(1) of this section.

(iv) *Requirements for the additional appraisal.* In addition to meeting the requirements for an appraisal under paragraph (b)(1) of this section, the additional appraisal must include an analysis of:

(A) The difference between the price at which the seller acquired the property and the price that the

consumer is obligated to pay to acquire the property, as specified in the consumer's agreement to acquire the property from the seller;

(B) Changes in market conditions between the date the seller acquired the property and the date of the consumer's agreement to acquire the property; and

(C) Any improvements made to the property between the date the seller acquired the property and the date of the consumer's agreement to acquire the property.

(v) *No charge for the additional appraisal.* If the creditor must obtain two appraisals under paragraph (b)(3)(i) of this section, the creditor may charge the consumer for only one of the appraisals.

(vi) *Creditor's determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.*

(A) *Reasonable diligence.* A creditor shall exercise reasonable diligence to determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section are met.

(B) *Inability to make the determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.* If, after exercising reasonable diligence, a creditor cannot determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section are met, the creditor shall not extend a higher-risk mortgage loan without obtaining, prior to consummation, two written appraisals in accordance with paragraphs (b)(3)(ii) through (v) of this section. However, the additional appraisal shall include an analysis of the factors in paragraph (b)(3)(iv) of this section only to the extent that the information necessary for the appraiser to perform the analysis can be determined.

(c) *Required disclosure.* (1) *In general.* A creditor shall disclose the following statement, in writing, to a consumer who applies for a higher-risk mortgage loan: ''We may order an appraisal to determine the property's value and charge you for this appraisal. We will promptly give you a copy of any appraisal, even if your loan does not close. You can pay for an additional appraisal for your own use at your own cost.''

(2) *Timing of disclosure.* The disclosure required by paragraph (c)(1) of this section shall be mailed or delivered not later than the third business day after the creditor receives the consumer's application. If the disclosure is not provided to the consumer in person, the consumer is presumed to have received the disclosures three business days after they are mailed or delivered.

(d) *Copy of appraisals.* (1) *In general.* A creditor shall provide to the consumer a copy of any written appraisal performed in connection with a higher-risk mortgage loan pursuant to the requirements of paragraph (b) of this section.

(2) *Timing.* A creditor shall provide a copy of each written appraisal pursuant to paragraph (d)(1) of this section no later than three business days prior to consummation of the higher-risk mortgage loan.

(3) *Form of copy.* Any copy of a written appraisal required by paragraph (d)(1) of this section may be provided to the applicant in electronic form, subject to compliance with the consumer consent and other applicable provisions of the Electronic Signatures in Global and National Commerce Act (E-Sign Act) (15 U.S.C. 7001 *et seq.*).

(4) *No charge for copy of appraisal.* A creditor shall not charge the applicant for a copy of a written appraisal required to be provided to the consumer pursuant to paragraph (d)(1) of this section.

(e) *Relation to other rules.* These rules were developed jointly by the Federal Reserve Board (Board), the Office of the Comptroller of the Currency (OCC), the Federal Deposit Insurance Corporation, the National Credit Union Administration, the Federal Housing Finance Agency, and the Bureau. These rules are substantively identical to the Board's and the OCC's higher-risk mortgage appraisal rules published separately in 12 CFR 226.43 (for the Board), 12 CFR part 34, subpart G and 12 CFR 164.20 through 34.21 (for the OCC).

14. New Appendix N to Part 1026 is added to read as follows:

Appendix N to Part 1026—Appraisal Safe Harbor Review

To qualify for the safe harbor provided in § 1026.XX(b)(2) a creditor must check to confirm that the written appraisal:

1. Identifies the creditor who ordered the appraisal and the property and the interest being appraised.

2. Indicates whether the contract price was analyzed.

3. Addresses conditions in the property's neighborhood.

4. Addresses the condition of the property and any improvements to the property.

5. Indicates which valuation approaches were used, and includes a reconciliation if more than one valuation approach was used.

6. Provides an opinion of the property's market value and an effective date for the opinion.

7. Indicates that a physical property visit of the interior of the property was performed.

8. Includes a certification signed by the appraiser that the appraisal was prepared in accordance with the requirements of the Uniform Standards of Professional Appraisal Practice.

9. Includes a certification signed by the appraiser that the appraisal was prepared in accordance with the requirements of title XI of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, as amended (12 U.S.C. 3331 *et seq.*), and any implementing regulations.

15. In Supplement I to part 1026, new *Section 1026.XX—Appraisals for Higher-Risk Mortgage Loans* is added to read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Section 1026.XX—Appraisals for Higher-Risk Mortgage Loans

XX(a) Definitions.

XX(a)(1) Certified or licensed appraiser.

1. *USPAP.* The Uniform Standards of Professional Appraisal Practice (USPAP) are established by the Appraisal Standards Board of the Appraisal Foundation (as defined in 12 U.S.C. 3350(9)). Under § 1026.XX(a)(1), the relevant USPAP standards are those found in the edition of USPAP in effect at the time the appraiser signs the appraiser's certification.

2. *Appraiser's certification.* The appraiser's certification refers to the certification that must be signed by the appraiser for each appraisal assignment. This requirement is specified in USPAP Standards Rule 2–3.

3. *FIRREA title XI and implementing regulations.* The relevant regulations are those prescribed under section 1110 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA), as amended (12 U.S.C. 3339), that relate to an appraiser's development and reporting of the appraisal in effect at the time the appraiser signs the appraiser's certification. Paragraph (3) of FIRREA section 1110 (12 U.S.C. 3339(3)), which relates to the review of appraisals, is not relevant for determining whether an appraiser is a certified or licensed appraiser under § 1026.XX(a)(1).

XX(a)(2) Higher-risk mortgage loan.

Paragraph XX(a)(2)(i).

1. *Principal dwelling.* The term ''principal dwelling'' has the same meaning under § 1026.XX(a)(2) as under § 1026.2(a)(24). *See* comment 2(a)(24)–3.

2. *Average prime offer rate.* For guidance on average prime offer rates, see comment 35(a)(2)–1.

3. *Comparable transaction.* For guidance on determining the average prime offer rate for comparable transactions, see comments 35(a)(2)–2 and –4.

4. *Rate set.* For guidance on the date the annual percentage rate is set, see comment 35(a)(2)–3.

Paragraph XX(a)(2)(ii)(C).

1. *Secured solely by a residential structure.* Loans secured solely by a residential structure cannot be ''higher-risk mortgage loans.'' Thus, for example, a loan secured by a manufactured home and the land on which it is sited could be a ''higher-risk mortgage loan.'' By contrast, a loan secured solely by a manufactured home cannot be a ''higher-risk mortgage loan.''

XX(b) Appraisals required for higher-risk mortgage loans.

XX(b)(1) In general.

1. *Written appraisal—electronic transmission.* To satisfy the requirement that the appraisal be ''written,'' a creditor may obtain the appraisal in paper form or via electronic transmission.

XX(b)(2) Safe harbor.

1. *Safe harbor.* A creditor that satisfies the conditions in § 1026.XX(b)(2)(i) through (iv) will be deemed to have complied with the appraisal requirements of § 1026.XX(b)(1). A creditor that does not satisfy the conditions in § 1026.XX(b)(2)(i) through (iv) does not necessarily violate the appraisal requirements of § 1026.XX(b)(1).

Paragraph XX(b)(2)(iii).

1. *Confirming elements in the appraisal.* To confirm that the elements in appendix N to this part are included in the written appraisal, a creditor need not look beyond the face of the written appraisal and the appraiser's certification.

XX(b)(3) Additional appraisal for certain higher-risk mortgage loans.

1. *Acquisition.* For purposes of § 1026.XX(b)(3), the terms ''acquisition'' and ''acquire'' refer to the acquisition of legal title to the property pursuant to applicable State law, including by purchase.

XX(b)(3)(i) In general.

1. *Two appraisals.* An appraisal that was previously obtained in connection with the seller's acquisition or the financing of the seller's acquisition of the property does not satisfy the requirements of § 1026.XX(b)(3).

Paragraph XX(b)(3)(i)(A).

1. *180-day calculation.* The time period described in § 1026.XX(b)(3)(i)(A) is calculated by counting the day after the date on which the seller acquired the property, up to and including the date of the consumer's agreement to acquire the property that secures the transaction. *See also* comments XX(b)(3)(i)(A)–2 and –3. For example, assume that the creditor determines that date of the consumer's acquisition agreement is October 15, 2012, and that the seller acquired the property on April 17, 2012. The first day to be counted in the 180-day calculation would be April 18, 2012, and the last day would be October 15, 2012. In this case, the number of days would be 181, so an additional appraisal is not required.

2. *Date of the consumer's agreement to acquire the property.* For the date of the consumer's agreement to acquire the property under § 1026.XX(b)(3)(i)(A), the creditor should use the date on which the consumer and the seller signed the agreement provided to the creditor by the consumer. The date on which the consumer and the seller signed the agreement might not be the date on which the consumer became contractually obligated under State law to acquire the property. For purposes of § 1026.XX(b)(3)(i)(A), a creditor is not obligated to determine whether and to what extent the agreement is legally binding on both parties. If the dates on which the consumer and the seller signed the agreement differ, the creditor should use the later of the two dates.

3. *Date seller acquired the property.* For purposes of § 1026.XX(b)(3)(i)(A), the date on which the seller acquired the property is the date on which the seller became the legal owner of the property pursuant to applicable State law. *See also* comments XX(b)(3)(vi)(A)–1 and –2 and comment (b)(3)(vi)(B)–1.

Paragraph XX(b)(3)(i)(B).

1. *Price at which the seller acquired the property.* The price at which the seller acquired the property refers to the amount paid by the seller to acquire the property. The price at which the seller acquired the property does not include the cost of financing the property. *See also* comments XX(b)(3)(vi)(A)–1 and (b)(3)(vi)(B)–1.

2. *Price the consumer is obligated to pay to acquire the property.* The price the consumer is obligated to pay to acquire the property is the price indicated on the consumer's agreement with the seller to acquire the property. *See* comment XX(b)(3)(i)(A)–2. The price the consumer is obligated to pay to acquire the property from the seller does not include the cost of financing the property. For purposes of § 1026.XX(b)(3)(i)(B), a creditor is not obligated to determine whether and to what extent the agreement is legally binding on both parties.

XX(b)(3)(iv) Requirements for the additional appraisal.

1. *Determining acquisition dates and prices used in the analysis of the additional appraisal.* For guidance on identifying the date the seller acquired the property, see comment XX(b)(3)(i)(A)–3. For guidance on identifying the date of the consumer's agreement to acquire the property, see comment XX(b)(3)(i)(A)–2. For guidance on identifying the price at which the seller acquired the property, see comment XX(b)(3)(i)(B)–1. For guidance on identifying the price the consumer is obligated to pay to acquire the property, see comment XX(b)(3)(i)(B)–2.

XX(b)(3)(v) No charge for additional appraisal.

1. *Fees and mark-ups.* The creditor is prohibited from charging the consumer for the performance of one of the two appraisals required under § 1026.XX(b)(3)(i), including by imposing a fee specifically for that appraisal or by marking up the interest rate or any other fees payable by the consumer in connection with the higher-risk mortgage loan.

Paragraph XX(b)(3)(vi) Creditor's determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.

XX(b)(3)(vi)(A) In general.

1. *Reasonable diligence—documentation required.* A creditor acts with reasonable diligence to determine when the seller acquired the property and whether the price at which the seller acquired the property is lower than the price reflected in the consumer's agreement to acquire the property if, for example, the creditor bases its determination on information contained in written source documents, such as:

i. A copy of the recorded deed from the seller.

ii. A copy of a property tax bill.

iii. A copy of any owner's title insurance policy obtained by the seller.

iv. A copy of the RESPA settlement statement from the seller's acquisition (*i.e.,* the HUD–1 or any successor form [142]).

v. A property sales history report or title report from a third-party reporting service.

vi. Sales price data recorded in multiple listing services.

vii. Tax assessment records or transfer tax records obtained from local governments.

viii. A written appraisal signed by an appraiser who certifies that the appraisal was performed in conformity with USPAP that shows any prior transactions for the subject property.

ix. A copy of a title commitment report [143] detailing the seller's ownership of the property, the date it was acquired, or the price at which the seller acquired the property.

x. A property abstract.

2. *Reasonable diligence—oral statements insufficient.* Reliance on oral statements of interested parties, such as the consumer, seller, or mortgage broker, does not constitute reasonable diligence under § 1026.XX(b)(3)(vi)(A).

XX(b)(3)(vi)(B) Inability to make the determination under paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of this section.

1. *Lack of information and conflicting information—two appraisals required.* Unless a creditor can demonstrate that the requirement to obtain two appraisals under § 1026.XX(b)(3)(i) does not apply, the creditor must obtain two written appraisals in compliance with § 1026.XX(b)(3)(vi)(B). *See also* comment XX(b)(3)(vi)(B)–2. For example:

i. Assume a creditor orders and reviews the results of a title search and the seller's acquisition price was not included. In this case, the creditor would not be able to determine whether the price at which the seller acquired the property was lower than the price the consumer is obligated to pay under the consumer's acquisition agreement, pursuant to § 1026.XX(b)(3)(i)(B). Before extending a higher-risk mortgage loan, the creditor must either: perform additional diligence to obtain information showing the seller's acquisition price and determine whether two written appraisals would be required based on that information; or obtain two written appraisals in compliance with § 1026.XX(b)(3)(vi)(B). *See* also comment XX(b)(3)(vi)(B)–2.

ii. Assume a creditor reviews the results of a title search indicating that the last recorded

[142] The Bureau has developed a successor form to the RESPA settlement statement as explained in the Bureau's proposal for an integrated TILA–RESPA disclosure form. See the Bureau's 2012 TILA–RESPA Proposal.

[143] The ''title commitment report'' is a document from a title insurance company describing the property interest and status of its title, parties with interests in the title and the nature of their claims, issues with the title that must be resolved prior to closing of the transaction between the parties to the transfer, amount and disposition of the premiums, and endorsements on the title policy. This document is issued by the title insurance company prior to the company's issuance of an actual title insurance policy to the property's transferee and/or creditor financing the transaction. In different jurisdictions, this instrument may be referred to by different terms, such as a title commitment, title binder, title opinion, or title report.

purchase was more than 180 days before the consumer's agreement to acquire the property. Assume also that the creditor subsequently receives a written appraisal indicating that the seller acquired the property fewer than 180 days before the consumer's agreement to acquire the property. In this case, the creditor would not be able to determine whether seller acquired the property within 180 days of the date of the consumer's agreement to acquire the property from the seller, pursuant to § 1026.XX(b)(3)(i)(A). Before extending a higher-risk mortgage loan, the creditor must either: perform additional diligence to obtain information confirming the seller's acquisition date and determine whether two written appraisals would be required based on that information; or obtain two written appraisals in compliance with § 1026.XX(b)(3)(vi)(B). *See also* comment XX(b)(3)(vi)(B)–2.

2. *Lack of information and conflicting information—requirements for the additional appraisal.* In general, the additional appraisal required under § 1026.XX(b)(3)(i) should include an analysis of the factors listed in § 1026.XX(b)(3)(iv)(A) through (C). However, if, following reasonable diligence, a creditor cannot determine whether the criteria in paragraphs (b)(3)(i)(A) and (b)(3)(i)(B) of § 1026.XX are met due to a lack of information or conflicting information, the required additional appraisal must include the analyses required under § 1026.XX(b)(3)(iv)(A) through (C) only to the extent that the information necessary to perform the analysis is known. For example:

i. Assume that a creditor is able, following reasonable diligence, to determine that the date on which the seller acquired the property occurred 180 or fewer days prior to the date of the consumer's agreement to acquire the property. However, the creditor is unable, following reasonable diligence, to determine the price at which the seller acquired the property. In this case, the creditor is required to obtain an additional written appraisal that includes an analysis under paragraphs (b)(3)(iv)(B) and (b)(3)(iv)(C) of § 1026.XX of the changes in market conditions and any improvements made to the property between the date the seller acquired the property and the date of the consumer's agreement to acquire the property. However, the creditor is not required to obtain an additional written appraisal that includes analysis under § 1026.XX(b)(3)(iv)(A) of the difference between the price at which the seller acquired the property and the price that the consumer is obligated to pay to acquire the property.

XX(c) Required disclosure.

XX(c)(1) In general.

1. *Multiple applicants.* When two or more consumers apply for a loan subject to this section, the creditor is required to give the disclosure to only one of the consumers.

XX(d) Copy of appraisals.

XX(d)(1) In general.

1. *Multiple applicants.* When two or more consumers apply for a loan subject to this section, the creditor is required to give the copy of each required appraisal to only one of the consumers.

XX(d)(4) No charge for copy of appraisal.

1. *Fees and mark-ups.* The creditor is prohibited from charging the consumer for any copy of an appraisal required to be provided under § 1026.XX(d)(1), including by imposing a fee specifically for a required copy of an appraisal or by marking up the interest rate or any other fees payable by the consumer in connection with the higher-risk mortgage loan.

Federal Housing Finance Agency

Authority and Issuance

For the reasons stated in the Supplementary Information, and under the authority of 15 U.S.C. 1639h and 12 U.S.C. 4511(b), 4526, and 4617, the Federal Housing Finance Agency proposes to add Part 1222 to subchapter B of chapter XII of title 12 of the Code of Federal Regulations as follows:

Chapter XII—Federal Housing Finance Agency

Subchapter B—Entity Regulations

PART 1222—APPRAISALS

Subpart A—Requirements for Higher-Risk Mortgages

Authority: 12 U.S.C. 4511(b), 4526, and 4617; 15 U.S.C. 1639h (TILA).

§ 1222.1 Purpose and scope.

This subpart cross-references the requirement that creditors extending credit in the form of higher-risk mortgage loans comply with Section 129H of the Truth-in-Lending Act (TILA), 15 U.S.C. 1639h, and its implementing regulations in Regulation Z, 12 CFR 1026.XX. Neither the Banks nor the Enterprises is subject to Section 129H of TILA or 12 CFR 1026.XX. Originators of higher-risk mortgage loans, including Bank members and institutions that sell mortgage loans to the Enterprises, are subject to those provisions. A failure of those institutions to comply with Section 129H of TILA and 12 CFR 1026.XX may limit their ability to sell such loans to the Banks or Enterprises or to pledge such loans to the Banks as collateral, to the extent provided in the parties' agreements.

§ 1222.2 Reservation of authority.

Nothing in this subpart A shall be read to limit the authority of the Director of the Federal Housing Finance Agency to take supervisory or enforcement action, including action to address unsafe and unsound practices or conditions, or violations of law. In addition, nothing in this subpart A shall be read to limit the authority of the Director to impose requirements for any purchase of higher-risk mortgage loans by an Enterprise or a Federal Home Loan Bank, or acceptance of higher-risk mortgage loans as collateral to secure advances by a Federal Home Loan Bank.

Subparts B to Z—[Reserved]

By order of the Board of Governors of the Federal Reserve System.

August 14, 2012.

Margaret McCloskey Shanks,

Associate Secretary of the Board.

Dated: August 13, 2012.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

This rule is being proposed by the FDIC jointly with the other agencies as mandated by section 129H of the Truth in Lending Act as added by section 1471 of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

By order of the Board of Directors.

Dated at Washington, DC, this 13th day of August, 2012.

Robert E. Feldman,

Executive Secretary. Federal Deposit Insurance Corporation.

Dated August 14, 2012.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

By the National Credit Union Administration Board.

Dated: August 14, 2012.

Jon J. Canerday

Acting Secretary of the Board

Dated: August 13, 2012.

Thomas J. Curry,

Comptroller of the Currency.

[FR Doc. 2012–20432 Filed 8–28–12; 4:15 pm]

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Part IV

The President

Executive Order 13624—Accelerating Investment in Industrial Energy Efficiency

Executive Order 13625—Improving Access to Mental Health Services for Veterans, Service Members, and Military Families

Federal Register
Vol. 77, No. 172
Wednesday, September 5, 2012

Presidential Documents

Title 3—

The President

Executive Order 13624 of August 30, 2012

Accelerating Investment in Industrial Energy Efficiency

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to promote American manufacturing by helping to facilitate investments in energy efficiency at industrial facilities, it is hereby ordered as follows:

Section 1. *Policy.* The industrial sector accounts for over 30 percent of all energy consumed in the United States, and, for many manufacturers, energy costs affect overall competitiveness. While our manufacturing facilities have made progress in becoming more energy efficient over the past several decades, there is an opportunity to accelerate and expand these efforts with investments to reduce energy use through more efficient manufacturing processes and facilities and the expanded use of combined heat and power (CHP). Instead of burning fuel in an on-site boiler to produce thermal energy and also purchasing electricity from the grid, a manufacturing facility can use a CHP system to provide both types of energy in one energy-efficient step. Accelerating these investments in our Nation's factories can improve the competitiveness of United States manufacturing, lower energy costs, free up future capital for businesses to invest, reduce air pollution, and create jobs.

Despite these benefits, independent studies have pointed to under-investment in industrial energy efficiency and CHP as a result of numerous barriers. The Federal Government has limited but important authorities to overcome these barriers, and our efforts to support investment in industrial energy efficiency and CHP should involve coordinated engagement with a broad set of stakeholders, including States, manufacturers, utilities, and others. By working with all stakeholders to address these barriers, we have an opportunity to save industrial users tens of billions of dollars in energy costs over the next decade.

There is no one-size-fits-all solution for our manufacturers, so it is imperative that we support these investments through a variety of approaches, including encouraging private sector investment by setting goals and highlighting the benefits of investment, improving coordination at the Federal level, partnering with and supporting States, and identifying investment models beneficial to the multiple stakeholders involved.

To formalize and support the close interagency coordination that is required to accelerate greater investment in industrial energy efficiency and CHP, this order directs certain executive departments and agencies to convene national and regional stakeholders to identify, develop, and encourage the adoption of investment models and State best practice policies for industrial energy efficiency and CHP; provide technical assistance to States and manufacturers to encourage investment in industrial energy efficiency and CHP; provide public information on the benefits of investment in industrial energy efficiency and CHP; and use existing Federal authorities, programs, and policies to support investment in industrial energy efficiency and CHP.

Sec. 2. *Encouraging Investment in Industrial Efficiency.* The Departments of Energy, Commerce, and Agriculture, and the Environmental Protection Agency, in coordination with the National Economic Council, the Domestic Policy Council, the Council on Environmental Quality, and the Office of Science and Technology Policy, shall coordinate policies to encourage investment in industrial efficiency in order to reduce costs for industrial users,

improve U.S. competitiveness, create jobs, and reduce harmful air pollution. In doing so, they shall engage States, industrial companies, utility companies, and other stakeholders to accelerate this investment. Specifically, these agencies shall, as appropriate and consistent with applicable law:

(a) coordinate and strongly encourage efforts to achieve a national goal of deploying 40 gigawatts of new, cost-effective industrial CHP in the United States by the end of 2020;

(b) convene stakeholders, through a series of public workshops, to develop and encourage the use of best practice State policies and investment models that address the multiple barriers to investment in industrial energy efficiency and CHP;

(c) utilize their respective relevant authorities and resources to encourage investment in industrial energy efficiency and CHP, such as by:

(i) providing assistance to States on accounting for the potential emission reduction benefits of CHP and other energy efficiency policies when developing State Implementation Plans (SIPs) to achieve national ambient air quality standards;

(ii) providing incentives for the deployment of CHP and other types of clean energy, such as set-asides under emissions allowance trading program state implementation plans, grants, and loans;

(iii) employing output-based approaches as compliance options in power and industrial sector regulations, as appropriate, to recognize the emissions benefits of highly efficient energy generation technologies like CHP; and

(iv) seeking to expand participation in and create additional tools to support the Better Buildings, Better Plants program at the Department of Energy, which is working with companies to help them achieve a goal of reducing energy intensity by 25 percent over 10 years, as well as utilizing existing partnership programs to support energy efficiency and CHP;

(d) support and encourage efforts to accelerate investment in industrial energy efficiency and CHP by:

(i) providing general guidance, technical analysis and information, and financial analysis on the value of investment in industrial energy efficiency and CHP to States, utilities, and owners and operators of industrial facilities;

(ii) improving the usefulness of Federal data collection and analysis; and

(iii) assisting States in developing and implementing State-specific best practice policies that can accelerate investment in industrial energy efficiency and CHP.

In implementing this section, these agencies should consult with the Federal Energy Regulatory Commission, as appropriate.

Sec. 3. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) 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.

THE WHITE HOUSE,
August 30, 2012.

[FR Doc. 2012–22030
Filed 9–4–12; 2:00 pm]
Billing code 3295–F2–P

Presidential Documents

Executive Order 13625 of August 31, 2012

Improving Access to Mental Health Services for Veterans, Service Members, and Military Families

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby order as follows:

Section 1. *Policy.* Since September 11, 2001, more than two million service members have deployed to Iraq or Afghanistan. Long deployments and intense combat conditions require optimal support for the emotional and mental health needs of our service members and their families. The need for mental health services will only increase in the coming years as the Nation deals with the effects of more than a decade of conflict. Reiterating and expanding upon the commitment outlined in my Administration's 2011 report, entitled ''Strengthening Our Military Families,'' we have an obligation to evaluate our progress and continue to build an integrated network of support capable of providing effective mental health services for veterans, service members, and their families. Our public health approach must encompass the practices of disease prevention and the promotion of good health for all military populations throughout their lifespans, both within the health care systems of the Departments of Defense and Veterans Affairs and in local communities. Our efforts also must focus on both outreach to veterans and their families and the provision of high quality mental health treatment to those in need. Coordination between the Departments of Veterans Affairs and Defense during service members' transition to civilian life is essential to achieving these goals.

Ensuring that all veterans, service members (Active, Guard, and Reserve alike), and their families receive the support they deserve is a top priority for my Administration. As part of our ongoing efforts to improve all facets of military mental health, this order directs the Secretaries of Defense, Health and Human Services, Education, Veterans Affairs, and Homeland Security to expand suicide prevention strategies and take steps to meet the current and future demand for mental health and substance abuse treatment services for veterans, service members, and their families.

Sec. 2. *Suicide Prevention.* (a) By December 31, 2012, the Department of Veterans Affairs, in continued collaboration with the Department of Health and Human Services, shall expand the capacity of the Veterans Crisis Line by 50 percent to ensure that veterans have timely access, including by telephone, text, or online chat, to qualified, caring responders who can help address immediate crises and direct veterans to appropriate care. Further, the Department of Veterans Affairs shall ensure that any veteran identifying him or herself as being in crisis connects with a mental health professional or trained mental health worker within 24 hours. The Department of Veterans Affairs also shall expand the number of mental health professionals who are available to see veterans beyond traditional business hours.

(b) The Departments of Veterans Affairs and Defense shall jointly develop and implement a national suicide prevention campaign focused on connecting veterans and service members to mental health services. This 12-month campaign, which shall begin on September 1, 2012, will focus on the positive benefits of seeking care and encourage veterans and service members to proactively reach out to support services.

(c) To provide the best mental health and substance abuse prevention, education, and outreach support to our military and their family members,

the Department of Defense shall review all of its existing mental health and substance abuse prevention, education, and outreach programs across the military services and the Defense Health Program to identify the key program areas that produce the greatest impact on quality and outcomes, and rank programs within each of these program areas using metrics that assess their effectiveness. By the end of Fiscal Year 2014, existing program resources shall be realigned to ensure that highly ranked programs are implemented across all of the military services and less effective programs are replaced.

Sec. 3. *Enhanced Partnerships Between the Department of Veterans Affairs and Community Providers.* (a) Within 180 days of the date of this order, in those service areas where the Department of Veterans Affairs has faced challenges in hiring and placing mental health service providers and continues to have unfilled vacancies or long wait times, the Departments of Veterans Affairs and Health and Human Services shall establish pilot projects whereby the Department of Veterans Affairs contracts or develops formal arrangements with community-based providers, such as community mental health clinics, community health centers, substance abuse treatment facilities, and rural health clinics, to test the effectiveness of community partnerships in helping to meet the mental health needs of veterans in a timely way. Pilot sites shall ensure that consumers of community-based services continue to be integrated into the health care systems of the Department of Veterans Affairs. No fewer than 15 pilot projects shall be established.

(b) The Department of Veterans Affairs shall develop guidance for its medical centers and service networks that supports the use of community mental health services, including telehealth services and substance abuse services, where appropriate, to meet demand and facilitate access to care. This guidance shall include recommendations that medical centers and service networks use community-based providers to help meet veterans' mental health needs where objective criteria, which the Department of Veterans Affairs shall define in the form of specific metrics, demonstrate such needs. Such objective criteria should include estimates of wait-times for needed care that exceed established targets.

(c) The Departments of Health and Human Services and Veterans Affairs shall develop a plan for a rural mental health recruitment initiative to promote opportunities for the Department of Veterans Affairs and rural communities to share mental health providers when demand is insufficient for either the Department of Veterans Affairs or the communities to independently support a full-time provider.

Sec. 4. *Expanded Department of Veterans Affairs Mental Health Services Staffing.* The Secretary of Veterans Affairs shall, by December 31, 2013, hire and train 800 peer-to-peer counselors to empower veterans to support other veterans and help meet mental health care needs. In addition, the Secretary shall continue to use all appropriate tools, including collaborative arrangements with community-based providers, pay-setting authorities, loan repayment and scholarships, and partnerships with health care workforce training programs to accomplish the Department of Veterans Affairs' goal of recruiting, hiring, and placing 1,600 mental health professionals by June 30, 2013. The Department of Veterans Affairs also shall evaluate the reporting requirements associated with providing mental health services and reduce paperwork requirements where appropriate. In addition, the Department of Veterans Affairs shall update its management performance evaluation system to link performance to meeting mental health service demand.

Sec. 5. *Improved Research and Development.* (a) The lack of full understanding of the underlying mechanisms of Post-Traumatic Stress Disorder (PTSD), other mental health conditions, and Traumatic Brain Injury (TBI) has hampered progress in prevention, diagnosis, and treatment. In order to improve the coordination of agency research into these conditions and reduce the number of affected men and women through better prevention, diagnosis, and treatment, the Departments of Defense, Veterans Affairs, Health and Human Services, and Education, in coordination with the Office of

Science and Technology Policy, shall establish a National Research Action Plan within 8 months of the date of this order.

(b) The National Research Action Plan shall include strategies to establish surrogate and clinically actionable biomarkers for early diagnosis and treatment effectiveness; develop improved diagnostic criteria for TBI; enhance our understanding of the mechanisms responsible for PTSD, related injuries, and neurological disorders following TBI; foster development of new treatments for these conditions based on a better understanding of the underlying mechanisms; improve data sharing between agencies and academic and industry researchers to accelerate progress and reduce redundant efforts without compromising privacy; and make better use of electronic health records to gain insight into the risk and mitigation of PTSD, TBI, and related injuries. In addition, the National Research Action Plan shall include strategies to support collaborative research to address suicide prevention.

(c) The Departments of Defense and Health and Human Services shall engage in a comprehensive longitudinal mental health study with an emphasis on PTSD, TBI, and related injuries to develop better prevention, diagnosis, and treatment options. Agencies shall continue ongoing collaborative research efforts, with an aim to enroll at least 100,000 service members by December 31, 2012, and include a plan for long-term follow-up with enrollees through a coordinated effort with the Department of Veterans Affairs.

Sec. 6. *Military and Veterans Mental Health Interagency Task Force.* There is established an Interagency Task Force on Military and Veterans Mental Health (Task Force), to be co-chaired by the Secretaries of Defense, Veterans Affairs, and Health and Human Services, or their designated representatives.

(a) *Membership.* In addition to the Co-Chairs, the Task Force shall consist of representatives from:

(i) the Department of Education;

(ii) the Office of Management and Budget;

(iii) the Domestic Policy Council;

(iv) the National Security Staff;

(v) the Office of Science and Technology Policy;

(vi) the Office of National Drug Control Policy; and

(vii) such other executive departments, agencies, or offices as the Co-Chairs may designate.

A member agency of the Task Force shall designate a full-time officer or employee of the Federal Government to perform the Task Force functions.

(b) *Mission.* Member agencies shall review relevant statutes, policies, and agency training and guidance to identify reforms and take actions that facilitate implementation of the strategies outlined in this order. Member agencies shall work collaboratively on these strategies and also create an inventory of mental health and substance abuse programs and activities to inform this work.

(c) *Functions.*

(i) Not later than 180 days after the date of this order, the Task Force shall submit recommendations to the President on strategies to improve mental health and substance abuse treatment services for veterans, service members, and their families. Every year thereafter, the Task Force shall provide to the President a review of agency actions to enhance mental health and substance abuse treatment services for veterans, service members, and their families consistent with this order, as well as provide additional recommendations for action as appropriate. The Task Force shall define specific goals and metrics that will aid in measuring progress in improving mental health strategies. The Task Force will include cost analysis in the development of all recommendations, and will ensure any new requirements are supported within existing resources.

(ii) In addition to coordinating and reviewing agency efforts to enhance veteran and military mental health services pursuant to this order, the Task Force shall evaluate:

(1) agency efforts to improve care quality and ensure that the Departments of Defense and Veterans Affairs and community-based mental health providers are trained in the most current evidence-based methodologies for treating PTSD, TBI, depression, related mental health conditions, and substance abuse;

(2) agency efforts to improve awareness and reduce stigma for those needing to seek care; and

(3) agency research efforts to improve the prevention, diagnosis, and treatment of TBI, PTSD, and related injuries, and explore the need for an external research portfolio review.

(iii) In performing its functions, the Task Force shall consult with relevant nongovernmental experts and organizations as necessary.

Sec. 7. *General Provisions.* (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) 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.

THE WHITE HOUSE,
August 31, 2012.

[FR Doc. 2012–22062
Filed 9–4–12; 2:00 pm]
Billing code 3295–F2–P

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Federal Register

Vol. 77, No. 172

Wednesday, September 5, 2012

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Other Services	
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FEDERAL REGISTER PAGES AND DATE, SEPTEMBER

53769–54352 4
54353–54786 5

CFR PARTS AFFECTED DURING SEPTEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Executive Orders:
13642 54779
13625 54783

10 CFR

2 53769
171 53769

12 CFR

Proposed Rules:
34 54722
164 54722
226 54722
722 54722
1026 54722
1222 54722

14 CFR

39 54353

Proposed Rules:
235 53779

15 CFR

Proposed Rules:
1400 53780

16 CFR

Proposed Rules:
1240 53781

17 CFR

4 54355

Proposed Rules:
230 54464
239 54464

21 CFR

Proposed Rules:
172 53801

23 CFR

Proposed Rules:
172 53802

26 CFR

Proposed Rules:
1 54482

29 CFR

Proposed Rules:
1610 53814

30 CFR

Proposed Rules:
901 54490
944 54491

33 CFR

165 53769

Proposed Rules:
110 54493
165 54495

34 CFR

Proposed Rules:
Ch. I 53819

36 CFR

Proposed Rules:
7 53826

37 CFR

1 54360
41 54360

Proposed Rules:
202 53829

38 CFR

1 54367
17 54368

39 CFR

Proposed Rules:
111 53830
966 53830

40 CFR

52 ..... 53772, 53773
70 54382
86 54384
180 54402

Proposed Rules:
122 53834
725 54499

42 CFR

412 53968
413 53968
495 53968

44 CFR

64 53775

45 CFR

162 54664
170 54163

47 CFR

101 54421

Proposed Rules:
101 54511

50 CFR

17 54434
20 54451
622 53776

Proposed Rules:
17 ..... 54294, 54332, 54517, 54548

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H.R. 1402/P.L. 112–170

To authorize the Architect of the Capitol to establish battery recharging stations for privately owned vehicles in parking areas under the jurisdiction of the House of Representatives at no net cost to the Federal Government. (Aug. 16, 2012; 126 Stat. 1303)

H.R. 3670/P.L. 112–171

To require the Transportation Security Administration to comply with the Uniformed Services Employment and Reemployment Rights Act. (Aug. 16, 2012; 126 Stat. 1306)

H.R. 4240/P.L. 112–172

Ambassador James R. Lilley and Congressman Stephen J. Solarz North Korea Human Rights Reauthorization Act of 2012 (Aug. 16, 2012; 126 Stat. 1307)

S. 3510/P.L. 112–173

To prevent harm to the national security or endangering the military officers and civilian employees to whom internet publication of certain information applies, and for other purposes. (Aug. 16, 2012; 126 Stat. 1310)

Last List August 16, 2012

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