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FEDERAL REGISTER

Vol. 80 Tuesday,
No. 134 July 14, 2015

Pages 40895–41408

OFFICE OF THE FEDERAL REGISTER

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

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Contents

Federal Register

Vol. 80, No. 134

Tuesday, July 14, 2015

Agriculture Department
See Grain Inspection, Packers and Stockyards Administration

Bonneville Power Administration
NOTICES
Records of Decisions:
Electrical Interconnection of the Whistling Ridge Energy Project, 41019–41029

Census Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Redistricting Data Program, 40993–40995

Centers for Medicare & Medicaid Services
RULES
Acquisition, Protection, and Disclosure of Quality Improvement Organization Information; CFR Correction, 40923
Conditions of Participation for Hospitals; CFR Correction, 40923
PROPOSED RULES
Medicare Program:
Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, 41198–41316
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 41042–41044

Children and Families Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Annual Report on Households Assisted by the Low Income Home Energy Assistance Program, 41044

Civil Rights Commission
NOTICES
Meetings:
Indiana Advisory Committee, 40992–40993
Oklahoma Advisory Committee; Testimony on Civil Rights Concerns School-to-prison Pipeline in Oklahoma, 40992

Coast Guard
RULES
Safety Zones:
POLAR PIONEER, Outer Continental Shelf Drill Unit, Chukchi Sea, AK, 40903–40905

Commerce Department
See Census Bureau
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration
See National Telecommunications and Information Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 40995
Privacy Act; Systems of Records, 40995–40997

Commodity Futures Trading Commission
PROPOSED RULES
Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants:
Cross-Border Application of the Margin Requirements, 41376–41408

Defense Department
PROPOSED RULES
Federal Acquisition Regulations:
Fair Pay and Safe Workplaces; Extension of Comment Period, 40968–40969
NOTICES
Arms Sales, 41015–41017

Drug Enforcement Administration
NOTICES
Decisions and Orders:
Odette L. Campbell, M.D., 41062–41079
Trenton F. Horst, D.O., 41079–41092

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
An Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior, 41017
Department of Education Pre-Authorized Debit Account Brochure and Application, 41018–41019
Early Childhood Longitudinal Study, Kindergarten Class of 2010–11, Spring Fifth-Grade National Data Collection, 41018

Employee Benefits Security Administration
RULES
Coverage of Certain Preventive Services Under the Affordable Care Act, 41318–41347

Energy Department
See Bonneville Power Administration
See Federal Energy Regulatory Commission
PROPOSED RULES
Energy Conservation Standards:
Intent to Establish the Central Air Conditioners and Heat Pumps Working Group; Meeting, Appliance Standards and Rulemaking Federal Advisory Committee, 40938–40942
NOTICES
Applications to Export Electric Energy:
Elan Energy Services, LLC, 41029–41030

Environmental Protection Agency
RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
Arizona, Infrastructure Requirements for Lead and Ozone, 40905–40909
California, South Coast Air Quality Management District, 40915–40917
California, Ventura and Eastern Kern Air Pollution Control Districts; Permit Exemptions, 40909–40910

Maryland, Low Emissions Vehicle Program Revisions, 40917–40922
Montana, Determinations of Attainment of the 1997 Annual Fine Particulate Matter Standard for the Libby Nonattainment Area, 40911–40912
New Mexico, Revisions to the Particulate Matter Less than 2.5 Micrometers Prevention of Significant Deterioration Permitting Program, 40913–40915
Clean Air Act Operating Permit Program:
Pennsylvania; Revision, 40922–40923
PROPOSED RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
California, South Coast Air Quality Management District, 40955
Maryland, Low Emissions Vehicle Program Revisions, 40955–40956
New Mexico, Revisions to the Particulate Matter Less than 2.5 Micrometers Prevention of Significant Deterioration Permitting Program, 40954–40955
South Dakota; Revisions to South Dakota Administrative Code, 40952–40954
NOTICES
Analysis of the Greenhouse Gas Emissions Attributable to Production and Transport of Cotton (Gossypium spp.) Seed Oil for Use in Biofuel Production, 41033–41040
Receipt of Test Data under the Toxic Substances Control Act, 41040–41041

Farm Credit Administration
RULES
Organization and Functions:
Field Office Locations, 40896–40897

Federal Aviation Administration
RULES
Airworthiness Directives:
GE Aviation Czech s.r.o. Turboprop Engines, 40897–40899
The Boeing Company Airplanes, 40899–40903
PROPOSED RULES
Airworthiness Directives:
Airbus Airplanes, 40942–40947
Airbus Helicopters, 40947–40949
PILATUS AIRCRAFT LTD. Airplanes, 40949–40951

Federal Communications Commission
RULES
Lifeline and Link Up Reform and Modernization, Telecommunications Carriers Eligible for Universal Service Support, Connect America Fund, 40923–40936
PROPOSED RULES
Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions:
Channel Sharing by Full Power and Class A Stations Outside the Broadcast Television Spectrum Incentive Auction Context, 40957–40968
Wireline Competition Bureau Further Extends Comment Deadlines in Special Access Proceeding, 40956–40957
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 41041

Federal Energy Regulatory Commission
NOTICES
Authorizations for Continued Project Operations:
Erie Boulevard Hydropower, LP, 41031
Gresham Municipal Utilities, 41030
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
Breckinridge Wind Project, LLC, 41031–41032
Slate Creek Wind Project, LLC, 41033
Meetings; Sunshine Act, 41032–41033
Requests under Blanket Authorizations:
Florida Gas Transmission Co., LLC, 41030–41031

Federal Highway Administration
RULES
National Tunnel Inspection Standards, 41350–41373
NOTICES
Federal Agency Actions:
Proposed Highway in California, 41139–41140

Federal Reserve System
NOTICES
Changes in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 41042
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 41042
Proposals to Engage in or to Acquire Companies Engaged in Permissible Nonbanking Activities, 41042

Federal Transit Administration
NOTICES
Meetings:
Transit Advisory Committee for Safety, 41140

Fish and Wildlife Service
NOTICES
Endangered and Threatened Wildlife and Plants; Incidental Take Permit Applications:
Proposed Diversified Pacific Low-effect Habitat Conservation Plan, etc., Redlands, San Bernardino County, CA, 41052–41053

Food and Drug Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring, 41044–41046
Guidance:
Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices, 41046–41047

General Services Administration
PROPOSED RULES
Federal Acquisition Regulations:
Fair Pay and Safe Workplaces; Extension of Comment Period, 40968–40969

Geological Survey
NOTICES
Exclusive Licenses:
Glosten Associates, 41053–41054

Grain Inspection, Packers and Stockyards Administration
NOTICES
Designations:
Montgomery, AL; Essex, IL; and Savage, MN Areas, 40991–40992
Specified Geographical Areas in Texas, 40991

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

See Children and Families Administration
See Food and Drug Administration
See National Institutes of Health
RULES
Coverage of Certain Preventive Services Under the Affordable Care Act, 41318–41347

Homeland Security Department
See Coast Guard
See Transportation Security Administration

Indian Affairs Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Loan Guarantee, Insurance and Interest Subsidy Program, 41054

Industry and Security Bureau
NOTICES
Meetings:
Information Systems Technical Advisory Committee, 40997–40998

Interior Department
See Fish and Wildlife Service
See Geological Survey
See Indian Affairs Bureau
See Land Management Bureau
See National Park Service
See Reclamation Bureau

Internal Revenue Service
RULES
Coverage of Certain Preventive Services Under the Affordable Care Act, 41318–41347
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 41141–41142
Meetings:
Taxpayer Advocacy Panel Taxpayer Communications Project Committee, 41140–41141

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Certain Steel Nails From the Socialist Republic of Vietnam, 41006–41007
Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China, 40998–41006
Multilayered Wood Flooring from the People's Republic of China, 41007–41010

International Trade Commission
NOTICES
Meetings; Sunshine Act, 41062

Justice Department
See Drug Enforcement Administration

Labor Department
See Employee Benefits Security Administration
See Labor Statistics Bureau
NOTICES
Guidance:
Fair Pay and Safe Workplaces, 41093

Labor Statistics Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 41093–41094

Land Management Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 41057–41059
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Surveys and Focus Groups to Support Outcomes-Focused Management, 41056–41057
Realty Actions:
Recreation and Public Purposes Act Classification for Conveyance of Public Lands in Utah County, UT, 41054–41055

Management and Budget Office
NOTICES
Audits of States, Local Governments, and Non-Profit Organizations; Circular A–133 Compliance Supplement, 41094–41095

National Aeronautics and Space Administration
PROPOSED RULES
Federal Acquisition Regulations:
Fair Pay and Safe Workplaces; Extension of Comment Period, 40968–40969

National Institutes of Health
NOTICES
Meetings:
Center for Scientific Review, 41049–41050
National Eye Institute, 41051
National Institute of Allergy and Infectious Diseases, 41048
National Institute of Environmental Health Sciences, 41047
National Institute of General Medical Sciences, 41049
Office of the Director, 41050
Scientific Advisory Committee on Alternative Toxicological Methods, 41047–41048

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic:
Coastal Migratory Pelagic Resources in the Gulf of Mexico and Atlantic Region; Framework Amendment, 40936–40937
PROPOSED RULES
Endangered and Threatened Wildlife and Plants:
12-Month Finding and Proposal to List Three Angelshark Species as Endangered under the Endangered Species Act, 40969–40988
Fisheries of the Exclusive Economic Zone Off Alaska:
Groundfish Fisheries in the Gulf of Alaska, 40988–40990
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Alaska Region Amendment 80 Permits and Reports, 41010–41011
Draft 2015 Edition of the U.S. Arctic Nautical Charting Plan, 41013
Environmental Impact Statements; Availability, etc.:
Five Early Winter Steelhead Hatchery Programs in Puget Sound, 41011–41012

Meetings:
Mid-Atlantic Fishery Management Council, 41012–41013

National Park Service
NOTICES
Designations:
Official Trail Marker for the Washington–Rochambeau Revolutionary Route National Historic Trail, 41060
Requests for Nominations:
Captain John Smith Chesapeake National Historic Trail Advisory Council, 41060–41061

National Science Foundation
NOTICES
Committee Renewals:
Proposal Review Panel for Integrative Activities, 41095

National Telecommunications and Information Administration

NOTICES
Meetings:
Multistakeholder Process to Develop Best Practices for Privacy, Transparency, and Accountability Regarding Commercial and Private Use of Unmanned Aircraft Systems, 41013–41015

National Transportation Safety Board
NOTICES
Meetings; Sunshine Act, 41095

Nuclear Regulatory Commission
NOTICES
Direct Transfers of Licenses:
Duke Energy Progress, Inc., and North Carolina Eastern Municipal Power Agency; Shearon Harris Nuclear Power Plant, Unit 1, 41097–41099
Duke Energy Progress, Inc., and North Carolina Eastern Municipal Power Agency; Brunswick Steam Electric Plant, Units 1 and 2, 41095–41097
Memoranda of Understanding:
Cooperation on Radioactive Materials Transportation Security; Department of Homeland Security, Department of Transportation, Nuclear Regulatory Commission, 41097

Personnel Management Office
RULES
Prevailing Rate Systems:
Redefinition of the Jacksonville, FL; Savannah, GA; Hagerstown–Martinsburg–Chambersburg, MD; Richmond, VA; and Roanoke, VA, Appropriated Fund Federal Wage System Wage Areas, 40895–40896

Railroad Retirement Board
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 41099–41100
Meetings; Sunshine Act, 41100

Reclamation Bureau
NOTICES
Environmental Impact Statements; Availability, etc.:
Long-Term Plan to Protect Adult Salmon in the Lower Klamath River, Humboldt County, CA, 41061–41062

Securities and Exchange Commission
PROPOSED RULES
Listing Standards for Recovery of Erroneously Awarded Compensation, 41144–41196
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 41125
Fiscal Year 2014 Service Contract Inventory, 41119
Meetings; Sunshine Act, 41119
Self-Regulatory Organizations; Proposed Rule Changes:
Chicago Board Options Exchange, Inc., 41112–41114
EDGA Exchange, Inc., 41109–41111, 41126–41131
EDGX Exchange, Inc., 41104–41109, 41131–41133
Financial Industry Regulatory Authority, Inc., 41119–41123
ICE Clear Credit LLC, 41112
NASDAQ OMX BX, Inc., 41114–41119
NASDAQ Stock Market LLC, 41100–41104, 41133–41136
NYSE MKT LLC, 41123–41125

Small Business Administration
NOTICES
Conflicts of Interest Exemptions under the Small Business Investment Act:
New Canaan Funding Mezzanine V SBIC, LP, 41136–41137
Disaster Declarations:
Oklahoma; Amendment 6, 41136
Surrender of License of Small Business Investment Companies:
North Carolina Economic Opportunities Funds, LP, 41137

State Department
PROPOSED RULES
Privacy Act:
Records Maintained by the Office of Civil Rights, 40951–40952
NOTICES
Culturally Significant Objects Imported for Exhibition:
Made in the Americas: The New World Discovers Asia, 41137
Meetings:
Advisory Committee on International Postal and Delivery Services, 41137
Privacy Act; Systems of Records, 41137–41139

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Federal Transit Administration

Transportation Security Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Maryland Three Airports: Enhanced Security Procedures for Operations at Certain Airports in the Washington, DC, Metropolitan Area Flight Restricted Zone, 41051

Treasury Department
See Internal Revenue Service

Veterans Affairs Department
NOTICES
Meetings:
Health Services Research and Development Service Scientific Merit Review Board, 41142

Separate Parts In This Issue

Part II
Securities and Exchange Commission, 41144–41196

Part III
Health and Human Services Department, Centers for Medicare & Medicaid Services, 41198–41316

Part IV
Health and Human Services Department, 41318–41347
Labor Department, Employee Benefits Security Administration, 41318–41347
Treasury Department, Internal Revenue Service, 41318–41347

Part V
Transportation Department, Federal Highway Administration, 41350–41373

Part VI
Commodity Futures Trading Commission, 41376–41408

Reader Aids

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

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

CFR PARTS AFFECTED IN THIS ISSUE

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

5 CFR
532 40895

10 CFR
Proposed Rules:
430 40938

12 CFR
600 40896

14 CFR
39 (2 documents) 40897, 40899
Proposed Rules:
39 (3 documents) 40942, 40947, 40949

17 CFR
Proposed Rules:
23 41376
229 41144
240 41144
249 41144
274 41144

22 CFR
Proposed Rules:
171 40951

23 CFR
650 41350

26 CFR
54 41318

29 CFR
2510 41318
2590 41318

33 CFR
147 40903

40 CFR
52 (6 documents) 40905, 40909, 40911, 40913, 40915, 40917
70 40922
Proposed Rules:
52 (4 documents) 40952, 40954, 40955

42 CFR
480 40923
482 40923
Proposed Rules:
510 41198

45 CFR
147 41318

47 CFR
54 40923
Proposed Rules:
69 40956
73 40957

48 CFR
Proposed Rules:
1 40968
4 40968
8 40968
17 40968
22 40968
52 40968

50 CFR
622 40936
Proposed Rules:
224 40969
679 40988

Rules and Regulations

Federal Register
Vol. 80, No. 134
Tuesday, July 14, 2015

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

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206–AN15

Prevailing Rate Systems; Redefinition of the Jacksonville, FL; Savannah, GA; Hagerstown-Martinsburg-Chambersburg, MD; Richmond, VA; and Roanoke, VA, Appropriated Fund Federal Wage System Wage Areas

AGENCY: U.S. Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing a final rule to redefine the geographic boundaries of the Jacksonville, FL; Savannah, GA; Hagerstown-Martinsburg-Chambersburg, MD; Richmond, VA; and Roanoke, VA, appropriated fund Federal Wage System (FWS) wage areas. The final rule redefines Brantley, Glynn, and Pierce Counties, GA, from the Jacksonville wage area to the Savannah wage area; Greene County, VA, from the Hagerstown-Martinsburg-Chambersburg wage area to the Richmond wage area; and Nelson County, VA, from the Roanoke wage area to the Richmond wage area. These changes are based on consensus recommendations of the Federal Prevailing Rate Advisory Committee (FPRAC) to best match the counties proposed for redefinition to a nearby FWS survey area.

DATES: *Effective date:* This regulation is effective on July 14, 2015. *Applicability date:* This change applies on the first day of the first applicable pay period beginning on or after August 13, 2015.

FOR FURTHER INFORMATION CONTACT: Madeline Gonzalez, (202) 606–2838; email *pay-leave-policy@opm.gov;* or FAX: (202) 606–4264.

SUPPLEMENTARY INFORMATION: On February 2, 2015, OPM issued a proposed rule (80 FR 5487) to redefine Brantley, Glynn, and Pierce Counties, GA, from the Jacksonville, FL, wage area to the Savannah, GA, wage area; Greene County, VA, from the Hagerstown-Martinsburg-Chambersburg, MD, wage area to the Richmond, VA, wage area; and Nelson County, VA, from the Roanoke, VA, wage area to the Richmond wage area.

FPRAC, the national labor-management committee responsible for advising OPM on matters concerning the pay of FWS employees, reviewed and recommended these changes by consensus.

The proposed rule had a 30-day comment period, during which OPM received no comments.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

U.S. Office of Personnel Management.

Katherine Archuleta,

Director.

Accordingly, the U.S. Office of Personnel Management amends 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

■ 1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

■ 2. Appendix C to subpart B is amended by revising the wage area listings for the Jacksonville, FL; Savannah, GA; Hagerstown-Martinsburg-Chambersburg, MD; Richmond, VA; and Roanoke, VA, wage areas to read as follows:

Appendix C to Subpart B of Part 532—Appropriated Fund Wage and Survey Areas

* * * * *

FLORIDA

* * * * *

Jacksonville

Survey Area

Florida:
- Alachua
- Baker
- Clay
- Duval
- Nassau
- St. Johns

Area of Application. Survey area plus:

Florida:
- Bradford
- Citrus
- Columbia
- Dixie
- Flagler
- Gilchrist
- Hamilton
- Lafayette
- Lake
- Levy
- Madison
- Marion
- Orange
- Osceola
- Putnam
- Seminole
- Sumter
- Suwannee
- Taylor
- Union
- Volusia

Georgia:
- Camden
- Charlton

* * * * *

GEORGIA

* * * * *

Savannah

Survey Area

Georgia:
- Bryan
- Chatham
- Effingham
- Liberty

Area of Application. Survey area plus:

Georgia:
- Appling
- Bacon
- Brantley
- Bulloch
- Candler
- Evans
- Glynn
- Jeff Davis
- Long
- McIntosh
- Pierce
- Screven
- Tattnall
- Toombs
- Wayne

South Carolina:
- Beaufort (the portion south of Broad River)

Hampton
Jasper

* * * * *

MARYLAND

* * * * *

Hagerstown-Martinsburg-Chambersburg

Survey Area

Maryland:
Washington
Pennsylvania:
Franklin
West Virginia:
Berkeley

Area of Application. Survey area plus:

Maryland:
Allegany
Garrett
Pennsylvania:
Fulton
Virginia (cities):
Harrisonburg
Winchester
Virginia (counties):
Frederick
Madison
Page
Rockingham
Shenandoah
West Virginia:
Hampshire
Hardy
Mineral
Morgan

* * * * *

VIRGINIA

* * * * *

Richmond

Survey Area

Virginia (cities):
Colonial Heights
Hopewell
Petersburg
Richmond
Virginia (counties):
Charles City
Chesterfield
Dinwiddie
Goochland
Hanover
Henrico
New Kent
Powhatan
Prince George

Area of Application. Survey area plus:

Virginia (cities):
Charlottesville
Emporia
Virginia (counties):
Albemarle
Amelia
Brunswick
Buckingham
Caroline
Charlotte
Cumberland
Essex
Fluvanna
Greene
Greensville
King and Queen
King William
Lancaster
Louisa
Lunenburg
Mecklenburg
Middlesex
Nelson
Northumberland
Nottoway
Orange
Prince Edward
Richmond
Sussex
Westmoreland

Roanoke

Survey Area

Virginia (cities):
Radford
Roanoke
Salem
Virginia (counties):
Botetourt
Craig
Montgomery
Roanoke

Area of Application. Survey area plus:

Virginia (cities):
Bedford
Buena Vista
Clifton Forge
Covington
Danville
Galax
Lexington
Lynchburg
Martinsville
South Boston
Staunton
Waynesboro
Virginia (counties):
Alleghany
Amherst
Appomattox
Augusta
Bath
Bedford
Bland
Campbell
Carroll
Floyd
Franklin
Giles
Halifax
Henry
Highland
Patrick
Pittsylvania
Pulaski
Rockbridge
Wythe

* * * * *

[FR Doc. 2015–17212 Filed 7–13–15; 8:45 am]

BILLING CODE 6325–39–P

FARM CREDIT ADMINISTRATION

12 CFR Part 600

RIN 3052–AD07

Organization and Functions; Field Office Locations

AGENCY: Farm Credit Administration

ACTION: Final rule.

SUMMARY: The Farm Credit Administration (FCA, we, our or Agency) issues a final rule amending our regulation in order to change the address for a field office as a result of a recent office relocation.

DATES: The regulation shall become effective no earlier than 30 days after publication in the **Federal Register** during which either or both Houses of Congress are in session. We will publish notice of the effective date in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Michael T. Wilson, Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4124, TTY (703) 883–4056, or Jane Virga, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4071, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION:

I. Objective

The objective of this final rule is to reflect the change of address for an FCA field office location. The Freedom of Information Act, 5 U.S.C. 552, requires, in part, that each Federal agency publish in the **Federal Register** for the guidance of the public a description and the location of its central and field organizations. As one of FCA's field offices recently changed location, this final rule amends our regulation to include the new address, in accordance with the Freedom of Information Act.

II. Certain Finding

We have determined that the amendment involves Agency management and personnel. Therefore, this amendment does not constitute a rulemaking under the Administrative Procedure Act (APA), 5 U.S.C. 551, 553(a)(2). Under the APA, the public may participate in the promulgation of rules that have a substantial impact on the public. This amendment to our regulation relates to Agency management and personnel only and has no direct impact on the public and, therefore, does not require public participation.

Even if this amendment was a rulemaking under 5 U.S.C. 551,

553(a)(2) of the APA, we have determined that notice and public comment are unnecessary and contrary to the public interest. Under 5 U.S.C. 553(b)(A) and (B) of the APA, an agency may publish regulations in final form when they involve matters of agency organization or where the agency for good cause finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest. As discussed above, this amendment results from recent address changes due to the relocation of one field office. Because the amendment will provide accurate and current information on field office addresses to the public, it would be contrary to the public interest to delay amending the regulation.

III. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), FCA hereby certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Each of the banks in the Farm Credit System (System), considered together with its affiliated associations, has assets and annual income in excess of the amounts that would qualify them as small entities. Therefore, System institutions are not ''small entities'' as defined in the Regulatory Flexibility Act.

List of Subjects in 12 CFR Part 600

Organization and functions (Government agencies).

As stated in the preamble, part 600 of chapter VI, title 12, of the Code of Federal Regulations is amended as follows:

PART 600—ORGANIZATION AND FUNCTIONS

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

Authority: Secs. 5.7, 5.8, 5.9, 5.10, 5.11, 5.17, 8.11 of the Farm Credit Act (12 U.S.C. 2241, 2242, 2243, 2244, 2245, 2252, 2279aa–11).

■ 2. Amend § 600.2 by revising paragraph (b) to read as follows:

§ 600.2 Farm Credit Administration.

* * * * *

(b) *Locations.* FCA's headquarters address is 1501 Farm Credit Drive, McLean, Virginia 22102–5090. The FCA has the following field offices:

1501 Farm Credit Drive, McLean, VA 22102–5090
7900 International Drive, Suite 200, Bloomington, MN 55425–2563
500 East John Carpenter Freeway, Suite 400, Irving, TX 75602–3957
8101 East Prentice Avenue, Suite 1200, Greenwood Village, CO 80111–2939
2180 Harvard Street, Suite 300, Sacramento, CA 95815–3323.

Dated: July 8, 2015.

Dale L. Aultman,

Secretary, Farm Credit Administration.

[FR Doc. 2015–17242 Filed 7–13–15; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0482; Directorate Identifier 2015–NE–06–AD; Amendment 39–18200; AD 2015–14–02]

RIN 2120–AA64

Airworthiness Directives; GE Aviation Czech s.r.o. Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain serial number GE Aviation Czech s.r.o. M601E–11, M601E–11A, and M601F turboprop engines. This AD requires inspection of the reduction gearbox and supporting cone. This AD was prompted by the determination that wear or cracking, and subsequent misalignment of the quill shaft of the engine and the power turbine (PT) shaft, may lead to rupture of the quill shaft, overspeed of the PT, and uncontained engine failure. We are issuing this AD to prevent misalignment and rupture of the quill shaft, which could lead to overspeed of the PT, uncontained engine failure, and damage to the airplane.

DATES: This AD becomes effective August 18, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 18, 2015.

ADDRESSES: For service information identified in this AD, contact GE Aviation Czech s.r.o., Beranových 65, 199 02 Praha 9—Letňany, Czech Republic; phone: +420 222 538 111; fax: +420 222 538 222. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0482. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0482; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: *philip.haberlen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to the specified products. The NPRM was published in the **Federal Register** on April 10, 2015 (80 FR 19244). The NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> It has been identified that misalignment between the quill shaft of the engine and the Power Turbine (PT) shaft may lead to a rupture of the quill shaft.
>
> This condition, if not detected and corrected, could lead to overspeed of the PT and consequent uncontained engine failure, possibly resulting in damage to the aeroplane and injury to occupants and/or persons on the ground.

Related Service Information Under 1 CFR Part 51

We reviewed GE Aviation Czech s.r.o. Alert Service Bulletins (ASBs) No. M601E–11/28, M601E–11A/15, and M601F/26, all Revision 2, all dated January 23, 2015. This service information describes procedures for inspecting the M601 reduction gearbox and supporting cone. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (80 FR 19244, April 10, 2015).

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting this AD as proposed.

Costs of Compliance

We estimate that this AD affects 16 engines installed on airplanes of U.S. registry. We also estimate that it would take about 112 hours per engine to comply with this AD. The average labor rate is $85 per hour. Required parts cost about $21,376 per engine. Based on these figures, we estimate the cost of this AD on U.S. operators to be $494,336. Our cost estimate is exclusive of possible warranty coverage.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed above, I certify this AD:

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

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

(3) Will not affect intrastate aviation in Alaska 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.

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):

2015–14–02 GE Aviation Czech s.r.o. (Type Certificate previously held by WALTER Engines a.s., Walter a.s., and MOTORLET a.s.): Amendment 39–18200; Docket No. FAA–2015–0482; Directorate Identifier 2015–NE–06–AD.

(a) Effective Date

This AD becomes effective August 18, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to GE Aviation Czech s.r.o. M601E–11, M601E–11A, and M601F turboprop engines with the following serial numbers (S/Ns):

(1) Model M601E–11: S/Ns 833244, 841289, 852239, 861007, 881217, 884021, 892046, 892219, 894018, 903028, 913038, and 912023.

(2) Model M601E–11A: S/Ns 902004 and 883046.

(3) Model M601F: S/Ns 912001 and 924002.

(d) Reason

This AD was prompted by the determination that wear or cracking, and subsequent misalignment of the quill shaft of the engine and the power turbine (PT) shaft, may lead to rupture of the quill shaft, overspeed of the PT, and uncontained engine failure. We are issuing this AD to prevent misalignment and rupture of the quill shaft, which could lead to overspeed of the PT, uncontained engine failure, and damage to the airplane.

(e) Actions and Compliance

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

(1) Within 300 flight hours, or six months after the effective date of this AD, whichever occurs first, inspect the reduction gearbox and supporting cone. Use GE Aviation Czech s.r.o. Alert Service Bulletins (ASBs) No. M601E–11/28, M601E–11A/15, and M601F/26, all Revision 2, all dated January 23, 2015, including Appendix 2, paragraph 4., Inspection, (the issue date is not specified in the appendix), as applicable, to do the inspection.

(2) If any crack is detected on the quill shaft, PT shaft, or the supporting cone, or if the quill shaft or PT shaft involute spline wear exceeds 0.12 mm, then before further flight, replace each cracked or worn part with a part eligible for installation.

(f) Credit for Previous Actions

If you performed the actions required by paragraphs (e)(1) and (e)(2) of this AD before the effective date of this AD using GE Aviation Czech s.r.o. ASBs No. M601E–11/28, M601E–11A/15, or M601F/26, all Revision 1, all dated December 23, 2014, as applicable, or Initial Issues, all dated June 27, 2014, as applicable, you have met the requirements of this AD.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(h) Related Information

(1) For more information about this AD, contact Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: *philip.haberlen@faa.gov.*

(2) Refer to MCAI European Aviation Safety Agency AD 2015–0014, dated January 30, 2015, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2015–0482.

(i) Material Incorporated by Reference

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

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

(i) GE Aviation Czech s.r.o. Alert Service Bulletin (ASB) No. M601E–11/28, Revision 2, dated January 23, 2015, including Appendix 2, (the issue date is not specified in the appendix).

(ii) GE Aviation Czech s.r.o. ASB No. M601E–11A/15, Revision 2, dated January 23, 2015, including Appendix 2, (the issue date is not specified in the appendix).

(iii) GE Aviation Czech s.r.o. ASB No. M601F/26, Revision 2, dated January 23, 2015, including Appendix 2, (the issue date is not specified in the appendix).

Note 1 to paragraph (i)(2): GE Aviation Czech s.r.o. ASBs No. M601E–11/28, M601E–11A/15, and M601F/26, all Revision 2, all dated January 23, 2015, including Appendix 2, are co-published as one document with ASBs No. M601D/44, M601D–1/29, M601D–11NZ/18, M601E/59, and M601E–21/26, which are not incorporated by reference.

(3) For GE Aviation Czech s.r.o. service information identified in this AD, contact GE Aviation Czech s.r.o., Beranových 65, 199 02 Praha 9—Letňany, Czech Republic; phone: +420 222 538 111; fax: +420 222 538 222.

(4) You may view this service information at FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

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

Issued in Burlington, Massachusetts, on June 26, 2015.

Ann C. Mollica,

Acting Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015–16584 Filed 7–13–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0339; Directorate Identifier 2014–NM–025–AD; Amendment 39–18192; AD 2015–13–05]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This AD was prompted by reports of fatigue cracks found in the upper corners of the forward entry door skin cutout. This AD requires repetitive inspections for cracking in the upper corners of the forward entry door skin cutout, and repair if necessary. Accomplishment of this repair or a preventive modification terminates the repetitive inspections. We are issuing this AD to detect and correct cracking in the doorway upper corners, which could result in cabin depressurization.

DATES: This AD is effective August 18, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 18, 2015.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0339.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0339; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Nenita Odesa, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; telephone: 562–627–5234; fax: 562–627–5210; email: *nenita.odesa@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. The NPRM published in the **Federal Register** on June 11, 2014 (79 FR 33484). The NPRM was prompted by reports of fatigue cracks found in the upper corners of the forward entry door skin cutout. The NPRM proposed to require repetitive inspections for cracking in the upper corners of the forward entry door skin cutout, and repair if necessary. Accomplishment of this repair or a preventive modification would terminate the repetitive inspections. We are issuing this AD to detect and correct cracking in the doorway upper corners, which could result in cabin depressurization.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 33484, June 11, 2014) and the FAA's response to each comment.

Support for the NPRM (79 FR 33484, June 11, 2014)

Boeing stated that it supports the NPRM (79 FR 33484, June 11, 2014).

Request To Clarify Terminating Action

Southwest Airlines (SWA) requested confirmation that paragraph 3.B.4. of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, is an acceptable terminating action for the inspection requirements of paragraph (g)(1) of this NPRM (79 FR 33484, June 11, 2014) for the repaired door corners.

SWA stated that the repairs provided in Part 3 of the Accomplishment

Instructions of Boeing Service Bulletin 737–53–1163, dated December 21, 1993, and in Part 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, contain instructions using the service information figures or using the structural repair manual. SWA stated that there are no provisions in the NPRM (79 FR 33484, June 11, 2014) for repairs installed using FAA Form 8100–9 prior to the issuance of the NPRM. SWA stated that paragraph 3.B.4. of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, states that, ''For door corners that have a repair provided by Boeing and approved via FAA Form 8100–9 installed, the inspection in this service bulletin is not required for the repaired door corner(s).''

We agree that paragraph 3.B.4. of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, is an acceptable terminating action for the inspection requirements of paragraph (g)(1) of this AD. We have added a new paragraph (h)(3) to this AD accordingly.

Request To Change the Compliance Time

SWA requested that the compliance time for paragraph (i) in the proposed AD (79 FR 33484, June 11, 2014) be revised. SWA suggested that the proposed requirement of paragraph (i) of the proposed AD state that the compliance time in table 3 of paragraph 1.E., ''Compliance'' of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, be implemented during the operator's repair assessment program (RAP), provided that the operator's RAP was developed using the ''D6–38669, Repair Assessment Guidelines-Model 737–100 to –500,'' and approved by the FAA principal maintenance inspector.

SWA stated that the 60,000-total-flight-cycle requirement may not coincide with the operator's implementation of the ''D6–38669, Repair Assessment Guidelines-Model 737–100 to –500.'' SWA stated that airplanes with existing preventive modifications and repairs that have already surpassed the compliance time in table 3 of 1.E., ''Compliance'' of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, will immediately be rendered out of compliance by paragraph (i) of the proposed AD (79 FR 33484, June 11, 2014) if the table 3 requirement of 1.E., ''Compliance'' of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, does not coincide with the operator's RAP.

We partially agree with the commenter's request. We disagree with the commenter's proposed compliance time because our examination of this issue shows that the compliance period for the RAP may be too long to address the unsafe condition. However, we agree that some airplanes would be rendered immediately out of compliance, and therefore, a compliance grace period should be added. We have added a grace period of ''4,500 flight cycles after the effective date of this AD'' to the compliance time in paragraph (i) of this AD.

Request To Provide Conditional Relief From Inspection Requirements

SWA requested that the NPRM (79 FR 33484, June 11, 2014) provide relief from the external detailed inspection in areas that are hidden by an existing non-corner Boeing repair approved using FAA form 8100–9. SWA stated that an external detailed inspection is still required in the area not hidden by the repair.

We agree with the commenter's request. As we stated previously, we have added a new paragraph (h)(3) to this AD for door corners that have an existing repair installed, as provided by Boeing and approved using FAA Form 8100–9. Under these conditions, the inspection in paragraph (g)(1) of this AD is not required for the repaired door corners.

Request to Revise the Requirements for Post-Modification and Post-Repair Inspections

SWA requested that the post-modification and post-repair inspections specified in table 3 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, not be required in paragraph (i) of the proposed AD (79 FR 33484, June 11, 2014). SWA stated that the post-modification and post-repair inspections are currently mandated under 14 CFR 129.109(b)(2)14 and CFR 121.1109(c)(2).

We partially agree with the commenter's request. As we stated previously, our examination of this issue shows that the compliance period for the RAP may be too long to address the unsafe condition. However, we agree that these inspections are required under 14 CFR 129.109(b)(2)14 and CFR 121.1109(c)(2). Operators who have already begun inspections of this area using the RAP should not be burdened with an additional and identical inspection requirement. Therefore, we have redesignated paragraph (i) of the proposed AD (79 FR 33484, June 11, 2014) as paragraph (i)(1) and added new paragraph (i)(2) to this final rule, which states that the inspection requirement in paragraph (i)(1) of this AD does not apply to operators who have added inspections of this area in accordance with 14 CFR 121.1109(c)(2) or § 129.109(b)(2) to their FAA-approved maintenance program. These inspections may be used in support of compliance with 14 CFR 121.1109(c)(2) or § 129.109(b)(2).

Effect of Winglets on AD

Aviation Partners Boeing stated that accomplishing the supplemental type certificate (STC) ST01219SE does not affect the actions specified in the NPRM (79 FR 33484, June 11, 2014).

We concur with the commenter. We have redesignated paragraph (c) of the NPRM (79 FR 33484, June 11, 2014) as (c)(1) and added new paragraph (c)(2) to this final rule to state that installation of STC ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/%24FILE/ST01219SE.pdf*)) does not affect the ability to accomplish the actions required by this final rule. Therefore, for airplanes on which STC ST01219SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the change described previously, and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 33484, June 11, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 33484, June 11, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–53A1163, dated December

21, 1993; and Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014. The service information describes repetitive inspections for cracking in the upper corners of the forward entry door skin cutout, and repair if necessary. Accomplishment of this repair or a preventive modification terminates the repetitive inspections. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

Costs of Compliance

We estimate that this AD affects 371 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS—REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	3 work-hours × $85 per hour = $255	$0	$255	$94,605

ESTIMATED COSTS—OPTIONAL ACTIONS

Action	Labor cost	Parts cost	Cost per product
Preventive modification	44 work-hours × $85 per hour = $3,740	Up to $3,912	Up to $7,652.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair	60 work-hours × $85 per hour = $5,100	Up to $4,964	Up to $10,064.

We have received no definitive data that would enable us to provide a cost estimate for the post-repair or post-preventive modification inspections specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2015–13–05 The Boeing Company: Amendment 39–18192; Docket No. FAA–2014–0339; Directorate Identifier 2014–NM–025–AD.

(a) Effective Date

This AD is effective August 18, 2015.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes; certificated in any category; as identified in Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/%24FILE/ST01219SE.pdf*) does not affect the

ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of fatigue cracks found in the upper corners of the forward entry door skin cutout. We are issuing this AD to detect and correct cracking in the doorway upper corners, which could result in cabin depressurization.

(f) Compliance

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

(g) Inspection

(1) For airplanes identified in Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, as Groups 1 and 2, Configuration 2, and Group 3: Before the accumulation of 27,000 total flight cycles, or within 4,500 flight cycles after the effective date of this AD, whichever occurs later, do an external detailed inspection for cracking of the skin assembly, and a low frequency eddy current (LFEC) inspection for cracking of the skin assembly and bear strap, and all applicable corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, except as required by paragraph (j) of this AD. Repeat the inspections thereafter at intervals not to exceed 4,500 flight cycles. Do all applicable corrective actions before further flight.

(2) For airplanes identified as Group 4 in Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014: Within 120 days after the effective date of this AD, do inspections of the skin assembly and bear strap and all applicable corrective actions using a method approved in accordance with the procedures specified in paragraph (m) of this AD.

(h) Terminating Actions

(1) Accomplishment of the preventive change specified in Part II of the Accomplishment Instructions of Boeing Service Bulletin 737–53–1163, dated December 21, 1993; or the preventive modification specified in Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014; terminates the inspection requirements specified in paragraph (g)(1) of this AD.

(2) Accomplishment of the repair specified in Part III of the Accomplishment Instructions of Boeing Service Bulletin 737–53–1163, dated December 21, 1993; or Part 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014; terminates the inspection requirements specified in paragraph (g)(1) of this AD.

(3) For door corners that have a repair installed, as provided by Boeing, which inhibits the inspections required by paragraph (g)(1) of this AD, and approved before the effective date of this AD using FAA Form 8100–9, the inspection in paragraph (g)(1) of this AD is not required. Refer to the repair approval for any supplemental inspection of the repair area.

(i) Post-Modification and Post-Repair Inspections

(1) For airplanes identified in Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, as Groups 1 and 2, on which a repair or preventive modification has been installed in accordance with Boeing Service Bulletin 737–53–1163, dated December 21, 1993; or Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014: At the applicable time specified in table 3 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, or within 4,500 flight cycles after the effective date of this AD, whichever occurs later, inspect the fuselage skin assembly, bear strap, and frame and sill outer chords, as applicable, for cracking, in accordance with table 3 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014. Repeat the inspection thereafter at the times specified in table 3 of paragraph 1.E., ''Compliance'' of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014. If any crack is found during any inspection required by this paragraph, repair before further flight using a method approved in accordance with the procedures specified in paragraph (m) of this AD.

(2) The inspection requirement in paragraph (i)(1) of this AD does not apply to operators who have added the inspection program for this area specified in table 3 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, in accordance with 14 CFR 121.1109(c)(2) or § 129.109(b)(2) to their FAA-approved maintenance program. These inspections may be used in support of compliance with 14 CFR 121.1109(c)(2) or § 129.109(b)(2).

(j) Exception to Service Information Specifications

If any cracking is found during any inspection required by this AD, and Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, specifies to contact Boeing for appropriate action: Before further flight, repair the crack using a method approved in accordance with the procedures specified in paragraph (m) of this AD.

(k) Explanation of Service Information and AD: Repair/Preventative Modification Required

The Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014, state that Group 1 and 2, Configuration 1 airplanes on which the repair or preventive modification has been installed as specified in Boeing Service Bulletin 737–53–1163, dated December 21, 1993, are not required to be inspected. However, this AD requires inspections of Group 1 and 2 airplanes, as identified in and in accordance with paragraph (i) of this AD, which correspond with table 3 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014.

(l) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 737–53–1163, dated December 21, 1993.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (n)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov*.

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(n) Related Information

(1) For more information about this AD, contact Nenita Odesa, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles ACO, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; telephone: 562–627–5234; fax: 562–627–5210; email: *nenita.odesa@faa.gov*.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(3) and (o)(4) of this AD.

(o) Material Incorporated by Reference

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

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

(i) Boeing Service Bulletin 737–53–1163, dated December 21, 1993.

(ii) Boeing Alert Service Bulletin 737–53A1163, Revision 1, dated January 8, 2014.

(3) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data &

Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com*.

(4) You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

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

Issued in Renton, Washington, on June 19, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–15852 Filed 7–13–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket No. USCG–2015–0247]

RIN 1625–AA00

Safety Zone; POLAR PIONEER, Outer Continental Shelf Drill Unit, Chukchi Sea, Alaska

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone that extends 500 meters from the outer edge of the DRILL UNIT POLAR PIONEER. This safety zone will be in effect when the DRILL UNIT POLAR PIONEER is on location in order to drill exploratory wells at various prospects located in the Chukchi Sea Outer Continental Shelf, Alaska, from 12:01 a.m. on July 1, 2015 through 11:59 p.m. on October 31, 2015. The purpose of the temporary safety zone is to protect the drillship from vessels operating outside the normal shipping channels and fairways. Placing a safety zone around the drillship will significantly reduce the threat of allisions, which could result in oil spills and releases of natural gas, and thereby protects the safety of life, property, and the environment. Lawful demonstrations may be conducted outside of the safety zone.

DATES: This rule is effective without actual notice from July 14, 2015 until October 31, 2015. For the purposes of enforcement, actual notice will be used from July 1, 2015, until July 14, 2015.

ADDRESSES: Documents mentioned in this preamble are part of docket number USCG–2015–0247. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email LCDR Jason Boyle, Seventeenth Coast Guard District (dpi); telephone 907–463–2821, *Jason.t.boyle@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl F. Collins, 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. Regulatory History and Information

The Coast Guard published an NPRM for this safety zone on May 1, 2015 (80 FR 24863). One comment from the public was received during the 30 day comment period. No public meeting on this NPRM was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Information regarding the size and location of this safety zone was not provided to the Coast Guard in sufficient detail for the Coast Guard to initiate this rulemaking activity at an earlier date. Delaying the implementation of this safety zone would increase the possibility of an allision in the Chukchi Sea.

B. Basis and Purpose

The request for the temporary safety zone was made by Shell Exploration & Production Company due to safety concerns for both the personnel aboard the DRILL UNIT POLAR PIONEER and the environment. Shell Exploration & Production Company indicated that it is highly likely that any allision or inability to identify, monitor or mitigate any risks or threats, including ice-related hazards that might be encountered, may result in a catastrophic event. Incursions into the area by unapproved vessels could degrade the ability to monitor and mitigate such risks. In evaluating this request, the Coast Guard explored relevant safety factors and considered several criteria, including but not limited to: (1) The level of shipping activity around the operation; (2) safety concerns for personnel aboard the vessel; (3) concerns for the environment given the sensitivity of the environmental and the importance of fishing and hunting to the indigenous population; (4) the lack of any established shipping fairways, and fueling and supply storage/operations which increase the likelihood that an allision would result in a catastrophic event; (5) the recent and potential future maritime traffic in the vicinity of the proposed areas; (6) the types of vessels navigating in the vicinity of the proposed area; (7) the structural configuration of the vessel; and (8) the need to allow for lawful demonstrations without endangering the safe operation of the vessel. For any group intending to conduct lawful demonstrations in the vicinity of the rig, these demonstrations must be conducted outside the safety zone.

Results from a thorough and comprehensive examination of the criteria, IMO guidelines, and existing regulations warrant the establishment of the temporary safety zone. The regulation significantly reduces the threat of allisions that could result in oil spills, and other releases. Furthermore, the regulation increases the safety of life, property, and the environment in the Chukchi Sea by prohibiting entry into the zone unless specifically authorized by the Commander, Seventeenth Coast Guard District, or a designated representative. Due to the remote location and the need to protect the environment, the Coast Guard may use criminal sanctions to enforce the safety zone as appropriate.

The temporary safety zone will be around the DRILL UNIT POLAR PIONEER while anchored or deploying and recovering moorings on location in order to drill exploratory wells in various locations in the Chukchi Sea Outer Continental Shelf, Alaska during the 2015 timeframe.

Shell Exploration & Production Company has proposed and received permits for drill sites within the Burger prospects, Chukchi Sea, Alaska.

During the 2015 timeframe, Shell Exploration & Production Company has proposed drilling exploration wells at various Chukchi Sea prospects

depending on favorable ice conditions, weather, sea state, and any other pertinent factors. Each of these drill sites will be permitted for drilling in 2015 to allow for operational flexibility in the event sea ice conditions prevent access to one of the locations. The number of actual wells that will be drilled will depend on ice conditions and the length of time available for the 2015 drilling season. The predicted ''average'' drilling season, constrained by prevailing ice conditions and regulatory restrictions, is long enough for two to three typical exploration wells to be drilled.

The actual order of drilling activities will be controlled by an interplay between actual ice conditions immediately prior to a rig move, ice forecasts, any regulatory restrictions with respect to the dates of allowed operating windows, whether the planned drilling activity involves only drilling the shallow non-objective section or penetrating potential hydrocarbon zones, the availability of permitted sites having approved shallow hazards clearance, the anticipated duration of each contemplated drilling activity, the results of preceding wells and Marine Mammal Monitoring and Mitigation plan requirements.

All planned exploration drilling in the identified lease will be conducted with the DRILL UNIT POLAR PIONEER.

The DRILL UNIT POLAR PIONEER has a ''persons on board'' capacity of 110, and it is expected to be at capacity for most of its operating period. The DRILL UNIT POLAR PIONEER's personnel will include its crew, as well as Shell employees, third party contractors, Alaska Native Marine Mammal Observers and possibly Bureau of Safety and Environmental Enforcement (BSEE) personnel.

While conducting exploration drilling operations, the DRILL UNIT POLAR PIONEER will be anchored using an anchoring system consisting of an 8-point anchored mooring spread attached to the onboard turret and could have a maximum anchor radius of 3,600 ft (1,100 m). The center point of the DRILL UNIT POLAR PIONEER will be positioned within the prospect location in the Chukchi Sea.

The DRILL UNIT POLAR PIONEER will move into the Chukchi Sea on or about July 1, 2015 and onto a prospect location when ice allows. Drilling will conclude on or before October 31, 2015. The drillship and support vessels will depart the Chukchi Sea at the conclusion of the 2015 drilling season.

C. Discussion of Comments, Changes, and the Final Rule

One comment was received regarding the NPRM. One comment from the public was received during the 30 day comment period expressing concern that the safety zone was larger than necessary. Citing the need to conduct fishing activities, the comment instead suggested the safety zone prohibit getting within 50 meters of vessel, with a ''no wake'' restriction extending 250 meters. The Coast Guard disagrees with the commenter. We note that the safety zone is established for the protection of vessels entering the zone, not for the protection of the drilling vessels, and that considering the size of the drilling vessel and its operations, 500 meters is a reasonable distance. A ''no-wake'' restriction would not relate to the safety of a vessel getting so close to drilling operations. Furthermore, we note that the 500-meter restriction around the vessel will not significantly impact fishing operations, considering the size of the ocean.

The Coast Guard made one change to the proposed rule. The original proposed rule had called for safety zones at every point where the vessel's mooring spread intersected with the ocean's surface. After additional analysis, the Coast Guard determined that the mooring system utilized on this vessel is configured such that its lines will not break the ocean's surface beyond the vessel's outer edge. Therefore, the Coast Guard deleted reference to such additional safety zones and corresponding marking buoys from the final rule.

The temporary safety zone will encompass the area that extends 500 meters from the outer edge of the DRILL UNIT POLAR PIONEER. This safety zone will be in effect both when the DRILL UNIT POLAR PIONEER is anchored and when deploying and recovering moorings. No vessel would be allowed to enter or remain in this proposed safety zone except the following: An attending vessel or a vessel authorized by the Commander, Seventeenth Coast Guard District or a designated representative. They may be contacted on VHF–FM Channel 13 or 16 or by telephone at 907–463–2000.

D. Regulatory Analyses

The Coast Guard developed this final rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 14 of these statutes or executive orders.

1. Regulatory Planning and Review

This 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 Section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under that Order.

This rule is not a significant regulatory action due to the location of the DRILL UNIT POLAR PIONEER on the Outer Continental Shelf and its distance from both land and safety fairways. Vessels traversing waters near the safety zone will be able to safely travel around the zone without incurring additional costs.

2. Small Entities

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612), the Coast Guard has considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in the Burger Prospects of the Chukchi Sea.

This safety zone will not have a significant economic impact or a substantial number of small entities for the following reasons: This rule will enforce a safety zone around a drilling unit facility that is in areas of the Chukchi Sea not frequented by vessel traffic and is not in close proximity to a safety fairway. Further, vessel traffic can pass safely around the safety zone without incurring additional costs.

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), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

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

4. Collection of Information

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

5. Federalism

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

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 $100,000,000.00 (adjusted for inflation) or more in any one year. Though this rule would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will 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 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

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

11. Indian Tribal Governments

This 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

The Coast Guard analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

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

14. Environment

We have analyzed this 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. An 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 rule. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant's Instruction.

List of Subjects in 33 CFR Part 147

Continental shelf, Marine safety, Navigation (water).

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 85; 43 U.S.C. 1333; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 147.T17–0247 to read as follows:

§ 147.T17–0247 Safety Zone; DRILL UNIT POLAR PIONEER, Outer Continental Shelf Drillship, Chukchi Sea, Alaska.

(a) Description. The DRILL UNIT POLAR PIONEER will be engaged in exploratory drilling operations at various locations in the Chukchi Sea from July 1, 2015 through October 31, 2015. The area that extends 500 meters from the outer edge of the DRILL UNIT POLAR PIONEER is a safety zone. Lawful demonstrations may be conducted outside of the safety zone.

(b) *Regulation.* No vessel may enter or remain in this safety zone except the following:

(1) An attending vessel; or

(2) A vessel authorized by the Commander, Seventeenth Coast Guard District, or a designated representative.

Dated: June 17, 2015.

Daniel B. Abel,

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

[FR Doc. 2015–17129 Filed 7–13–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0297; FRL–9930–28–Region 9

Partial Approval and Partial Disapproval of Air Quality State Implementation Plans; Arizona; Infrastructure Requirements for Lead and Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is partially approving and partially disapproving State Implementation Plan (SIP) revisions submitted by the State of Arizona to address the requirements of section 110(a)(1) and (2) of the Clean Air Act (CAA) for the 2008 Lead (Pb) and 2008 ozone national ambient air quality standards (NAAQS). Section 110(a) of the CAA requires that each State adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA. We refer to such SIP revisions as ''infrastructure'' SIPs because they are intended to address basic structural SIP requirements for new or revised NAAQS including, but not limited to, legal authority, regulatory structure, resources, permit programs, monitoring, and modeling necessary to assure attainment and maintenance of the standards.

DATES: This final rule is effective on August 13, 2015.

ADDRESSES: EPA has established a docket for this action, identified by Docket ID Number EPA–R09–OAR–2015–0297. The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne, San Francisco, California. While all documents in the docket are listed in the index, some information may be publically available only at the hard copy location (*e.g.,* copyrighted material) and some may not be publically available in either location (*e.g.,* confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed directly below.

FOR FURTHER INFORMATION CONTACT: Jeffrey Buss, Office of Air Planning, U.S. Environmental Protection Agency, Region 9, (415) 947–4152, email: *buss.jeffrey@epa.gov.*

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

Table of Contents

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

I. Background

CAA section 110(a)(1) requires each state to submit to EPA, within three years after the promulgation of a primary or secondary NAAQS or any revision thereof, an infrastructure SIP revision that provides for the implementation, maintenance, and enforcement of such NAAQS. Section 110(a)(2) sets the content requirements of such a plan, which generally relate to the information and authorities, compliance assurances, procedural requirements, and control measures that constitute the ''infrastructure'' of a state's air quality management program. These infrastructure SIP elements required by section 110(a)(2) are as follows:

- Section 110(a)(2)(A): Emission limits and other control measures.
- Section 110(a)(2)(B): Ambient air quality monitoring/data system.
- Section 110(a)(2)(C): Program for enforcement of control measures and regulation of new and modified stationary sources.
- Section 110(a)(2)(D)(i): Interstate pollution transport.
- Section 110(a)(2)(D)(ii): Interstate and international pollution abatement.
- Section 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local and regional government agencies.
- Section 110(a)(2)(F): Stationary source monitoring and reporting.
- Section 110(a)(2)(G): Emergency episodes.
- Section 110(a)(2)(H): SIP revisions.
- Section 110(a)(2)(J): Consultation with government officials, public notification, prevention of significant deterioration (PSD), and visibility protection.
- Section 110(a)(2)(K): Air quality modeling and submittal of modeling data.
- Section 110(a)(2)(L): Permitting fees.
- Section 110(a)(2)(M): Consultation/participation by affected local entities.

Two elements identified in section 110(a)(2) are not governed by the three-year submittal deadline of section 110(a)(1) and are therefore not addressed in this action. These two elements are: (i) Section 110(a)(2)(C) to the extent it refers to permit programs required under part D (nonattainment new source review (NSR)), and (ii) section 110(a)(2)(I), pertaining to the nonattainment planning requirements of part D. As a result, this action does not address infrastructure for the nonattainment NSR portion of section 110(a)(2)(C) or the whole of section 110(a)(2)(I).

On November 12, 2008, the EPA issued a revised NAAQS for Pb.[1] This action triggered a requirement for states to submit an infrastructure SIP to address the applicable requirements of section 110(a)(2) within three years of issuance of the revised NAAQS. On October 14, 2011, EPA issued ''Guidance on Section 110 Infrastructure SIPs for the 2008 Pb NAAQS'', referred to herein as EPA's 2011 Pb Guidance.[2] Depending on the timing of a given submittal, some states relied on the earlier draft version of this guidance, referred to herein as EPA's 2011 Draft Pb Guidance.[3] EPA issued additional guidance on infrastructure SIPs on September 13, 2013.[4]

On March 27, 2008, EPA issued a revised NAAQS for 8-hour Ozone.[5] This action triggered a requirement for states to submit an infrastructure SIP to address the applicable requirements of section 110(a)(2) within three years of issuance of the revised NAAQS. EPA did not, however, prepare guidance at this time for states in submitting I–SIP revisions for the 2008 Ozone NAAQS.[6] On September 13, 2013, EPA issued ''Guidance of Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2),'' which provides advice on the development of infrastructure SIPs for the 2008 ozone NAAQS (among other pollutants) as well as infrastructure SIPs for new or revised NAAQS promulgated in the future.[7]

The Arizona Department of Environmental Quality (ADEQ) has submitted infrastructure SIP revisions pursuant to EPA's promulgation of the NAAQS addressed by this rule, including the following:

[1] 73 FR 66964 (November 12, 2008). The 1978 Pb standard (1.5 μg/m^3 as a quarterly average) was modified to a rolling 3 month average not to be exceeded of 0.15 μg/m^3. EPA also revised the secondary NAAQS to 0.15 μg/m^3 and made it identical to the revised primary standard. Id.

[2] See Memorandum from Stephen D. Page, Director, Office of Air Quality Planning and Standards, to Regional Air Division Directors, Regions 1–10 (October 14, 2011).

[3] ''DRAFT Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS),'' June 17, 2011 version.

[4] *See* Memorandum dated September 13, 2013 from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards, to Regional Air Directors, EPA Regions 1–10, ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)'' (referred to herein as ''2013 Infrastructure SIP Guidance'').

[5] 73 FR 16436 (March 27, 2008).

[6] Preparation of guidance for the 2008 Ozone NAAQS was postponed given EPA's reconsideration of the standard. See 78 FR 34183 (June 6, 2013).

[7] See Memorandum dated September 13, 2013 from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards, to Regional Air Directors, EPA Regions 1–10, ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)'' (referred to herein as ''2013 Infrastructure SIP Guidance'').

• October 14, 2011—''Arizona State Implementation Plan Revision under Clean Air Act Section 110(a)(1) and (2); 2008 Lead NAAQS,'' to address all of the CAA section 110(a)(2) requirements, except for section 110(a)(2)(G),[8] for the 2008 Pb NAAQS (2011 Pb I–SIP Submittal).

• December 27, 2012—''Arizona State Implementation Plan Revision under Clean Air Act Section 110(a)(1) and (2); 2008 8-hour Ozone NAAQS,'' to address all of the CAA section 110(a)(2) requirements for the 2008 8-hour Ozone NAAQS (2012 Ozone I–SIP Submittal).

On February 19, 2015 EPA approved elements of the above submittals with respect to the 2008 Pb and 2008 8-hour ozone NAAQS infrastructure requirements in CAA sections 110(a)(2)(A), (B), (E), (F), (G), (H), (L) and (M).[9] That action also explained that we would separately act on the permitting infrastructure SIP elements in CAA sections 110(a)(2)(C), (D), (J), and (K) in a subsequent rulemaking. These permit related elements are the subject of today's final rule.

In addition to the above 2011 and 2012 infrastructure SIP submittals, ADEQ submitted ''New Source Review State Implementation Plan Submission'' on October 29, 2012, and ''Supplemental Information to 2012 New Source Review State Implementation Plan Submission'' on July 2, 2014 (NSR Submittals). In addition to addressing revisions to Arizona's NSR program, these submissions also relate to our analysis of infrastructure SIP elements in CAA sections 110(a)(2)(C), (D), (J), and (K).

II. Proposed Action

On May 12, 2015 (80 FR 27127), EPA proposed to partially approve and partially disapprove Arizona's 2011 Pb I–SIP Submittal and 2012 Ozone I–SIP Submittal with respect to the permitting infrastructure SIP elements in CAA sections 110(a)(2)(C), (D), (J), and (K). Our proposed action and associated technical support document (TSD) provide detailed discussion of Arizona's demonstration for each element. Generally, we proposed a partial approval because the submittals show that Arizona largely fulfills the relevant infrastructure requirements. But we proposed a simultaneous partial disapproval because of these deficiencies:

• With respect to § 110(a)(2)(C), EPA proposed to: (1) Disapprove the 2011 Pb and 2012 Ozone Infrastructure SIPs for ADEQ and Pinal County because the SIP-approved PSD programs lack certain ''structural'' PSD program elements as identified in our TSD; and (2) disapprove both Infrastructure SIPs for Maricopa and Pima counties, which do not have SIP approved PSD programs.

• With respect to the third prong of § 110(a)(D)(i), EPA proposed to disapprove both Infrastructure SIPs regarding ''structural'' PSD requirements under § 110(a)(2)(C).

• With respect to § 110(a)(2)(D)(ii), EPA proposed to disapprove both Infrastructure SIPs with respect to Maricopa County and Pima County, which do not have SIP approved PSD programs.

• With respect to § 110(a)(2)(J), we proposed to disapprove both Arizona Infrastructure SIPs for failure to fully satisfy the requirements of part C relating to PSD.

• With respect to § 110(a)(2)(K), we proposed to disapprove both Infrastructure SIPs because ADEQ, Pinal, Pima, and Maricopa counties have not submitted adequate provisions or a narrative that explain how existing state and county law satisfy the requirements of 110(a)(2)(K).

III. Public Comments and EPA Responses

The public comment period on EPA's proposed rule opened on May 12, 2015, the date of its publication in the **Federal Register** at 80 FR 27127, and closed on June 11, 2015. During this period, EPA did not receive any comments. Therefore, EPA is finalizing our action as proposed.

IV. Final Action

Under CAA section 110(k)(3) and based on the evaluation and rationale presented in the proposed rule, the TSD and this final rule, EPA is partially approving the 2011 Pb I–SIP Submittal and the 2012 Ozone I–SIP Submittal with respect to the following infrastructure SIP requirements:

• Section 110(a)(2)(C) (in part): Program of enforcement of control measures and regulation of new and modified stationary sources.

• Section 110(a)(2)(D)(i) (in part): Interstate pollution transport.

• Section 110(a)(2)(D)(ii) (in part): Interstate pollution abatement and international air pollution.

• Section 110(a)(2)(J) (in part): Consultation with government officials, public notification, PSD, and visibility protection.

• Section 110(a)(2)(K): Air quality modeling and submission of modeling data.

EPA is simultaneously partially disapproving the submittals because of deficiencies described in our proposed rule and TSD and summarized in the proposed rule section above. For all I–SIP elements that do not meet the CAA § 110(a)(2) requirements there are existing FIPs in place, with the exception of the modeling requirements under CAA § 110(a)(2)(K) for Pinal County and ADEQ. To the extent our proposed approval or proposed disapproval of an I–SIP element relied on our March 18, 2015 proposed action on ADEQ's NSR SIP submittal, our final action on the I–SIP elements identified in this notice relies on our final action on ADEQ's NSR SIP submittal, signed contemporaneously primarily in the form of a limited approval/limited disapproval.[10] Furthermore, the partial disapprovals in this action do not result in sanctions under section 179 of the Act because infrastructure SIPs are not required under Title I, Part D of the Act.

V. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled ''Regulatory Planning and Review.''

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the

[8] In a separate rulemaking, EPA fully approved Arizona's SIP to address the requirements regarding air pollution emergency episodes in CAA section 110(a)(2)(G) for the 1997 8-hour ozone NAAQS. 77 FR 62452 (October 15, 2012). Although ADEQ did not submit an analysis of Section 110(a)(2)(G) requirements, we discuss them in our technical support document (TSD), which is in the docket for this rulemaking.

[9] ''Approval and Promulgation of State Implementation Plans; Arizona; Infrastructure requirements for the 2008 Lead (Pb) and the 2008 8-Hour Ozone National Ambient Air Quality Standards (NAAQS)'' was signed on February 19, 2015 but, as of June 29, 2015, has not yet published in the **Federal Register**. This action was proposed in the **Federal Register** on November 24, 2014 (79 FR 69796).

[10] EPA's action on ADEQ's NSR SIP submittal was largely finalized as proposed, with the exception of certain changes in response to public comments. These changes resulted in our finding fewer bases for disapproval as compared with our proposed action on ADEQ's NSR SIP submittal and do not affect today's final action on Arizona's I–SIP submittals.

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 not-for-profit enterprises, and small governmental jurisdictions.

This rule will not have a significant impact on a substantial number of small entities because SIP partial approvals/partial disapprovals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because EPA's approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* v. *U.S. EPA,* 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates Reform Act

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the partial approval/partial disapproval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Order 13175, Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires the EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This final rule does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this rule.

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 rule is not subject to Executive Order 13045, because it approves a State rule implementing a Federal standard.

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

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

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

Executive Order (E.O.) 12898 (59 FR 7629 (Feb. 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 lacks the discretionary authority to address environmental justice in this rulemaking.

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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective *August 13, 2015.*

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by *September 14, 2015.* Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Lead, Reporting and recordkeeping requirements.

Dated: June 29, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart D—Arizona

■ 2. Section 52.123 is amended by adding paragraphs (o) and (p) to read as follows:

§ 52.123 Approval status.

* * * * *

(o) *2008 8-hour ozone NAAQS:* The SIPs submitted on October 14, 2011 and December 27, 2012 are fully or partially disapproved for Clean Air Act (CAA) elements 110(a)(2)(C), (D)(ii), (J) and (K) for all portions of the Arizona SIP.

(p) *2008 Lead (Pb) NAAQS:* The SIPs submitted on October 14, 2011 and December 27, 2012 are fully or partially disapproved for Clean Air Act (CAA) elements 110(a)(2)(C), (D)(ii), (J) and (K) for all portions of the Arizona SIP.

[FR Doc. 2015–17057 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0082; FRL–9929–64–Region 9]

Revisions to the California SIP, Ventura & Eastern Kern Air Pollution Control Districts; Permit Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Ventura County Air Pollution Control District (VCAPCD) and Eastern Kern Air Pollution Control District (EKAPCD) portions of the California State Implementation Plan (SIP). These revisions clarify, update, and revise exemptions from New Source Review (NSR) permitting requirements, for various air pollution sources.

DATES: This rule will be effective on *August 13, 2015.*

ADDRESSES: EPA has established docket number EPA–R09–OAR–2015–0082 for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps, multi-volume reports), and some may not be available in either location (*e.g.,* confidential business information (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: Lawrence Maurin, EPA Region IX, (415) 972–3943, *Maurin.Lawrence@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 Action
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Proposed Action

On April 14, 2015 (80 FR 19932), EPA proposed to approve the following rules into the California SIP. Table 1 lists the rules addressed by this proposal, including the dates they were revised by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Revision date	Submittal date
VCAPCD	23	Exemptions from Permit	11/12/13	05/13/14
EKAPCD	202	Permit Exemptions	01/13/11	06/21/11

We proposed to approve these rules because we determined that they complied with the relevant Clean Air Act (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 received no comments.

III. EPA Action

No comments were submitted. Therefore, as authorized in Section 110(k)(3) of the Act, EPA is fully approving these rules into the California SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Ventura County Air Pollution Control District and Eastern Kern Air Pollution Control District rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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 (Public Law 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Incorporation by reference, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 16, 2015.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 52—Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS.

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(391) (i)(A)(*2*) and (c)(441)(i)(C)(*3*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(391) * * *

(i) * * *

(A) * * *

(*2*) Rule 202, ''Permit Exemptions,'' amended on January 13, 2011.

* * * * *

(441) * * *

(i) * * *

(C) * * *

(*3*) Rule 23, ''Exemptions from Permit,'' revised on November 12, 2013.

* * * * *

[FR Doc. 2015–17064 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2014–0254; FRL–9930–47–Region 8]

Determinations of Attainment of the 1997 Annual Fine Particulate Matter Standard for the Libby, Montana Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing two separate and independent determinations regarding the Libby, Montana nonattainment area for the 1997 annual fine particulate matter ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS). First, EPA is determining that the Libby nonattainment area attained the 1997 annual $PM_{2.5}$ NAAQS by the applicable attainment date, April 2010. This determination is based on quality-assured and certified ambient air quality data for the 2007–2009 monitoring period. Second, EPA is finalizing that the Libby nonattainment area has continued to attain the 1997 annual $PM_{2.5}$ NAAQS, based on quality-assured and certified ambient air quality data for the 2012–2014 monitoring period. Based on the second determination, EPA will suspend certain nonattainment area planning obligations. These determinations do not constitute a redesignation to attainment. The Libby nonattainment area will remain designated nonattainment for the 1997 annual $PM_{2.5}$ NAAQS until such time as EPA determines that the Libby nonattainment area meets the Clean Air Act (CAA) requirements for redesignation to attainment, which include an approved maintenance plan. These proposed actions are being taken under the CAA.

DATES: This final rule is effective on August 13, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2014–0254. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Crystal Ostigaard, Air Program, U.S. Environmental Protection Agency, Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6602, *ostigaard.crystal@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Libby nonattainment area is comprised of the City of Libby within Lincoln County. *See* 40 CFR 81.327. On April 14, 2015 (71 FR 19935), EPA published a proposed rulemaking for the Libby nonattainment area. In the April 14, 2015 rulemaking action, EPA proposed to make a determination that the Libby nonattainment area attained the 1997 annual $PM_{2.5}$ NAAQS by the area's attainment date, April 2010. EPA also proposed to make a determination that the Libby nonattainment area continues to attain the 1997 annual $PM_{2.5}$ NAAQS. No comments were received on the April 14, 2015 proposed rule.

II. Summary of Rulemaking Actions

These actions do not constitute a redesignation of the Libby nonattainment area to attainment for the 1997 annual $PM_{2.5}$ NAAQS under CAA section 107(d)(3). Neither determination of attainment involves approving a maintenance plan for the Libby nonattainment area, nor determines that the Libby nonattainment area has met all the requirements for redesignation under the CAA, including that the attainment be due to permanent and enforceable measures. Therefore, the designation status of the Libby nonattainment area will remain nonattainment for the 1997 annual $PM_{2.5}$ NAAQS until such time as EPA takes a final rulemaking action to determine that the Libby nonattainment area meets the CAA requirements for redesignation to attainment.

A. Determination of Attainment by the Attainment Date

Pursuant to section 188(b)(2) of the CAA, EPA is making a determination that the Libby nonattainment area has attained the 1997 annual $PM_{2.5}$ NAAQS by the area's attainment date, April 2010. This determination is based upon quality-assured and certified ambient air monitoring data for the 2007–2009 monitoring period that shows the area has monitored attainment to the 1997 $PM_{2.5}$ annual NAAQS attainment date. The effect of this final determination of attainment to the 1997 $PM_{2.5}$ annual NAAQS attainment date is to discharge EPA's obligation under CAA section 181(b)(2) to determine, based on the Libby nonattainment area's air quality whether the area attained the standard.

B. ''Clean Data'' Determination of Attainment

EPA is also making a determination that the Libby nonattainment area continues to attain the 1997 annual $PM_{2.5}$ NAAQS. This ''clean data'' determination is based upon quality assured and certified ambient air monitoring data that show the area has monitored attainment of the 1997 annual $PM_{2.5}$ NAAQS for the 2012–2014 monitoring period. As a result of this determination, the requirement for the Libby nonattainment area to submit an attainment demonstration, reasonably available control measures (RACM), reasonable further progress (RFP), and contingency measures related to attainment of the 1997 annual $PM_{2.5}$ NAAQS shall be suspended for so long as the area continues to attain the NAAQS.[1]

C. EPA's Analysis of the Relevant Air Quality Data

Consistent with the requirements contained in 40 CFR part 50, EPA has reviewed the annual $PM_{2.5}$ ambient air quality monitoring data for the 2007–2009 and 2012–2014 monitoring periods for the Libby nonattainment area, as recorded in EPA's Air Quality System (AQS) database. On the basis of that review, EPA has concluded that the Libby nonattainment area attained the 1997 annual $PM_{2.5}$ NAAQS, based on data for the 2007–2009 monitoring period. EPA has also concluded that the Libby nonattainment area continues to attain, based on data for the 2012–2014 monitoring period.

III. Final Action

EPA is making two separate and independent determinations regarding the Libby nonattainment area. First,

[1] Even though the requirements are suspended, EPA is not precluded from acting upon these elements at any time if submitted to EPA for review and approval. On March 17, 2011 (76 FR 14584), EPA took final action to approve the submitted SIP revision for the Libby $PM_{2.5}$ nonattainment area, which included an attainment demonstration, RACM, RFP, and contingency measures.

pursuant to section 188(b)(2) of the CAA, EPA is making a determination that the Libby nonattainment area has attained the 1997 annual $PM_{2.5}$ NAAQS attainment date of April 2010. Second, EPA is making a determination that the Libby nonattainment area is attaining the 1997 annual $PM_{2.5}$ NAAQS, based on quality assured and certified ambient air monitoring data for the 2012–2014 monitoring period. This final determination suspends the requirements for the Libby nonattainment area to submit an attainment demonstration and associated RACM, RFP plan, contingency measures, and any other planning requirements related to attainment of the 1997 annual $PM_{2.5}$ NAAQS for so long as the area continues to attain the 1997 annual $PM_{2.5}$ NAAQS. These determinations do not constitute a redesignation to attainment. The Libby nonattainment area will remain designated nonattainment for the 1997 annual $PM_{2.5}$ NAAQS until such time as EPA determines that the Libby nonattainment area meets the CAA requirements for redesignation to attainment, including an approved maintenance plan.

IV. Statutory and Executive Orders Review

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: June 25, 2015.

Debra H. Thomas,

Acting Regional Administrator, Region 8.

40 CFR part 52 is amended to read as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. Section 52.1374 is amended by adding paragraph (c) to read as follows:

§ 52.1374 Control strategy: Particulate matter.

* * * * *

(c) *Determination of Attainment.* EPA has determined, July 14, 2015, based on quality-assured air monitoring data for 2007–2009 and 2012–2014 ambient air quality data, that the Libby, MT fine particulate matter ($PM_{2.5}$) nonattainment area attained the 1997 annual $PM_{2.5}$ national ambient air quality standards (NAAQS). Therefore, EPA has met the requirement of CAA section 188(b)(2) to determine, based on the area's air quality as of the attainment date or as expeditiously as practicable, whether the area attained the 1997 annual $PM_{2.5}$ NAAQS. Additionally, this determination suspends the requirements for this area to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIPs related to attainment of the standard for as long as this area continues to meet the 1997 annual $PM_{2.5}$ NAAQS. If EPA determines, after notice-and-comment rulemaking, that this area no longer meets the 1997 annual $PM_{2.5}$ NAAQS, the corresponding determination of attainment for that area shall be withdrawn.

[FR Doc. 2015–17054 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2014–0626; FRL–9930–27–Region 6]

Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$) Prevention of Significant Deterioration (PSD) Permitting Program State Implementation Plan (SIP)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving portions of two revisions to the New Mexico SIP for the permitting of $PM_{2.5}$ emissions submitted on May 23, 2011, and August 6, 2014. Together, these submittals revise the New Mexico PSD program to be consistent with the federal PSD regulations regarding the use of a significant impact level (SIL) or significant monitoring concentration (SMC) for $PM_{2.5}$ emissions. We are approving these SIP revisions to regulate $PM_{2.5}$ emissions in accordance with requirements of section 110 and part C of the Clean Air Act.

DATES: This rule is effective on September 14, 2015 without further notice, unless the EPA receives adverse comment by August 13, 2015. If the EPA receives relevant adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R06–OAR–2014–0626, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions.
- *Email:* Ms. Adina Wiley at *wiley.adina@epa.gov*
- *Mail:* Ms. Adina Wiley, Air Planning Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Ste. 1200, Dallas, TX 75202–2733.
- *Hand Delivery:* Ms. Adina Wiley, Air Planning Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Ste. 700, Dallas, TX 75202–2733. Such deliveries are only accepted during the hours between 8:00 a.m. and 4:00 p.m. weekdays, and not on legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2014–0626. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Adina Wiley, 214–665–2115, *wiley.adina@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Adina Wiley or Mr. Bill Deese at 214–665–7253.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' means the EPA.

I. Background

A. CAA and SIPs

Section 110 of the CAA requires states to develop and submit to the EPA a SIP to ensure that state air quality meets National Ambient Air Quality Standards. These ambient standards currently address six criteria pollutants: Carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide. Each federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin through air pollution regulations and control strategies. The EPA approved SIP regulations and control strategies are federally enforceable.

B. Prior Federal Action

Under Section 165 of the Clean Air Act, PSD permit applications must contain air quality monitoring data representing air quality in the area affected by the proposed source for the 1-year period preceding receipt of the application. In 2010, the EPA promulgated regulations for PSD $PM_{2.5}$ permits which included two screening tools: SILs and SMCs. These tools were established to determine whether a PSD permit application may be exempted from the 1-year air monitoring requirement for $PM_{2.5}$ based on the grounds that the increase of the pollutant is *de minimis.* In response to a request from the EPA and a petition, the United States Court of Appeals for the District of Columbia Circuit (the Court) vacated and remanded to the EPA the portions of the 2010 PSD regulations establishing the $PM_{2.5}$ SILs and SMC.

In response to the Court's decision, the EPA amended its regulations to remove the $PM_{2.5}$ SILs and SMC provisions. *See* 78 FR 73702, December 9, 2013. More detail about this action is available in our Technical Support Document, which is available in our rulemaking docket.

C. New Mexico's Submittals

On May 23, 2011, New Mexico submitted revisions to its air permitting regulations at 20.2.74 NMAC that reflected the $PM_{2.5}$ SILs and SMC screening tools. On January 22, 2013, the EPA approved all of the May 23, 2011 submission except for the portion that relates to the screening tools. *See* 78 FR 4339. On August 6, 2014, in accordance with the EPA's changes to the federal regulations, New Mexico submitted revisions to 20.2.74 NMAC to remove the $PM_{2.5}$ SILs and SMC which had previously been adopted and submitted as a SIP revision. More detail about these actions is available in our Technical Support Document, which is available in our rulemaking docket.

II. The EPA's Evaluation

A. Revisions to 20.2.74.303 NMAC, Submitted May 23, 2011, and August 6, 2014

The May 23, 2011, submittal added language to paragraph A, implementing the ambient air impact analysis exemption for major sources or major modifications established by the EPA in the $PM_{2.5}$ PSD Increment—Significant Impact Levels (SILs)—Significant Monitoring Concentration (SMC) Rule. The August 6, 2014, submittal removes the language pertaining to the $PM_{2.5}$ SIL. The May 23, 2011, submittal also replaces the term ''particulate matter'' with ''PM_{10}'' in paragraph A.

The submitted regulations are approvable because they remove the $PM_{2.5}$ SIL consistent with the EPA's December 9, 2013, revisions to 40 CFR 51.166(k) and were adopted and submitted in accordance with sections 110 and 165 of the Clean Air Act.

B. Revisions to 20.2.74.503 NMAC, Submitted May 23, 2011, and August 6, 2014

The May 23, 2011, submittal added a line to TABLE 3—SIGNIFICANT MONITORING CONCENTRATIONS, including the pollutant $PM_{2.5}$, its Air Quality Concentration of 4 micrograms per cubic meter and an associated 24 hour Averaging Time. The August 6, 2014, submittal removes the $PM_{2.5}$ SMC by changing the $PM_{2.5}$ Air Quality Concentration from 4 micrograms per cubic meter to 0, and removes the ''24 hours'' from the $PM_{2.5}$ Averaging Time column. The May 23, 2011, submittal also replaced the term ''particulate matter'' with ''PM_{10}.''

The submitted regulations are approvable because they remove the $PM_{2.5}$ SMC consistent with the EPA's December 9, 2013, revisions to 40 CFR 51.166(i)(5)(i) and were adopted and submitted in accordance with sections 110 and 165 of the Clean Air Act.

III. Final Action

We are approving revisions to the New Mexico SIP that pertain to changes to 20.2.74 NMAC submitted May 23, 2011, and August 6, 2014. Specifically, we are approving the revisions to 20.2.74.303 NMAC—Ambient Impact Requirements, paragraph A and 20.2.74.503 NMAC Table 3—Significant Monitoring Concentrations. The EPA has made the determination that the submitted regulations are approvable because the submitted rules were adopted and submitted in accordance with the CAA and are consistent with the EPA's regulations regarding PSD permitting for $PM_{2.5}$ emissions.

The EPA is publishing this rule without prior proposal because we view this as a non-controversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if relevant adverse comments are received. This rule will be effective on September 14, 2015 without further notice unless we receive relevant adverse comment by August 13, 2015. If we receive relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so now. Please note that if we receive relevant adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Incorporation by Reference

In this rule, we are finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 40 CFR 51.5, we are finalizing the incorporation by reference of the revisions to the New Mexico regulations as described in the Final Action section above. We have made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the EPA Region 6 office.

V. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter, Reporting and recordkeeping requirements.

Dated: June 30, 2015.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart GG—New Mexico

■ 2. Section 52.1620 in paragraph (c), first table, is amended by revising the entry ''Part 74, Permits—Prevention of Significant Deterioration'' under ''New Mexico Administrative Code (NMAC) Title 20—Environment Protection Chapter 2—Air Quality'' to read as follows:

§ 52.1620 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED NEW MEXICO REGULATIONS

State citation	Title/subject	State approval/ effective date	EPA Approval date	Comments
New Mexico Administrative Code (NMAC) Title 20—Environment Protection Chapter 2—Air Quality				
*	*	*	*	*
Part 74	Permits—Prevention of Significant Deterioration.	7/11/2014	7/14/2015 [Insert **Federal Register** citation].	Revisions to 20.2.74.7(AZ)(2)(*a*) NMAC submitted 1/8/2013, effective 2/6/2913, are NOT part of SIP. 20.2.74.7(AZ)(2)(*a*) NMAC submitted 5/23/2011, effective 6/3/2011, remains SIP approved.
*	*	*	*	*

* * * * *

[FR Doc. 2015–17058 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0345; FRL–9929–58–Region 9]

Revisions to the California State Implementation Plan, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a revision to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP). This revision concerns volatile organic compound (VOC) emissions from graphic arts facilities. We are approving a local rule that regulates these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule is effective on September 14, 2015 without further notice, unless EPA receives adverse comments by August 13, 2015. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number [EPA–R09–OAR–2015–0345, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.

2. *Email: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air–4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. *www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. 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: 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 94105–3901. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), 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: Vanessa Graham, EPA Region IX, (415) 947–4120 *graham.vanessa@epa.gov.*

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

Table of Contents

I. The State's Submittal
A. What rule did the State submit?
B. Are there other versions of this rule?
C. What is the purpose of the submitted rule?
II. EPA's Evaluation and Action
A. How is EPA evaluating the rule?
B. Does the rule meet the evaluation criteria?
C. EPA Recommendations To Further Improve the Rule
D. Public Comment and Final Action
III. Incorporation by Reference
IV. Statutory and Executive Order Reviews

I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this action with the date that it was adopted by SCAQMD and submitted by the California Air Resource Board (CARB).

TABLE 1—SUBMITTED RULE

Local agency	Rule No.	Rule title	Amended	Submitted
SCAQMD	1130	Graphic Arts	05/02/14	11/06/14

On December 18, 2014, EPA determined that the submittal for SCAQMD Rule 1130 met the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

We approved an earlier version of Rules 1130 into the SIP on September 13, 2000 (65 FR 55201).

B. What is the purpose of the submitted rule?

VOCs help produce ground-level ozone and smog and fine particulate matter ($PM_{2.5}$), which harm human health and the environment. Section 110(a) of the CAA requires States to submit regulations that control VOC emissions. Rule 1130 limits VOC emissions from graphic arts processes, largely by establishing work practice requirements and limiting the amount of VOC in graphic arts coatings, inks and solvents. The amendments to Rule 1130 were submitted to satisfy Reasonably Available Control Technology (RACT) Requirements under CAA sections 172(c)(1) and 182(b).

EPA's technical support document (TSD) has more information about this rule.

II. EPA's Evaluation and Action.

A. How is EPA evaluating the rule?

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

SCAQMD regulates an ozone nonattainment area classified as extreme under both the 1997 and 2008 ozone NAAQS and a $PM_{2.5}$ nonattainment area classified as moderate under the 1997 and 2006 $PM_{2.5}$ NAAQS. 40 CFR 81.305. CAA section 172(c)(1) requires nonattainment areas to implement all reasonably available control measures (RACM), including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of RACT, as expeditiously as practicable. CAA section 189(a)(1)(C) also requires implementation of RACM in moderate $PM_{2.5}$ nonattainment areas. Additional control measures for graphic arts processes may be required pursuant to CAA section 172(c)(1) if both: (1) Additional measures are reasonably available; and (2) these additional reasonably available measures will advance attainment of one or more ozone standards in the area or contribute to reasonable further progress (RFP) when considered collectively (see 80 FR 12264, 12282). In addition, SIP rules must require RACT for each category of sources covered by a CTG document as well as each VOC major source in ozone nonattainment areas classified as moderate or above (see CAA section 182(b)(2)). Since Rule 1130 regulates sources subject to a CTG in an extreme nonattainment area, it must implement RACT.

Guidance and policy documents that we use to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations'' (''the Bluebook,'' U.S. EPA, May 25, 1988; revised January 11, 1990).
2. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies'' (''the Little Bluebook'', EPA Region 9, August 21, 2001).
3. ''Control Techniques Guidelines (CTG) for Offset Lithographic Printing and Letterpress Printing'', September 2006 (EPA 453/R–06–002).
4. ''Control Techniques Guidelines (CTG) for Flexible Package Printing'', September 2006 (EPA 453/R–06–003).

B. Does the rule meet the evaluation criteria?

We believe this rule is consistent with the relevant policy and guidance regarding enforceability, RACT, and SIP relaxations. We will act separately on the State's RACM demonstrations for the 2006 $PM_{2.5}$ NAAQS and 2008 ozone NAAQS the based on an evaluation of the control measures submitted as a whole and their overall potential to advance the applicable attainment dates for ozone. The TSD has more information on our evaluation.

C. EPA Recommendations To Further Improve the Rule

The TSD describes additional rule revisions that we recommend for the next time the local agency modifies the rule, but are not currently the basis for rule disapproval.

D. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, EPA is fully approving the submitted rule because we believe it fulfills all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rule. If we receive adverse comments by August 13, 2015, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on September 14,

2015. This will incorporate the rule into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the SCAQMD rule described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).]

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 9, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(457)(i)(E) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(457) * * *

(i) * * *

(E) South Coast Air Quality Management District.

(*1*) Rule 1130, ''Graphic Arts,'' amended on May 2, 2014.

* * * * *

[FR Doc. 2015–17061 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2015–0241; FRL–9930–35–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Low Emissions Vehicle Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve two revisions to the Maryland State Implementation Plan (SIP). The Clean Air Act (CAA) provides authority allowing California to adopt its own motor vehicle emissions

standards for newly manufactured vehicles, in lieu of federal vehicle standards. The CAA also allows other states to adopt California's vehicle standards, as long as they are identical to California's standards. Maryland's recent SIP submittals serve to amend Maryland's Clean Car Program to incorporate updates that California has made to its Low Emission Vehicle (LEV) program rules. Maryland adopted California's emission standards applicable to newly manufactured light and medium-duty vehicles in 2007, and EPA approved Maryland's Clean Car Program in prior rulemakings. However, since then California revised its LEV program regulations on several occasions, and Maryland subsequently amended its own rules to be consistent with those of California. Since the Clean Car Program is part of the SIP, Maryland then submits these amendments as a SIP revision. Maryland submitted such SIP revision requests in July 2014 and again in April 2015 to update its SIP to be consistent with California's latest LEV program rules. EPA's action to approve Maryland's most recent Clean Car Program SIP revisions is being taken under the CAA.

DATES: This rule is effective on September 14, 2015 without further notice, unless EPA receives adverse written comment by August 13, 2015. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2015–0241 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email*: *Fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2015–0241, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2015–0241. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means 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 *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Brian Rehn, (215) 814–2176, or by email at *rehn.brian@epa.gov.*

SUPPLEMENTARY INFORMATION: Maryland originally adopted a Low Emissions Vehicle Program in 2007 under Regulation .02 of COMAR 26.11.34 Low Emission Vehicles. Since then, Maryland updated its program rule on several occasions (in 2009 and 2011), to incorporate changes made by California to its own LEV program rule. Maryland originally submitted its Clean Car Program to EPA for inclusion in the SIP in December 2007 (Revision #07–16), with subsequent revisions in November 2010 (Revision #10–08) and again in June 2011 (Revision #11–05), to reflect Maryland regulatory updates made in 2009 and 2011. EPA approved Maryland's original Clean Car SIP submittal (and the November 2010 and June 2011 revisions) in a rulemaking action published in the **Federal Register** on June 11, 2013 (78 FR 34911). Maryland again submitted a revised SIP submittal in August 2013 (Revision #13–02), to incorporate regulatory changes made in 2012 to its Clean Car Program rule. EPA approved that SIP revision in a final rulemaking action published in the **Federal Register** on July 9, 2013 (79 FR 38787).

On July 28, 2014, Maryland submitted a revision for the SIP (Revision #14–01) to again amend its Clean Car Program SIP to include regulatory updates made in 2014 to ensure consistency with California's LEV rules. Maryland later submitted another revision for the SIP (Revision #15–02) on April 13, 2015 to adopt additional regulatory amendments made in 2015. It is these two most recent SIP revisions that are the subject of this rulemaking.

Table of Contents

I. Background
A. Maryland's Air Quality With Respect to the Federal National Ambient Air Quality Standard (NAAQS) for Ozone
B. Federal Vehicle Emission Standards
C. California's Low Emission Vehicle Standards
D. Maryland's Low Emissions Vehicle Program
II. Summary of SIP Revisions
III. Final Action
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Background

A. Maryland's Air Quality With Respect to the Federal National Ambient Air Quality Standard (NAAQS) for Ozone

The CAA, which was last amended in 1990, requires EPA to set NAAQS for pollutants considered harmful to public health and the environment. EPA establishes NAAQS for six principal pollutants, or ''criteria'' pollutants, which include: ozone, carbon monoxide (CO), lead, nitrogen dioxide, fine particulate matter (PM), and sulfur dioxide. The CAA establishes two types of NAAQS. Primary standards provide public health protection, including protecting the health of ''sensitive'' populations such as asthmatics, children, and the elderly. Secondary standards protect public welfare, including protection against decreased

visibility and damage to animals, crops, vegetation, and buildings. The CAA also requires EPA to periodically review the standards to ensure that they provide adequate health and environmental protection, and to update those standards as necessary.

Ozone is formed in the atmosphere by photochemical reactions between ozone precursor pollutants, including volatile organic compounds (VOCs) and nitrogen oxides (NO_X) in the presence of sunlight. In order to reduce ozone concentrations in the ambient air, the CAA directs areas designated as nonattainment to apply controls on VOC and NO_X emission sources to reduce the formation of ozone.

Although EPA has revised the ozone NAAQS several times since the CAA was reauthorized in 1990, Maryland has historically had three areas designated as nonattainment under each successive ozone NAAQS. These include portions of the Baltimore metropolitan area, the Maryland portion of the Washington, DC metropolitan area, and the Maryland portion of the Philadelphia metropolitan area. Most recently, EPA revised the 8-hour ozone NAAQS from 0.08 parts per million (ppm) to 0.075 ppm on March 27, 2008 (73 FR 16436). On May 21, 2012 (77 FR 30088), EPA finalized designations for this 2008 8-hour ozone NAAQS, including as nonattainment the same three Maryland areas.

B. Federal Vehicle Emission Standards

Vehicles sold in the United States are required by the CAA to be certified to meet either Federal motor vehicle emission standards or California emission standards. States other than California are forbidden from adopting their own standards, but may elect to adopt California emission standards for which EPA has granted a waiver of preemption. Specifically, section 209 of the CAA prohibits states from adopting or enforcing standards relating to the control of emissions from new motor vehicles (or new vehicle engines), however, EPA may waive that prohibition for any state that adopted its own standards prior to March 30, 1966. As California was the only state to do so, California has authority to adopt its own vehicle emissions standards. California must demonstrate to EPA that its newly adopted standards will be ''. . . in the aggregate, at least as protective of public health and welfare as applicable Federal standards,'' after which time EPA may then grant a waiver of preemption from Federal standards for California's standards.

Section 177 of the CAA authorizes other states to adopt California's standards in lieu of Federal vehicle standards, provided the state does so with at least two model years lead time prior to the effective date of its program and EPA has issued a waiver of preemption to California for such standards.

EPA has adopted several iterations, or ''tiers,'' of federal emissions standards since the CAA was reauthorized in 1990. When Maryland first adopted its Clean Car Program in 2007, the federal standards in effect were Tier 2 standards that were adopted by EPA on February 10, 2000 (65 FR 6698) and were implemented beginning with 2004 model year federally certified vehicles. These Federal Tier 2 standards set tailpipe emissions standards for passenger vehicles and light duty trucks and also limited gasoline sulfur levels. EPA later finalized Tier 3 Federal vehicle and fuel standards on April 28, 2014 (79 FR 23414). The Federal Tier 3 program set more stringent Federal vehicle emissions standards and further limited allowable sulfur content of gasoline for new cars, beginning in 2017. EPA attempted to closely harmonize the Tier 3 standards with California's most current Low Emissions Vehicle Program.

On May 7, 2010 (75 FR 25324), EPA and the U.S. Department of Transportation's National Highway Traffic Safety Administration (NHTSA) jointly established a national program consisting of new standards for light-duty motor vehicles to reduce greenhouse gases (GHG) emissions and to improve fuel economy. This program affected new passenger cars, light trucks, and medium-duty passenger vehicles sold in model years 2012 through 2016. On October 15, 2012 (77 FR 62624), EPA and NHTSA issued another joint rule to further tighten GHG emissions standards for model years 2017 through 2025. The Federal GHG standards were harmonized with similar GHG standards set by California, to ensure that automobile manufacturers would face a single set of national emissions standards to meet both Federal and California emissions requirements.

C. California's Low Emission Vehicle Standards

In 1990, California's Air Resources Board (CARB) adopted its first generation of LEV standards applicable to light and medium duty vehicles. California's LEV program standards were phased-in beginning in model year 1994 through model year 2003. In 1999, California adopted a second generation of LEV standards, known as LEV II, which were phased-in beginning model year 2004 through model year 2010. EPA granted a Federal preemption waiver for CA LEV II program on April 22, 2003 (68 FR 19811).

California's LEV II program reduces emissions in a similar manner to the Federal Tier 2 program by use of declining fleet average non-methane organic gas (NMOG) emission standards, applicable to each vehicle manufacturer each year. Separate fleet average standards are not established for NO_X, CO, PM, or formaldehyde as these emissions are controlled as a co-benefit of the NMOG fleet average (fleet average values for these pollutants are set by the certification standards for each set of California prescribed certification standards.) These allowable sets of standards range from LEV standards (the least stringent standard set) to Zero Emission Vehicle (ZEV) standards (the most stringent standard set). California's LEV II program establishes various other standards: The Ultra-Low Emission Vehicles (ULEV), Super-Ultra Low Emission Vehicles (SULEV), Partial Zero Emission Vehicles (PZEV), and Advanced Technology-Partial Zero Emission Vehicles (AT–PZEV). Each manufacturer may comply by selling a mix of vehicles meeting any of these standards, as long as their sales-weighted, overall average of the various standard sets meets the overall fleet average and ZEV requirements.

In January 2012, California approved a new emissions-control program for model years 2017 through 2025, called the Advanced Clean Cars Program, or the LEV III program. The program combines the control of smog, soot, and GHG and requirements for greater numbers of ZEV vehicles into a single package of standards. The regulations apply to light duty vehicles, light duty trucks, and medium duty passenger vehicles. Under California's Advanced Clean Cars Program, manufacturers can certify vehicles to the standards before model year 2015. Beginning with model year 2020, all vehicles must be certified to LEV III standards. The ZEV amendments add flexibility to California's existing ZEV program for 2017 and earlier model years, and establish new sales and technology requirements starting with the 2018 model year. The LEV III amendments establish more stringent criteria and GHG emission standards starting with the 2015 and 2017 model years, respectively. The California GHG standards are almost identical in stringency and structure to the Federal GHG standards for model years from 2017 to 2025. Additionally, on December 2012, California adopted a ''deemed to comply'' regulation that enables manufacturers to show

compliance with California GHG standards by demonstrating compliance with Federal GHG standards. On June 9, 2013 (78 FR 2112), EPA granted a Federal preemption waiver for California's Advanced Clean Cars Program. California's LEV III program rules are codified in Title 13 of the California Code of Regulations (CCR), under Division 3.

D. Maryland's Low Emissions Vehicle Program

Maryland's legislature adopted and the Governor signed into law the Maryland Clean Cars Act of 2007, establishing legal authority compelling Maryland to adopt California's LEV standards. Maryland adopted its ''Low Emission Vehicle Program,'' codified at COMAR 26.11.34 in 2007. Since then, Maryland has revised its program rules a number of times to ensure consistency with California's LEV program. As discussed in the Supplemental Information section, Maryland submitted revisions in 2009 and 2011, which EPA approved (along with the original 2007 Clean Car revision) on June 11, 2013 (78 FR 34911). Since then, Maryland amended its program in 2013 and submitted another SIP revision to EPA in August 2013, which EPA approved on July 9, 2014 (79 FR 38787).

The Maryland Clean Car Program has two objectives. The first is to reduce emissions of NO_X and VOCs, as precursors of ground level ozone, from new motor vehicles sold in Maryland. The second objective of the program is to reduce GHG emissions from motor vehicles. The program requires 2011 and newer model year passenger cars, light trucks, and medium-duty vehicles having a gross vehicle weight rating (GVWR) of 14,000 pounds or less that are sold as new cars or transferred in Maryland to meet the applicable California emissions standards. For purposes of the Clean Car Program, transfer means to sell, import, deliver, purchase, lease, rent, acquire, or receive a motor vehicle for titling or registration in Maryland.

II. Summary of SIP Revisions

On July 28, 2014, Maryland submitted a formal SIP Revision #14–01 containing Maryland's updated Clean Car regulations to reflect changes made to adopt California's LEV III Program. This SIP submittal consists of updates to make Maryland's Clean Car Program consistent with California's program. Specifically, California amended its LEV III program rule to allow as a compliance option the recent Federal GHG standards for model years 2017 to 2025. Since California's LEV III program addresses GHG pollutants, in addition to criteria pollutants that are precursors to ozone pollution, Maryland incorporated by reference this compliance alternative for California's LEV III program to its own Clean Car Program rule.

On April 30, 2015, Maryland submitted another revision to its SIP to update the Clean Car Program rules. This latest change relates to the ZEV requirements of California's rules, including adjustments to optional compliance path (OCP) for manufacturers related to the elimination of certain credits in qualifying for the OCP and pooling of credits across model years. Another ZEV-related provision establishes a minimum amount of ZEV credits to be used each year, specifically a limit to use of non-ZEV credits to satisfy ZEV requirements. Further, California amended the definition for fast refueling for purposes of determining the ZEV type to limit credits to only technologies that have actually been demonstrated in practice. Maryland incorporated by reference in its Clean Car Program these latest changes to California's LEV III program.

These two most recent Maryland SIP submittals are the subject of this rulemaking action. Maryland adopted California's updates to portions of CCR Title 13, Division 3 by amending COMAR 26.11.34.02, relating to incorporation by reference of California's LEV standards. The July 28, 2014 and April 13, 2015 SIP submittals include Maryland's adopted regulatory amendments to the Clean Car Program rule (with the exception of CCR, Title 13, Division 3, Article 5, Section 2030 ''Liquefied Petroleum Gas or Natural Gas Retrofit Systems,'' which Maryland requested EPA to exclude from the SIP). The April 13, 2015 SIP submittal will replace in its entirety the existing regulation COMAR 26.11.34.02 as approved in the SIP on July 9, 2014 with the revised version of COMAR 26.11.34.02 effective February 16, 2015. *See* 79 FR 38787. A list of California's regulations being incorporated by reference is included as part of Maryland's notice of proposed action dated December 1, 2014, which is included in the State submittal and available online at *www.regulations.gov,* Docket ID No. EPA–R03–OAR–2015–0241. These revisions to Maryland's Clean Car Program, as approved in the Maryland SIP, are important to ensure consistency with California's LEV program. This will ensure that Maryland's Clean Vehicle Program complies with the requirements for adoption of another state's vehicle standards in lieu of Federal vehicle standards, per section 177 of the CAA.

III. Final Action

EPA is approving Maryland's July 28, 2014 and April 13, 2015 SIP submittals. These revisions amend the prior approved Maryland Clean Vehicle Program, specifically with respect to Maryland's updated incorporation by reference (at COMAR 26.11.34.02) of California's LEV program rules (at Title 13, CCR, Division 3, with the exception of CCR, Title 13, Division 3, Article 5, Section 2030). Maryland's SIP revisions serve to ensure consistency of Maryland's Clean Vehicle Program with California's LEV III program, satisfying Federal requirements for state adoption of vehicle emission standards under section 177 of the CAA. EPA is publishing this rule without prior proposal because EPA views this as a noncontroversial amendment and anticipates no adverse comment. However, in the ''Proposed Rules'' section of this **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on *September 14, 2015* without further notice unless EPA receives adverse comment by *August 13, 2015.* If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

IV. Incorporation by Reference

In this rulemaking action, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of Maryland's Clean Vehicle Program rules at COMAR 26.11.34.02, as adopted on January 20, 2015 and effective on February 16, 2015. EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve SIP submissions

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

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

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

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking action. This action approving revisions to the Maryland Clean Car Program may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: June 26, 2015.

William C. Early,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart V—Maryland

■ 2. In § 52.1070, the table in paragraph (c) is amended by revising the entry for COMAR 26.11.34.02 to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

EPA—APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP

Code of Maryland Administrative Regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.1100
*	*	*	*	*
26.11.34	Low Emissions Vehicle Program			
*	*	*	*	*
26.11.34.02 (except .02B(20)).	Incorporation by Reference.	02/16/15	07/14/15 [*Insert **Federal Register** citation*].	Update to incorporate by reference California's Advanced Clean Car Program rules, with the exception of Title 13, California Code of Regulations, Division 3, Chapter 2, Article 5, Section 2030.
*	*	*	*	*

* * * * *

[FR Doc. 2015–17060 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[EPA–R03–OAR–2015–0119; FRL–9930–30–Region 3]

Clean Air Act Title V Operating Permit Program Revision; Pennsylvania

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a Title V Operating Permit Program revision submitted by the Commonwealth of Pennsylvania. The revision amends the Title V fee program that funds the Pennsylvania Title V Operating Permit Program. EPA is approving these revisions to increase Pennsylvania's annual emission fees to $85 per ton of emissions for emissions from Title V sources of up to 4,000 tons of each regulated pollutant in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on August 13, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2015–0119. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, *i.e.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Gerallyn Duke (215) 814–2084, or by email at *duke.gerallyn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On March 18, 2015 (80 FR 14037), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Pennsylvania. In the NPR, EPA proposed approval of the Pennsylvania Title V Operating Program revision to increase the annual Title V fees paid by the owners or operators of all Title V facilities throughout Pennsylvania, including Allegheny and Philadelphia Counties, from $57.50 per ton of regulated air pollutant to $85 per ton. The formal Title V Program revision was submitted by Pennsylvania on February 11, 2014.

Under 40 CFR 70.9(a) and (b), an approved state Title V operating permits program must require that the owners or operators of part 70 sources pay annual fees, or the equivalent over some other period, that are sufficient to cover the permit program costs and ensure that any fee required under 40 CFR 70.9 is used solely for permit program costs. Under Pennsylvania's Title V permit emission fee rules at 25 PA Code 127.705, the annual emission fee for emissions occurring in calendar year 2012 was $57.50 per ton of regulated pollutant for emissions of up to 4,000 tons of each regulated pollutant. The fee structure has not been revised since 1994. As discussed further in our proposed approval of Pennsylvania's Title V fee revision on March 18, 2015, Pennsylvania has determined that Title V annual emission fee revenues collected are no longer sufficient to cover Title V program costs.

II. Summary of Title V Operating Permit Program Revision

In the February 11, 2014 program revision, Pennsylvania included revised 25 PA Code 127.705 which Pennsylvania has amended to increase Pennsylvania's annual emission fees. Fees are increased to $85 per ton of emissions for emissions from Title V sources of up to 4,000 tons of each regulated pollutant. The provisions for increasing the annual emissions fees in response to increases in the Consumer Price Index at 25 PA Code 127.705(d) remain unchanged. The revised fees are designed to cover all reasonable costs required to develop and administer the Title V program as required by 40 CFR 70.9(a) and (b).

III. Final Action

EPA is approving the Pennsylvania Title V Operating Program revision submitted on February 11, 2014 to increase the annual Title V fees paid by the owners or operators of all Title V facilities throughout Pennsylvania, including Allegheny and Philadelphia Counties, from $57.50 per ton of regulated air pollutant to $85 per ton. The revision meets requirements in 40 CFR 70.9.

IV. Statutory and Executive Order Reviews

A. General Requirements

This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. For that reason, this action:

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

In addition, this rule related to Pennsylvania Title V fees does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the program 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.

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action related to Pennsylvania Title V fees may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 70

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

Dated: June 26, 2015.

William C. Early,

Acting Regional Administrator, Region III.

40 CFR part 70 is amended as follows:

PART 70—STATE OPERATING PERMIT PROGRAMS

■ 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 paragraph (d) to the entry for Pennsylvania to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permit Programs

* * * * *

Pennsylvania

* * * * *

(d) The Pennsylvania Department of Environmental Protection submitted a program revision on February 11, 2014; approval effective on July 14, 2015.

* * * * *

[FR Doc. 2015–16924 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 480

Acquisition, Protection, and Disclosure of Quality Improvement Organization Information

CFR Correction

In Title 42 of the Code of Federal Regulations, Parts 480 to 481, revised as of October 1, 2014, on page 614, in § 480.132, remove paragraphs (b)(1)(i) and (ii).

[FR Doc. 2015–17128 Filed 7–13–15; 8:45 am]

BILLING CODE 1505–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

Conditions of Participation for Hospitals

CFR Correction

In Title 42 of the Code of Federal Regulations, Part 482 to End, revised as of October 1, 2014, on page 40, in the introductory text of § 482.92, remove the term ''recipient'' and add ''beneficiary'' in its place.

[FR Doc. 2015–17127 Filed 7–13–15; 8:45 am]

BILLING CODE 1505–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 11–42, 09–197, 10–90; FCC 15–71]

Lifeline and Link Up Reform and Modernization, Telecommunications Carriers Eligible for Universal Service Support, Connect America Fund

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (the Commission) seeks to rebuild the current framework of the Lifeline program and continue its efforts to modernize the Lifeline program so that all consumers can utilize advanced networks.

DATES: This Order on Reconsideration and Second Report and Order is effective August 13, 2015. The amendments to these rules contain information collection requirements that are subject to Paperwork Reduction Act that have not yet been approved by the Office of Management and Budget (OMB). Upon OMB approval of the information collection requirements, the Commission will publish a document in the **Federal Register** announcing the effective date of the regulations.

FOR FURTHER INFORMATION CONTACT: Jonathan Lechter, Wireline Competition Bureau, (202) 418–7400 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration and Second Report and Order *(Order on Recon and 2nd R&O)* in WC Docket Nos. 11–42, 09–197, 10–90; FCC 15–71, adopted on June 18, 2015 and released on June 22, 2015. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554 or at the following Internet address: *https://www.fcc.gov/document/fcc-releases-lifeline-reform-and-modernization-item.*

I. Introduction

1. For nearly 30 years, the Lifeline program has ensured that qualifying low-income Americans have the opportunities and security that voice service brings, including being able to find jobs, access health care, and connect with family. As the Commission explained at the program's inception, ''[i]n many cases, particularly for the elderly, poor, and disabled, the

telephone [has] truly [been] a lifeline to the outside world.'' Thus, ''[a]ccess to telephone service has [been] crucial to full participation in our society and economy which are increasingly dependent upon the rapid exchange of information.'' In 1996, Congress recognized the importance and success of the program and enshrined its mission into the Telecommunications Act of 1996 (1996 Act). Over time, the Lifeline program has evolved from a wireline-only program, to one that supports both wireless and wireline voice communications. Consistent with the Commission's statutory mandate to provide consumers in all regions of the nation, including low-income consumers, with access to telecommunications and information services, the program must continue to evolve to reflect the realities of the 21st Century communications marketplace in a way that ensures both the beneficiaries of the program, as well as those who pay into the universal service fund (USF or Fund), are receiving good value for the dollars invested. The purpose of the Lifeline program is to provide a hand up, not a hand out, to those low-income consumers who truly need assistance connecting to and remaining connected to telecommunications and information services. The program's real success will be evident by the stories of Lifeline beneficiaries who move off of Lifeline because they have used the program as a stepping stone to improve their economic stability.

2. Over the past few years, the Lifeline program has become more efficient and effective through the combined efforts of the Commission and the states. The Lifeline program is heavily dependent on effective oversight at both the Federal and the state level and the Commission has partnered successfully with the states through the Federal-State Joint Board on Universal Service (Joint Board) to ensure that low-income Americans have affordable access to voice telephony service in every state and territory. In addition to working with the Commission on universal service policy initiatives on the Joint Board, many states administer their own low-income programs designed to ensure that their residents have affordable access to telephone service and connections. These activities provide the states the opportunity and flexibility to develop new and innovative ways to make the Lifeline program more effective and efficient, and ultimately bring recommendations to the Commission for the implementation of improvements on a national scale. As the Commission continues to modernize the Lifeline program, it deeply values the input of the states as it, among other reforms, seeks to streamline the Lifeline administrative process and enhance the program.

3. The Commission's 2012 *Lifeline Reform Order,* 77 FR 12951, March 2, 2012, substantially strengthened protections against waste, fraud, and abuse; improved program administration and accountability; improved enrollment and consumer disclosures; and took some preliminary steps to modernize the program for the 21st Century. These reforms provided a much needed boost of confidence in the Lifeline program among the public and interested parties, increased accountability, and set the Lifeline program on an improved path to more effectively and efficiently provide vital services to the Nation's low-income consumers. In particular, the reforms have resulted in approximately $2.75 billion in savings from 2012 to 2014 against what would have been spent in the absence of reform. Moreover, in the time since the reforms were adopted, the size of the Lifeline program has declined steadily. In 2012, the Universal Service Administrative Company (USAC), the Administrator of the Fund, disbursed approximately $2.2 billion in Lifeline support payments compared to approximately $1.6 billion in Lifeline support payments in 2014. These reforms have been transformational in minimizing the opportunity for Lifeline funds to be used by anyone other than eligible low-income consumers. The Commission is pleased that its previous reforms have taken hold and sustained the integrity of the Fund. However, the Commission's work is not complete. In light of the realities of the 21st Century communications marketplace, the Commission must overhaul the Lifeline program to ensure that it advances the statutory directive for universal service. At the same time, the Commission must ensure that adequate controls are in place as while implementing any further changes to the Lifeline program to guard against waste, fraud, and abuse. Therefore the Commission, among other things, seek to revise our documentation retention requirements and establish minimum service standards for any provider that receives a Lifeline subsidy. The Commission also seeks to focus our efforts on targeting funding to those low-income consumers who really need it while at the same time shifting the burden of determining consumer eligibility for Lifeline support from the provider. The Commission further seek to leverage efficiencies from other existing federal programs and expand our outreach efforts. By rebuilding the existing Lifeline framework, the Commission hopes to more efficiently and effectively address the needs of low-income consumers. The Commission ultimately seeks to equip low-income consumers with the necessary tools and support system to realize the benefits of broadband independent of Lifeline support.

4. Three years ago, the Commission took important steps to reform the Lifeline program. The reforms, adopted in the 2012 *Lifeline Reform Order,* focused on changes to eliminate waste, fraud, and abuse in the Lifeline program by, among other things: Setting a savings target; creating a National Lifeline Accountability Database (NLAD) to prevent multiple carriers from receiving support for the same household; and confirming a one-per-household rule applicable to all consumers and Lifeline providers in the program. It also took preliminary steps to modernize the Lifeline program by, among other things: Adopting express goals for the program; establishing a Broadband Adoption Pilot Program; and allowing Lifeline support for bundled service plans combining voice and broadband or packages including optional calling features. Now, 30 years after the Lifeline program was founded, the Commission believes it is past time for a fundamental, comprehensive restructuring of the program.

5. In the Order on Recon, the Commission grants in part a petition for reconsideration filed by TracFone of the Commission's 2012 *Lifeline Reform Order* and requires Lifeline providers to retain documentation demonstrating subscriber eligibility. In the 2nd R&O, the Commission takes further steps to adopt rules and procedures in response to proposals on which the Commission sought comment in the 2012 *Lifeline FNPRM,* and other outstanding issues regarding administration of the program to root out waste, fraud, and abuse. The Commission also takes further actions to put in place measures that increase accountability, efficiency, and transparency in the program. Specifically, the Commission:

- Establishes a uniform ''snapshot'' date each month for Lifeline providers to calculate their number of subscribers for the purpose of reimbursement;
- Eliminates the requirement that incumbent local exchange carriers (LECs) must resell retail Lifeline-discounted service, and limit reimbursement for Lifeline service to Lifeline providers directly serving Lifeline customers;

• Interprets ''former reservations in Oklahoma,'' as provided in the Commission's rules, as the geographic boundaries reflected in the Historical Map of Oklahoma 1870–1890 (Oklahoma Historical Map); and

• Waives, on the Commission's motion, the requirement to conduct desk audits on first-year ETCs for two Lifeline providers in order to maximize the use of audit program resources.

II. Order on Reconsideration

A. Retention of Eligibility Documentation

6. In the Order on Recon, the Commission requires ETCs to retain documentation demonstrating subscriber eligibility for the Lifeline Program as well as documentation used in NLAD processes and revise §§ 54.404 and 54.410 of the rules. In doing so, the Commission grants in part a petition and supplement filed by TracFone, which requests reconsideration of the prohibition on retention of eligibility documentation. The Commission takes these actions as another important step to significantly reduce waste, fraud, and abuse in the Lifeline program.

7. In the *Lifeline Reform Order,* the Commission adopted uniform eligibility criteria for the federal Lifeline program. Consumers must qualify based on either their income or their participation in at least one of a number of federal assistance programs. The Commission required eligible telecommunications carriers (ETCs) to examine certain documentation to verify a consumer's program or income based eligibility, but prohibited ETCs from retaining copies of the documentation. Instead, the Commission directed ETCs to review the documentation and keep accurate records detailing how the consumer demonstrated his or her eligibility. In support of its decision to prohibit the retention of eligibility documents, the Commission cited to comments that raised concerns such as the risk related to retaining sensitive subscriber eligibility documentation and the burden on ETCs.

8. Subsequent to the *Lifeline Reform Order,* TracFone filed a petition for reconsideration and supplement. In its petition for reconsideration, TracFone argues that the Commission should not have required consumers to produce documentation to prove eligibility. In its late-filed supplement to its petition for reconsideration, TracFone argues that given that the Commission had not reconsidered the new rule requiring proof of eligibility, the Commission should require all ETCs to retain the program eligibility documentation for not less than three years, in accordance with the rules on record retention. Recently, in a petition for waiver, TracFone broadened its original request to allow ETCs to retain documentation related to both program and income-based eligibility.

9. *Procedural Issues.* Section 1.429 of the Commission's rules states that late filed supplements to petitions for reconsideration are not considered, ''except upon leave granted pursuant to a separate pleading stating the grounds for acceptance of the supplement.'' TracFone filed a separate pleading requesting that the Commission accept and consider the late-filed supplement because the arguments raised in the supplement are a logical outgrowth of the issues raised in the 2011 *Lifeline NPRM.* TracFone notes that its proposal was subject to public comment and all but one of the commenters supported its position to permit retention of eligibility documentation. The Commission finds that TracFone has stated adequate grounds to justify consideration of its supplement. The Commission view the argument raised in TracFone's supplement as an alternative argument to Tracfone's petition for reconsideration. The Commission also notes that both the petition for reconsideration and the supplement were the subject of public comment, and that the issue of eligibility documentation retention was directly discussed in the *Lifeline Reform Order.* The Commission therefore accepts TracFone's supplement to its petition for reconsideration and discuss the substantive issues below.

10. *Substantive Issues.* In its petitions, TracFone argues that retention of eligibility information is necessary to prevent waste, fraud, and abuse because the current rules do not provide the Commission or USAC with a way to verify through an audit or other mechanism whether an ETC has in fact reviewed the eligibility documentation provided by the Lifeline applicant. TracFone argues that by prohibiting ETCs from retaining documentation, the Commission created an opportunity for ETCs to fabricate records which indicate that they have reviewed valid documentation. In a related petition, TracFone argues that ETCs should retain documentation reviewed to verify the identity or information of a subscriber as part of the NLAD dispute resolution process for the NLAD. For these reasons, TracFone argues in its petitions that the Commission should change its rules to require ETCs to retain eligibility documentation in accordance with Commission retention rules.

11. All but one of the commenters filed in support of the TracFone petitions, asserting among other things that retention of documentation is in the public interest, and that requiring the retention of eligibility documents will curb waste, fraud, and abuse in the Lifeline program. Commenters also agree that the current requirement is difficult to audit. They explain that there is uncertainty in the industry with respect to what an ETC's records must contain and what auditors would consider when finding that an ETC is or is not compliant with the rules. Commenters agree that ETCs have methods to securely maintain customer eligibility documentation in an encrypted, electronic format and to limit access to such documentation to only certain employees. Some commenters also note that the administrative costs associated with retaining the documentation are minimal and, in all events, justified by the protection afforded against waste, fraud, and abuse.

12. *Retention of Subscriber Eligibility Documentation.* Based on the record, the Commission grants in part TracFone's request for reconsideration and require carriers to retain both program and income-based eligibility documentation. Under § 1.429 of the Commission's rules, petitions for reconsideration will only be granted when the petitioner shows that the facts or arguments relied on have changed since the last opportunity to present such matters, the facts or arguments were not known at the time of the last opportunity to present such matters, or the Commission determines that consideration of the facts or arguments relied on is required in the public interest. For the reasons set forth below, the Commission finds that TracFone has demonstrated that ''consideration of the facts or arguments relied on is required in the public interest.''

13. Based upon the record before us and for the reasons set forth below, the Commission finds that the overall benefits of requiring the retention of eligibility documentation outweigh the costs. The Commission thus revises § 54.410 of the rules to require retention of eligibility documentation. The Commission concludes that reversal of the eligibility documentation prohibition is in the public interest because it will improve the auditability and enforceability of our rules, significantly reduce falsified records, and provide certainty in the industry regarding the documents that need to be retained in the event of an audit or investigation.

14. The Commission also finds that the concerns that led us to prohibit such

retention in 2012, while still relevant, are largely overshadowed by the enormous benefits of requiring ETCs to retain eligibility documentation. For example, while the Commission is still concerned with the privacy and security of subscriber information, most ETCs themselves argue that there are IT and access security measures that can be taken to minimize the risks associated with maintaining sensitive subscriber eligibility documentation. In fact, in the General Accounting Office (GAO)'s recent report on the Lifeline Program, the ETCs interviewed reiterated their comments that subscriber information can be protected using multiple measures such as, but not limited to, firewalls and other boundary protections to prevent unauthorized access, authentication requirements for users, and usage restrictions for authorized users. Furthermore, while there still will be an additional burden on ETCs to retain eligibility documentation, the majority of ETCs contend that the burden is worth the benefits to the program and the Commission agrees. The Commission finds that the burdens of retention can be mitigated with electronic storage capabilities and the Commission concludes that the burden is outweighed by the benefits to the integrity of the program. While the Commission seeks comment on establishing a national verifier for the program, overall, the Commission finds that the Fund will be better protected, if at this time, ETCs are required to both retain and present the eligibility documentation to the Commission or USAC and that the revised rules will prevent significant waste, fraud, and abuse in the Lifeline program.

15. *Retention of Documentation Used in the NLAD Resolution Processes.* For the reasons set forth above, the Commission revises § 54.404 of the rules and also require ETCs to retain documentation that was reviewed to verify subscriber information for the NLAD dispute resolution process. The NLAD dispute resolution process requires ETCs to review additional documentation to verify the identity or information of a subscriber who has failed the third-party identification verification, and address or age check for the NLAD. All but one of the comments received support TracFone's position that ETCs should be allowed to retain documents reviewed for NLAD processes. In addition to the record support for this action, the Commission also finds that there is overlap between the documents reviewed by ETCs for the NLAD dispute resolution process and the eligibility documents listed in § 54.410. Furthermore, the Commission's rules on record retention mandate that ETCs retain documents demonstrating compliance with federal Lifeline requirements.

16. Therefore the Commission revises §§ 54.404 and 54.410 of the Commission's rules and requires that all ETCs retain documentation demonstrating subscriber income-based or program-based eligibility for participation in the Lifeline program for the purposes of production during audits or investigations or to the extent required by NLAD processes, including the dispute resolution processes that require verification of identity, address, or age of subscribers. The Commission reminds ETCs that pursuant to Section 222 of the Act, they have a duty to protect ''the confidentiality of proprietary information'' of customers. In this context, this includes all documentation submitted by a consumer or collected by an ETC to determine a consumer's eligibility for Lifeline service, as well as all personally identifiable information contained therein.

17. The Act's requirement that such practices be ''just and reasonable,'' also imposes a duty on ETCs related to document retention security practices. Accordingly, the Commission expects ETCs to live up to the assurances made in their comments in this proceeding that they can take appropriate measures to protect this data. In particular, the Commission expects that, at a minimum, ETCs must employ the following practices to secure any subscriber information that is stored on a computer connected to a network: firewalls and boundary protections; protective naming conventions; user authentication requirements; and usage restrictions, to protect the confidentiality of consumers' proprietary personal information retained for this or other allowable purposes. However, if the facts warrant further investigation, the Commission will still evaluate the security measures employed by ETCs on a case by case basis.

18. The Commission sought comment on extending to ten years the record retention requirement generally in the 2012 *Lifeline FNPRM.* The Commission does not take action on that proposal at this time. Therefore, Lifeline providers must retain documentation demonstrating compliance with the Commission's rules for three years. Documentation required by §§ 54.404(b)(11), 54.410(b), 54.410(c), 54.410(d) and (f) must be retained for as long as the subscriber receives Lifeline service from the ETC, but no less than three calendar years. Documents covered under §§ 54.404(b)(11), 54.410(b), and 54.410(c) are those documents in existence as of the effective date of this rule.

19. Finally, given the Commission's decision in the Second Report and Order to limit Lifeline support to ETCs directly serving Lifeline customers, the Commission also amends § 54.417 to require non-ETCs that have provided Lifeline service through resale to retain records establishing compliance with state and federal rules for at least three calendar years. Non-ETCs should also retain documentation required by §§ 54.404(b)(11), 54.410(b), 54.410(c), 54.410(d) and (f) for as long as the subscriber receives Lifeline service from the ETC, but no less than three calendar years. Such retention will allow the Commission to verify non-ETCs' past compliance with the Lifeline rules.

III. Second Report and Order

A. Establishing a Uniform Snapshot Date Going Forward

20. In the 2011 *Lifeline NPRM,* the Commission proposed to codify a rule that would require all ETCs to report partial or pro-rata dollar amounts when claiming reimbursement for Lifeline subscribers who received service for less than a month. The Commission reasoned that since ETCs are able to bill customers on a partial month basis, they should also be able to tell if a customer was a Lifeline subscriber for the full month of requested support.

21. The majority of comments received in response to the 2011 *Lifeline NPRM* opposed such a requirement and raised arguments regarding significant resources and cost involved if the Commission mandated pro-rata support reporting. For example, commenters explained that fundamental changes to systems, such as programming updates, additional storage requirements, and/or creating new internal IT systems may be necessary to comply with such a requirement. The commenters noted that the Commission should not assume that ETC billing systems could readily implement pro-rata support calculations. In contrast, commenters noted that the system of using a single snapshot date to calculate support amounts would alleviate the need for partial support requests. Some commenters noted that the creation of the database, which would track the number of days that subscribers received service and when they were activated and deactivated, could solve the issue permanently.

22. After reviewing the comments received, the Commission declines to adopt our proposal to require ETCs to calculate partial month support amounts. As the current FCC Form 497 does not collect pro-rata support requests, our actions today do not affect ETCs' FCC Form 497 filings currently pending with USAC.

23. Instead of requiring pro-rata support requests, at this time, the Commission revises § 54.407 of its rules to require ETCs to use a uniform snapshot date to request reimbursement from USAC for the provision of Lifeline support. As the commenters state, the Commission agrees that it is possible that subscribers who initiate service may offset those who terminate service mid-month. The Commission finds, therefore, that a uniform snapshot date will reduce waste in the program as effectively as partial support reporting would have done, but at much lower administrative and compliance cost to ETCs. The Commission also finds that a uniform snapshot date will be efficient for USAC to administer and will ultimately ease future changes to reimbursement processes if, for example, the Commission adopts proposals herein to reimburse based on the NLAD.

24. Following the 2012 *Lifeline Reform Order,* USAC encouraged ETCs to select a single ''snapshot date'' during the month (*e.g.,* the 15th of every month) to determine the number of eligible consumers for which it would seek reimbursement for that month. As a result, the snapshot dates vary from ETC to ETC. The Commission now decides that ETCs should all use the same snapshot date to determine the number of Lifeline subscribers served in a given month and report that month to USAC on the FCC Form 497. The Commission concludes that a snapshot date will produce substantial benefits. First, a uniform snapshot date will reduce the risk that two ETCs receive full support for providing service for the same subscriber in the same calendar month. Second, a uniform snapshot date will make it easier for USAC to adopt uniform audit procedures. Third, a uniform snapshot date will help ease the transition to a reimbursement process that calculates support based on the number of subscribers contained in the NLAD. Given the industry support and comment around the establishment of a snapshot date, compliance with the Commission's rules will be high and the administrative costs associated will be low. To promote efficiency and ease of administration, the Commission revises § 54.407 and directs ETCs to take a snapshot of their subscribers on the first day of the month.

25. Therefore, within 180 days of the effective date of this 2nd R&O, ETCs should transition to using the first day of the month as the snapshot date. Such a transition period is appropriate to ensure that ETCs have sufficient time to make whatever changes are necessary to their billing systems to take a snapshot on the first day of the month. In the interim, ETCs should use the same snapshot date of their choice from month to month.

B. Resale of Retail Lifeline Supported Services

26. The Commissions next attacks a potential source of waste and abuse in the Lifeline program by addressing issues raised by the Commission in the 2012 *Lifeline FNPRM* pertaining to resold Lifeline services. The Commission now finds that only ETCs providing Lifeline service directly to the consumer may seek reimbursement from the Lifeline program for the service provided. The Commission revises §§ 54.201, 54.400, 54.401, and 54.407 to reflect this change. The Commission will no longer provide any Lifeline reimbursement to carriers for any wholesale services to resellers, and the Commission therefore forebear, to the extent discussed herein, from the incumbent LECs' obligation under section 251(c)(4) to offer their Lifeline services to resellers.

27. By way of background, section 251(c)(4) of the Communications Act of 1934 as amended, states that incumbent LECs have the duty ''to offer for resale at wholesale rates any telecommunications service that the carrier provides at retail to subscribers who are not telecommunications carriers.'' In 1997, to encourage competition in the Lifeline market, the Commission concluded that resellers ''could obtain Lifeline service at wholesale rates that include the Lifeline support amounts and could pass these discounts through to qualifying low-income consumers.'' In its 2004 *Lifeline Report and Order,* the Commission required non-ETCs that provide Lifeline-discounted service to eligible consumers through resold retail service arrangements with the incumbent LECs to comply with all Lifeline/Link Up requirements, including certification and verification of subscribers. As of February 2014, there are approximately 46,281 lines offered to resellers for which incumbent LECs are seeking reimbursement.

28. In the 2012 *Lifeline Reform Order,* the Commission expressed concerns that permitting ETCs and non-ETCs to offer Lifeline-discounted service through resale of retail Lifeline service posed risks to the Fund. In particular, the Commission was concerned with the possibility of over-recovery by both wholesalers and resellers seeking reimbursement from USAC for the same Lifeline subscriber and the lack of direct oversight of non-ETC resellers by state and federal regulators. In the case where both the wholesaler and the reseller are ETCs, there is currently no way for USAC to determine whether both the wholesaler and the reseller are seeking reimbursement for the same subscriber. Meanwhile, while non-ETC resellers do not pose the same risk of duplicate discounts, they may not be complying with federal and state Lifeline rules. Even though non-ETC resellers must retain records to demonstrate compliance with the Lifeline program rules, the Commission found it difficult to oversee compliance ''where the entity with the retail relationship with the consumer is not interfacing directly'' with regulators.

29. In light of these concerns, the Commission sought comment in the Further Notice of Proposed Rulemaking section of the *Lifeline Reform Order* on a variety of proposals to reform or eliminate the resale of retail wireline Lifeline service. First, the Commission proposed to restrict reimbursement from the Fund to ETCs when they provide Lifeline-discounted service directly to retail customers. Under this proposal, if an ETC wholesaler provides retail telecommunications service to an ETC reseller for resale, only the ETC reseller can seek reimbursement from the Fund—the wholesaler ETC would not be permitted to take from the Fund on behalf of the reseller ETC. Second, the Commission proposed to eliminate incumbent LECs' obligation to resell retail Lifeline-discounted service. The Commission sought comment on whether it should eliminate this requirement by either reinterpreting the section 251(c)(4) resale obligation to exclude the resale of retail Lifeline-discounted service or by forbearing from the incumbent LECs' obligation to offer retail Lifeline service via section 251(c)(4) resale.

30. Commenters overwhelmingly support eliminating the resale of retail Lifeline service. Parties agree that only ETCs that provide Lifeline-discounted service directly to subscribers should be eligible to receive Lifeline support from the Fund. Commenters also support the Commission's proposal to eliminate the incumbent LECs' obligation to resell retail Lifeline-discounted services. A few commenters suggest that if the Commission were to eliminate the resale

of Lifeline retail service, it should provide a transitional period during which non-ETC providers could attempt to obtain ETC status.

31. To promote transparency and to protect the Fund from potential waste and abuse, the Commission now decides that only ETCs that provide Lifeline service directly to subscribers will be eligible for reimbursement from the Fund. The Commission will no longer provide reimbursement to incumbent LECs who sell Lifeline-discounted service to resellers. Since the Commission will not provide reimbursement to incumbent LECs for this purpose, the Commission now forbears from requiring incumbent LECs to resell retail Lifeline-discounted service under section 251 of the Act. The Commission's revised rules will effectively eliminate non-ETC resellers. Therefore, the Commission establishes a 180-day transition period following the effective date of this order during which non-ETC resellers may either obtain ETC status or cease providing Lifeline-discounted service after complying with state and federal rules on discontinuance. Following the 180-day period described below, the Commission will no longer provide any reimbursement to carriers for any wholesale Lifeline services sold to resellers. In the transition period section below, the Commission discusses potential issues such as amendments to interconnection agreements that may need to be resolved during the transition period and potential solutions for ETCs who need more time.

32. *Reimbursement Restricted to ETCs Directly Serving Lifeline Subscribers.* The Commission first determines that ETCs can only receive reimbursement from the Fund in instances where they provide Lifeline service directly to subscribers. Pursuant to the revised rules, only a single entity that is registered with USAC will provide Lifeline service, maintain the relationship with the subscriber, seek reimbursement from the Fund, and be subject to state and Commission oversight. The Commission's decision to only reimburse ETCs that directly serve subscribers is consistent with the Lifeline rules, the majority of which deal with the ETC-subscriber relationship.

33. In addition, this restriction will further protect the Fund from the risk of two ETCs seeking funds for the same subscriber. There is currently no way for USAC to determine if a particular service for which an ETC wholesaler sought reimbursement is also being used as a basis for reimbursement by the reseller ETC. When an incumbent LEC provides Lifeline retail service for resale, it provides the retail service for the ''wholesale rate'' discount minus the Lifeline discount. The incumbent LEC then seeks reimbursement from the Fund for that line to make itself whole for the Lifeline discount passed-through to the ETC reseller. Regardless of any contractual agreements that the wholesaler and ETC reseller may have for the reseller to forgo reimbursement from the Fund for that same line, the reseller could seek reimbursement from the Fund. Currently, there is no way for USAC or the incumbent LEC wholesaler to determine if the reseller has in fact sought reimbursement for the same subscriber. The NLAD is not able or intended to detect duplicate reimbursement by the wholesaler and reseller because the incumbent LEC's wholesale ''subscriber'' in this instance is the reseller, not an end-user. The NLAD only shows the reseller and all its customers (*i.e.,* end-users). For the foregoing reasons, the Commission amends §§ 54.201, 54.400, 54.401(a), and 54.407 of the rules to clarify that the ETC must have a direct service relationship with the qualifying low-income consumer to receive reimbursement from the Fund.

34. *Forbearance from the Obligation to Provide Lifeline at Resale.* Since the Commission will no longer provide reimbursement to the incumbent LEC for reselling retail Lifeline services, consistent with Section 10 of the Act, the Commission forbears the incumbent LECs' obligation to provide Lifeline-discounted service at resale pursuant to Section 251(c)(4) of the Act.

35. Under Section 10(a)(1) of the Act, the Commission must consider whether enforcement of the duty to offer Lifeline-discounted services at wholesale rates is necessary to ensure that the charges, practices, classifications, or regulations are just and reasonable and not unjustly or unreasonably discriminatory. Even if incumbent LECs are not allowed to offer for resale Lifeline-discounted services at wholesale rates, low-income consumers will still be able to receive Lifeline-supported services from both wireless and wireline providers. The percentage of resold lines by incumbent LECs in the Lifeline program is minimal, and wireline CETCs have a variety of methods to offer service without using resold Lifeline-discounted service, such as, but not limited to, the use of unbundled network elements (UNEs), wholesale telecommunications service provided at generally available commercial terms, as well as non-Lifeline section 251 resale. The Commission therefore concludes that applying the Section 251(c)(4) requirements in this context is not necessary to ensure that the charges, practices, classifications, and regulations for Lifeline service are just and reasonable.

36. Section 10(a)(2) requires the Commission to consider whether requiring incumbent LECs to offer Lifeline-discounted services at wholesale under Section 251(c)(4) is necessary to protect consumers. Even absent that requirement, low-income consumers will continue to have access to Lifeline-supported services from numerous providers. Furthermore, the Commission notes that, unlike ETCs, non-ETC resellers are not scrutinized by federal and state regulators prior to market entry. Non-ETC resellers are not required to obtain approval from the Bureau of their compliance plan nor, by definition, are they required to obtain an ETC designation. Therefore, following forbearance, consumers will be better protected because all providers of Lifeline will be required to comply with state and Federal Lifeline rules and be subject to direct USAC oversight. Requiring incumbent LECs to offer Lifeline-discounted services at wholesale rates is therefore not necessary for the protection of consumers.

37. Finally, Section 10(a)(3) requires that the Commission considers whether enforcement of section (c)(4) resale requirements for Lifeline-discounted service is in the public interest. The Commission has made clear its ongoing commitment to fight waste, fraud, and abuse in the Lifeline program. The Commission finds that it is in the public interest that Lifeline-discounted service be provided only by ETCs who have the federal or state designations. Furthermore, by limiting reimbursements to carriers that are directly subject to regulation as ETCs, the Commission will reduce the risk of waste, fraud, and abuse of the program, which is in the public interest. Section 10(b) requires that the analysis under Section 10(a)(3) include consideration of whether forbearance would promote competitive market conditions. Although the Commission does not believe that forbearance will necessarily increase competition in the market for Lifeline-discounted services, the Commission finds that the market for Lifeline services is already competitive and will remain so following forbearance. Incumbent LECs, wireline CETCs utilizing means other than Lifeline resale to serve their subscribers, and wireless ETCs offer Lifeline consumers significant competitive choice.

38. *Transition Period.* To provide for an orderly transition period for ETCs, non-ETCs and their consumers to move away from Lifeline resale services, the changes in this order will go into effect 180 days after the effective date of this Order. The comments received noted that 180 days would be sufficient time for incumbent LEC wholesalers to make the necessary changes to tariffs, interconnection agreements, and other regulatory filings. Forbearance here may trigger change of law provisions in ILEC interconnection agreements. The Commission reminds ILECs and CETCs to negotiate in good faith to make appropriate amendments for such agreements. Therefore, starting 180 days after the effective date of this Order, incumbent LECs no longer have an obligation under Section 251(c)(4) of the Act to offer for resale their Lifeline-discounted retail offerings. Also, starting at that time, USAC will no longer reimburse incumbent LECs for their Section 251(c)(4) services. Thereafter, USAC should only reimburse ETCs who directly provide Lifeline service to qualified low-income consumers, in accordance with all of the Lifeline program rules. This transition time will allow affected ETCs an opportunity to utilize other means of providing Lifeline service (*e.g.,* UNEs or non-Lifeline resale service). In order to participate in the Lifeline program, all ETCs and newly designated ETCs must be in compliance with all of our rules, including but not limited to, providing subscriber information into the NLAD, obtaining annual subscriber certifications, and de-enrolling subscribers in accordance with our rules.

C. Defining the ''Former Reservations in Oklahoma''

39. *Background.* In this section, the Commission departs from the staff's prior informal guidance and interpret the ''former reservations in Oklahoma'' within § 54.400(e) of the Commission's rules as the geographic boundaries reflected in the Historical Map of Oklahoma 1870–1890 (Oklahoma Historical Map). The Commission is convinced that this map, provided to us by BIA, is illustrative of the ''former reservations in Oklahoma.'' To ensure all impacted parties have sufficient time to transition to the new map, the Commission provides a transition period of 180 days from the effective date of this Order. During this time, the Commission will actively engage in consultation with the Tribal Nations of Oklahoma on the operational functionality and use of the Oklahoma Historical Map at the local and individual Tribal Nation level.

40. When the Commission first adopted Tribal Lifeline and Link Up support, it adopted a rule that stated consumers were eligible to receive enhanced support if they lived on ''Tribal lands.'' In further defining the term ''Tribal lands,'' the Commission stated in the 2000 *Tribal Order* that the term included ''any federally recognized Tribe's reservation, Pueblo, or Colony, including former reservations in Oklahoma,'' as well as ''near reservation'' areas. The Commission, however, has not formally defined the boundaries of the ''former reservations in Oklahoma'' for the purpose of the Lifeline rules, and there are inconsistencies between various maps at the state and Federal level that define the boundaries of the former reservations in Oklahoma. In practice, USAC has distributed Tribal support in Oklahoma based on a map displayed on the OCC's Web site, which was based upon informal guidance provided by FCC staff in 2004.

41. There is a vast and complicated legal history of Tribal property in the United States which involves ''the whole range of ownership forms known to our legal system.'' A large part of Oklahoma was once Indian Territory, and as the Tribal Nations of Oklahoma experienced many changes to their land tenures, Tribal lands in Oklahoma are an excellent example of that intricate legal history. The Commission's actions comport with the complex legal history within Oklahoma and uphold our government-to-government responsibilities to the Oklahoma Tribal Nations, while also improving administration of the Lifeline program and distribution of enhanced Tribal support.

42. *Discussion.* To provide efficiency, transparency, and clarity within the Lifeline program, and to ensure that universal service funds are distributed as intended, the Commission departs from the staff's prior informal guidance and interpret the ''former reservations in Oklahoma'' as the boundaries reflected in the Oklahoma Historical Map 180 days after the effective date of this Order. The Commission concludes that interpreting the ''former reservations in Oklahoma'' in § 54.400(e) of the Commission's rules based on the Oklahoma Historical Map will provide clarity to both Tribal consumers and ETCs, and will also be an accurate reflection of Tribal lands in Oklahoma.

43. The Tribal lands of Oklahoma and ''all land titles in Oklahoma stem from treaties with Indian tribes and acts of Congress vitalizing treaty provisions.'' The U.S. Department of Interior, through the delegated authorities of its Bureau of Indian Affairs, is the lead federal agency with respect to delivering federal services based on provisions of those treaties with Tribal Nations, as well as the administration of the federal government's trust relationship and responsibilities to Tribal Nations and Indians with respect to land titles and management. For these and other purposes, BIA maintains two Regional Offices in Oklahoma—the Southern Plains Regional Office in Anadarko, OK, and the Eastern Oklahoma Regional Office in Muscogee, OK, both of which have Land, Titles, and Records Departments. In inter-agency coordination, the Commission's Office of Native Affairs and Policy (ONAP) and the Bureau received the Oklahoma Historical Map from the Land, Titles, and Records Department of the Southern Plains Regional Office. Therefore, to better address the difficult administrative and eligibility issues in Oklahoma law, and for the purpose of determining eligibility for enhanced Tribal Lifeline and Link Up support in the state of Oklahoma, the Commission identifies and relies upon the Oklahoma Historical Map to determine the boundaries of ''former reservations in Oklahoma'' for purposes of § 54.400(e) of the Commission's rules.

44. The Commission recognizes that, given the Department of Interior's jurisdictional authority over many administrative trust responsibilities with respect to the Tribal lands in Oklahoma, adopting the Oklahoma Historical Map to identify the ''former reservations in Oklahoma'' is a more accurate representation of ''former reservations in Oklahoma'' than the map referenced on OCC's Web site. The Oklahoma Historical Map is a clear and historically accurate representation of ''former reservations in Oklahoma'' at a time prior to Oklahoma statehood in 1907. While the Commission concludes here that it was not unreasonable for USAC, the OCC, and ETCs to rely on the OCC Web site map for disbursing Tribal support consistent with prior informal staff guidance, going forward, the Commission believes the Oklahoma Historical Map provides more clarity to both Tribal consumers and Lifeline providers to ensure that funds are allocated for the intended purpose of assisting those living on Tribal lands, which typically have lower adoption rates for telecommunications services.

45. In addition, the Oklahoma Historical Map represents actual former reservation boundaries prescribed by Acts of Congress—both laws and treaties—as opposed to areas identified

for statistical purposes reflected in the Census Bureau's American Indians and Alaska Natives (AIAN) map of the Oklahoma Tribal Statistical Areas (OTSAs). Further, our inter-agency work with BIA reveals that the Oklahoma Historical Map is a more accurate representation of the individual former reservations of each Tribal Nation in Oklahoma. The Commission believes, therefore, that it is proper and accurate to adopt the Oklahoma Historical Map, and that the use of this map for purposes of the Lifeline program, which is a household based program that relies in large part on addresses for determining eligibility, will facilitate verification that consumers are in fact residing on Tribal lands. To further improve on these efforts, the Commission also seeks comment above on other ways for Lifeline providers to more accurately verify that consumers are residing on Tribal lands.

46. This clarification will result in a reduction in the geographical scope of ''former reservations in Oklahoma.'' In basic terms, use of the Oklahoma Historical Map will now result in:

- Exclusion from the ''former reservations in Oklahoma'' the region within central Oklahoma historically and commonly known as the ''Unassigned Lands''—referred to in the Oklahoma Historical Map as ''Oklahoma: Opened to settlement April 22, 1889''—which includes the majority of the area within the Oklahoma City municipal boundaries;
- Exclusion of the ''Cherokee Outlet;''
- Continued exclusion from the ''former reservations in Oklahoma'' the ''Panhandle,'' also historically known as the ''Cimarron Strip,'' or ''Neutral Strip,''—reflected in the Oklahoma Historical Map as the ''Public Lands Strip''—which presently encompasses Cimarron, Texas, and Beaver counties; and
- Continued exclusion of the southwest corner of the state lying within the western bank of the North Fork of the Red River—referred to in the map as ''Greer County: Disputed Territory''—which presently encompasses Greer, Harmon, and Jackson counties and includes the portion of Beckham county south of the North Fork of the Red River.

47. *Transition Period.* To ensure all impacted parties have sufficient time to transition to the Oklahoma Historical Map, the Commission provides a transition period of 180 days from the effective date of this Order. While the Commission believes that the Oklahoma Historical Map provides an accurate reflection of the ''former reservations in Oklahoma'' under the Commission's rules, it adopts this map and directs the Bureau, in coordination with the Office of Native Affairs and Policy to actively seek government-to-government consultation with Tribal Nations in Oklahoma on the efficacy and appropriateness of other maps and geospatial information assets developed both by federal agencies and individual Tribal Nations. The Commission recognizes that, as rightful governmental entities, Tribal Nations are an important source regarding the efficacy of the mapped boundaries of their lands. The Commission directs the Commission's Office of Native Affairs and Policy to coordinate with the Bureau, and other Commission Bureaus and Offices, as appropriate, to engage in government-to-government consultation with the Tribal Nations in Oklahoma for the specific purposes of ensuring the accuracy and operational effectiveness of the boundaries as presented in the Oklahoma Historical Map.

48. If, based on these consultations, the Bureau finds that the Oklahoma Historical Map should be departed from in any way to better reflect the complex legal history of the ''former reservations in Oklahoma'' for purposes of interpreting § 54.400(e) of the rules, the Commission directs the Bureau, in coordination with ONAP, to recommend to the Commission an order based on that consultation that would—if adopted by the Commission—provide a further revised interpretation of the appropriate boundaries of the former reservations in Oklahoma. The Commission anticipates that any such recommended order would also provide impacted parties an appropriate additional transition period prior to the new interpretation of the boundaries being applied.

49. The Commission also seeks the input of the OCC to ensure that the OCC and Tribal Nations in Oklahoma can work with ETCs to implement a seamless transition to the newly interpreted boundaries, which will impact those that receive enhanced Lifeline support under the boundaries that previously had been used in practice, but will no longer receive enhanced support under the Oklahoma Historical Map's boundaries. The Commission will work closely with Tribal Nations, the OCC, ETCs, and consumers to make this transition as seamless as possible. The Commission directs ETCs to work with the OCC to ensure Lifeline consumers have sufficient information regarding how the Oklahoma Historical Map's boundaries will affect them, so that consumers can adjust to any changes or alterations to the Lifeline service plans to which they currently subscribe.

D. Conserving Audit Resources

50. The Commission waives, on its own motion, the Commission's requirement in § 54.420(b) for two ETCs in order to maximize the use of audit program resources. The Commission has directed USAC to establish an audit program for all of the universal service programs, including Lifeline. As part of the audit program, in the 2012 *Lifeline Reform Order,* the Commission required USAC to conduct audits of new Lifeline carriers within the first year of their participation in the program, after the carrier completes its first annual recertification of its subscriber base. The Commission specifically declined to adopt a minimum dollar threshold for those audits and instead directed USAC to conduct a more limited audit of smaller newly established Lifeline providers.

51. USAC has indicated that two first-year Lifeline providers that must be audited pursuant to the Commission's rule in the near future have one subscriber within the scope of the audit. The carriers are Glandorf Telephone Company in Ohio and NEP Cellcorp Inc. in Pennsylvania. The Commission finds that these carriers have so few subscribers that an audit is not warranted and, in fact, would not provide a sufficient sample size for the auditor to infer compliance with Commission rules. The Commission also finds that delaying the audits until they are more useful will avoid wasting the resources of the Commission, of USAC and of these two providers. As such, the Commission waives the requirement that the audits for Glandorf Telephone Company and NET Cellcorp be conducted within a year of their receiving Lifeline support for their customers. The Commission finds that a waiver of our rules is in the public interest in these cases to more effectively and efficiently implement the Commission's overall audit strategy. The Commission directs OMD to work with USAC to obtain the data necessary for OMD to determine when these carriers should undergo an audit to evaluate their compliance with Commission rules, and USAC should conduct the audit at that time. In particular, OMD's determination should consider, based on the totality of the circumstances, when a quality audit of the relevant Lifeline provider would be useful considering, at a minimum, whether the Lifeline provider has a sufficient scope of Lifeline operations to provide a sufficient sample size for the

auditor to infer compliance with Commission rules.

52. The Commission also delegates to OMD the authority to waive the deadline for audits under § 54.420(b) of the Commission's rules as necessary in the future for similarly situated Lifeline providers, that is, those Lifeline providers for which OMD determine, based on a totality of the circumstances, that the first year audit specified in current § 54.420(b) of the rules would not be useful. The Commission emphasizes that it did not intend these Lifeline providers to avoid being audited, but OMD should grant appropriate waivers to delay the audits until such time as it would be possible to conduct a quality and cost-effective audit, as discussed above. The Commission seeks comment on revising our rules accordingly.

IV. Procedural Matters

A. Final Regulatory Flexibility Analysis

53. As required by the Regulatory Flexibility Act of 1980 (RFA), the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) relating to this Order on Reconsideration and Second Report and Order of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in the 2012 *Lifeline FNPRM* in WC Docket Nos. 12–23, 11–42, 03–109, and CC Docket No. 96–45. The Commission sought written public comment on the proposals in the 2012 *Lifeline FNPRM,* including comment on the IRFA.

B. Paperwork Reduction Act Analysis

54. This Order on Reconsideration and Second Report and Order contains new information collection requirements 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(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the revised information collection requirements contained in this proceeding. In addition, we note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, the Commission previously sought specific comment on how it might further reduce the information collection burden on small business concerns with fewer than 25 employees.

C. Need for, and Objectives of, the Final Rule

55. The Commission is required by section 254 of the Communications Act of 1934, as amended, to promulgate rules to implement the universal service provisions of section 254. The Lifeline program was implemented in 1985 in the wake of the 1984 divestiture of AT&T. On May 8, 1997, the Commission adopted rules to reform its system of universal service support mechanisms so that universal service is preserved and advanced as markets move toward competition. When the Commission overhauled the Lifeline program in its 2012 *Lifeline Reform Order,* it substantially strengthened protections against waste, fraud and abuse; improved program administration and accountability; improved enrollment and consumer disclosures; and took preliminary steps to modernize the Lifeline program for the 21st Century. In light of the realities of the 21st Century communications marketplace, the Commission must overhaul the Lifeline program to ensure it complies with the statutory directive to provide consumers in all regions of the nation, including low-income consumers, with access to telecommunications and information services. At the same time, the Commission must ensure that adequate controls are in place to implement any further changes to the Lifeline program to guard against waste, fraud and abuse. In this Order on Recon and 2nd R&O, the Commission thus seeks to rebuild the current framework of the Lifeline program and continue our effort to modernize the Lifeline program so that all consumers can utilize advanced networks. In doing so, the Commission adopts several rules that may potentially economically impact a substantial number of small entities. Specifically, the Commission: (1) Requires eligible telecommunications carriers (ETCs) to retain documentation demonstrating subscriber income-based or program-based eligibility and (2) limits reimbursement under the Lifeline program to ETCs for services provided directly to low-income consumers.

56. *Retention of Eligibility Documentation.* In the 2012 *Lifeline Reform Order,* the Commission adopted uniform eligibility criteria for the federal Lifeline program. Consumers must qualify based on either their income or their participation in at least one of a number of federal assistance programs. The Commission required ETCs to examine certain documentation to verify a consumer's program or income based eligibility, but prohibited ETCs from retaining copies of the documentation. In this Order on Recon, the Commission requires that all Lifeline ETCs retain documentation demonstrating subscriber income-based or program-based eligibility, including the dispute resolution processes which require verification of identity, address, or age of subscribers. The Commission finds that the concerns that led us to prohibit such retention in 2012, while still relevant, are largely overshadowed by the enormous benefits of allowing ETCs to retain eligibility documentation. ETCs themselves contend that the burden on ETCs is worth the benefits to the program and that there are information technology and access security measures that can be taken to minimize the risks associated with maintaining sensitive subscriber eligibility documentation. Further, the new rules allowing retention will significantly reduce falsified records and will provide certainty in the industry regarding the documents that need to be retained in the event of an audit or investigation. The Commission also finds that the burdens of retention can be mitigated with electronic storage capabilities. Overall, the universal service fund will be better protected if ETCs are required to both retain and present the eligibility documentation to the Commission or the Universal Service Administrative Company (USAC), the Administrator of the Lifeline program, and the new rules will prevent significant waste, fraud and abuse in the Lifeline program.

57. *Resale of Retail Lifeline Supported Services.* In the 2012 *Lifeline Reform Order,* the Commission expressed concerns that permitting ETCs and non-ETCs to offer Lifeline-discounted service through resale of retail Lifeline service posed risks to the Fund. In particular, the Commission was concerned with the possibility of over-recovery by both wholesalers and resellers seeking reimbursement from USAC for the same Lifeline subscriber and the lack of direct oversight of non-ETC resellers by state and federal regulators. In light of these concerns, the Commission sought comment in the 2012 *Lifeline FNPRM* on a variety of proposals to reform or eliminate the resale of retail wireline Lifeline service. In this Second Report and Order, in order to promote transparency and to protect the Fund from potential waste and abuse, the Commission now decides that only ETCs that provide Lifeline service directly to subscribers will be eligible for reimbursement from the Fund.

D. Summary of Significant Issues Raised by Public Comments to the IRFA

58. No comments specifically addressed the IRFA.

E. Description and Estimate of the Number of Small Entities to Which the Final Rules May Apply

59. 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, 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 that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). Nationwide, there are a total of approximately 28.2 million small businesses, according to the SBA. A ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.''

60. Nationwide, as of 2007, there were approximately 1.6 million small organizations. 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 2007 indicate that there were 87,476 local governmental jurisdictions in the United States. We estimate that, of this total, 84,506 entities were ''small governmental jurisdictions.'' Thus, we estimate that most governmental jurisdictions are small.

61. Wireline Providers

62. *Incumbent Local Exchange Carriers (Incumbent LECs).* Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent local exchange services. 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 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 or more. According to Commission data, 1,307 carriers reported that they were incumbent local exchange service providers. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Thus under this category and the associated small business size standard, the majority of these incumbent local exchange service providers can be considered small.

63. *Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate category for this service is the category Wired Telecommunications Carriers. Under the category of Wired Telecommunications Carriers, such a business is small if it has 1,500 or fewer employees. Census Bureau data for 2007 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 1,000 employees or more. Thus under this category and the associated small business size standard, the majority of these Competitive LECs, CAPs, Shared-Tenant Service Providers, and Other Local Service Providers can be considered small entities. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees and 186 have more than 1,500 employees. In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees. In addition, 72 carriers have reported that they are Other Local Service Providers, seventy of which have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities that may be affected by rules adopted pursuant to the Notice.

64. *Interexchange Carriers.* Neither the Commission nor the SBA has developed a small business size standard specifically for providers of interexchange services. The appropriate category for Interexchange Carriers is 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 had employment of 1,000 employees or more. Thus under this category and the associated small business size standard, the majority of these Interexchange carriers can be considered small entities. According to Commission data, 359 companies reported that their primary telecommunications service activity was the provision of interexchange services. Of these 359 companies, an estimated 317 have 1,500 or fewer employees and 42 have more than 1,500 employees. Consequently, the Commission estimates that the majority of interexchange service providers are small entities that may be affected by rules adopted pursuant to the Notice.

65. *Operator Service Providers (OSPs).* Neither the Commission nor the SBA has developed a small business size standard specifically for operator service providers. The appropriate category for Operator Service Providers is the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census Bureau data for 2007 show that there were 3,188 firms in this category that operated for the entire year. Of the total, 3,144 had employment of 999 or fewer, and 44 firms had had employment of 1,000 employees or more. Thus under this category and the associated small business size standard, the majority of these interexchange carriers can be considered small entities. According to Commission data, 33 carriers have reported that they are engaged in the provision of operator services. Of these, an estimated 31 have 1,500 or fewer employees and 2 have more than 1,500 employees. Consequently, the Commission estimates that the majority of OSPs are small entities that may be affected by the Commission's proposed action.

66. *Local Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2007 show that 1,523 firms provided resale services during that year. Of that number, 1,522 operated with fewer than 1,000

employees and one operated with more than 1,000. Thus under this category and the associated small business size standard, the majority of these local resellers can be considered small entities. According to Commission data, 213 carriers have reported that they are engaged in the provision of local resale services. Of these, an estimated 211 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of local resellers are small entities that may be affected by rules adopted pursuant to the Notice.

67. *Toll Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2007 show that 1,523 firms provided resale services during that year. Of that number, 1,522 operated with fewer than 1,000 employees and one operated with more than 1,000. Thus under this category and the associated small business size standard, the majority of these resellers can be considered small entities. According to Commission data, 881 carriers have reported that they are engaged in the provision of toll resale services. Of these, an estimated 857 have 1,500 or fewer employees and 24 have more than 1,500 employees. Consequently, the Commission estimates that the majority of toll resellers are small entities that may be affected by the Commission's action.

68. *Pre-paid Calling Card Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for pre-paid calling card providers. The appropriate size standard under SBA rules is for the category Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2007 show that 1,523 firms provided resale services during that year. Of that number, 1,522 operated with fewer than 1,000 employees and one operated with more than 1,000. Thus under this category and the associated small business size standard, the majority of these pre-paid calling card providers can be considered small entities. According to Commission data, 193 carriers have reported that they are engaged in the provision of pre-paid calling cards. Of these, an estimated all 193 have 1,500 or fewer employees and none have more than 1,500 employees. Consequently, the Commission estimates that the majority of pre-paid calling card providers are small entities that may be affected by rules adopted pursuant to the Notice.

69. *800 and 800-Like Service Subscribers.* Neither the Commission nor the SBA has developed a small business size standard specifically for 800 and 800-like service (''toll free'') subscribers. The appropriate category for these services is the category Telecommunications Resellers. Under that category and corresponding size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2007 show that 1,523 firms provided resale services during that year. Of that number, 1,522 operated with fewer than 1,000 employees and one operated with more than 1,000. Thus under this category and the associated small business size standard, the majority of resellers in this classification can be considered small entities. To focus specifically on the number of subscribers than on those firms which make subscription service available, the most reliable source of information regarding the number of these service subscribers appears to be data the Commission collects on the 800, 888, 877, and 866 numbers in use. According to the Commission's data, as of September 2009, the number of 800 numbers assigned was 7,860,000; the number of 888 numbers assigned was 5,888,687; the number of 877 numbers assigned was 4,721,866; and the number of 866 numbers assigned was 7,867,736. The Commission does not have data specifying the number of these subscribers that are not independently owned and operated or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of toll free subscribers that would qualify as small businesses under the SBA size standard. Consequently, the Commission estimates that there are 7,860,000 or fewer small entity 800 subscribers; 5,888,687 or fewer small entity 888 subscribers; 4,721,866 or fewer small entity 877 subscribers; and 7,867,736 or fewer small entity 866 subscribers. We do not believe 800 and 800-Like Service Subscribers will be affected by the Commission's proposed rules, however we choose to include this category and seek comment on whether there will be an effect on small entities within this category.

70. Wireless Carriers and Service Providers

71. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular phone services, paging services, wireless Internet access, and wireless video services. The appropriate size standard under SBA rules is for the category Wireless Telecommunications Carriers. The size standard for that category is that a business is small if it has 1,500 or fewer employees. For this category, census data for 2007 show that there were 11,163 establishments that operated for the entire year. Of this total, 10,791 establishments had employment of 999 or fewer employees and 372 had employment of 1000 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 the Commission's proposed action.

72. *Wireless Communications Services.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined ''small business'' for the wireless communications services auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a ''very small business'' as an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these definitions. The Commission auctioned geographic area licenses in the WCS service. In the auction, which commenced on April 15, 1997 and closed on April 25, 1997, seven bidders won 31 licenses that qualified as very small business entities, and one bidder won one license that qualified as a small business entity.

73. *Satellite Telecommunications Providers.* Two economic census categories address the satellite industry. The first category has a small business size standard of $32.5 million or less in average annual receipts, under SBA rules. The second has a size standard of $32.5 million or less in annual receipts.

74. 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 that 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 the Commission's action.

75. 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.'' The SBA has developed a small business size standard for All Other Telecommunications, which consists of all such firms with gross annual receipts of $32.5 million or less. 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 the Commission's action.

76. *Common Carrier Paging.* As noted, since 2007 the Census Bureau has placed paging providers within the broad economic census category of Wireless Telecommunications Carriers (except Satellite).

77. In addition, in the *Paging Second Report and Order,* 64 FR 12169, March 11, 1999, the Commission adopted a size standard for ''small businesses'' for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. A small business is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $15 million for the preceding three years. The SBA has approved this definition. An initial auction of Metropolitan Economic Area (''MEA'') licenses was conducted in the year 2000. Of the 2,499 licenses auctioned, 985 were sold. Fifty-seven companies claiming small business status won 440 licenses. A subsequent auction of MEA and Economic Area (''EA'') licenses was held in the year 2001. Of the 15,514 licenses auctioned, 5,323 were sold. One hundred thirty-two companies claiming small business status purchased 3,724 licenses. A third auction, consisting of 8,874 licenses in each of 175 EAs and 1,328 licenses in all but three of the 51 MEAs, was held in 2003. Seventy-seven bidders claiming small or very small business status won 2,093 licenses.

78. Currently, there are approximately 74,000 Common Carrier Paging licenses. According to the most recent Trends in Telephone Service, 291 carriers reported that they were engaged in the provision of ''paging and messaging'' services. Of these, an estimated 289 have 1,500 or fewer employees and two have more than 1,500 employees. We estimate that the majority of common carrier paging providers would qualify as small entities under the SBA definition.

79. *Wireless Telephony.* Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. As noted, the SBA has developed a small business size standard for Wireless Telecommunications Carriers (except Satellite). Under the SBA small business size standard, a business is small if it has 1,500 or fewer employees. According to the 2010 Trends Report, 413 carriers reported that they were engaged in wireless telephony. Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. We have estimated that 261 of these are small under the SBA small business size standard.

80. Internet Service Providers

81. The 2007 Economic Census places these firms, whose services might include voice over Internet protocol (VoIP), in either of two categories, depending on whether the service is provided over the provider's own telecommunications facilities (*e.g.,* cable and DSL ISPs), or over client-supplied telecommunications connections (*e.g.,* dial-up ISPs). The former are within the category of Wired Telecommunications Carriers, which has an SBA small business size standard of 1,500 or fewer employees. The latter are within the category of All Other Telecommunications, which has a size standard of annual receipts of $32.5 million or less.

F. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

82. Several of the Commission's rule changes will result in additional recordkeeping requirements for small entities. For those several rule changes, the Commission has determined that the benefit the rule change will bring for the program outweighs the burden of the increased recordkeeping requirement. The rule changes are listed below.

- *Retention of Eligibility Documentation.* Requiring all Lifeline ETCs to retain documentation demonstrating subscriber income-based or program-based eligibility, including the dispute resolution processes which require verification of identity, address, or age of subscribers increases recordkeeping requirements and potential costs for ETCs. The Commission finds that any concerns related to the risk of retaining sensitive subscriber eligibility documentation and the burden on ETCs is outweighed by the enormous benefits of allowing ETCs to retain eligibility documentation, such as: Significantly reducing falsified records; providing certainty in the industry regarding the documents that need to be retained in the event of an audit or investigation; and further reducing waste, fraud and abuse in the Lifeline program.
- *Resale of Retail Lifeline Supported Services.* Limiting reimbursement for Lifeline service to ETCs directly serving customers may increase compliance requirements for ETCs by potentially requiring ETCs to revise their interconnections agreements and other regulatory filings in order to comply with our rules. For non-ETCs, it may increase compliance requirements by requiring them to become ETCs to receive Lifeline support necessitating the completion of additional paperwork for those non-ETCs seeking ETC designations. By ensuring that only ETCs that provide Lifeline service directly to subscribers are eligible for reimbursement from the Fund, the Commission can also better promote transparency. Ultimately, the Commission can more efficiently and effectively protect the USF and prevent significant waste, fraud and abuse in the Lifeline program.

G. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

83. The RFA requires an agency to describe any significant, specifically small business, 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 and reporting requirements under the rule for such 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 such small entities.''

84. This rulemaking could impose minimal additional burdens on small entities. The Commission has considered alternatives to the rulemaking changes that increase recordkeeping and documentation requirements for small entities. The Commission finds that any minimal burdens on small entities are outweighed by the enormous benefits of the rule changes. Further, the Commission has encouraged ETCs to take advantage of electronic storage of documents to mitigate the additional expense of now having to retain documentation demonstrating subscriber income-based or program-based eligibility, including the dispute resolution processes.

H. Congressional Review Act

85. The Commission will include a copy of the Order on Reconsideration and Second Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act. In addition, this document will be sent to Congress and the Chief Counsel for Advocacy of the SBA pursuant to the SBREFA.

V. Ordering Clauses

86. ACCORDINGLY, IT IS ORDERED, that pursuant to the authority contained in Sections 1 through 4, 201 through 205, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154, 201–205, 254, 303(r), and 403, and Section 706 of the Telecommunications Act of 1996, 47 U.S.C. 1302, this Second Report and Order is effective August 13, 2015, except to the extent expressly addressed below.

87. *It is further ordered,* that pursuant to the authority contained in Sections 1 through 4, 201 through 205, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154, 201–205, 254, 303(r), and 403, and Section 706 of the Telecommunications Act of 1996, 47 U.S.C. 1302, part 54 of the Commission's rules, 47 CFR part 54, *is amended,* as set forth below, subject to OMB approval of the subject information collection requirements, which will become effective upon announcement by the Commission in the **Federal Register** of OMB approval.

88. *It is further ordered* that, pursuant to the authority contained in sections 1 through 5 and 254 of the Communications Act of 1934, as amended, 47 U.S.C. 151–155 and 254, and § 1.429 of the Commission's rules, 47 CFR 1.429, the Petition for Reconsideration and Clarification filed by TracFone Wireless, Inc. on April 2, 2012 and Supplement to its Petition for Reconsideration and Clarification filed on May 30, 2012 *are granted in part* to the extent provided herein, and otherwise remain pending.

89. *It is further ordered* that the Commission *shall send* a copy of the Order on Reconsideration and Second Report and Order to Congress and to the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

90. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of the Order on Reconsideration and Second Report 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 54

Communications common carriers, Reporting and recordkeeping requirements, Telecommunications, Telephone.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 54 as follows:

PART 54—UNIVERSAL SERVICE

■ 1. The authority citation for part 54 is revised to read as follows:

Authority: Sections 1, 4(i), 5, 201, 205, 214, 219, 220, 254, 303(r), and 403 of the Communications Act of 1934, as amended, and section 706 of the Communications Act of 1996, as amended; 47 U.S.C. 151, 154(i), 155, 201, 205, 214, 219, 220, 254, 303(r), 403, and 1302 unless otherwise noted.

■ 2. Amend § 54.201 by revising paragraph (a)(1) to read as follows:

§ 54.201 Definition of eligible telecommunications carriers generally.

(a) * * *

(1) Only eligible telecommunications carriers designated under this subpart shall receive universal service support distributed pursuant to subparts D and E of this part. Eligible telecommunications carriers designated under this subpart for purposes of receiving support only under subpart E of this part must provide Lifeline service directly to qualifying low-income consumers.

* * * * *

■ 3. Amend § 54.400 by adding paragraph (k) to read as follows:

§ 54.400 Terms and definitions.

* * * * *

(k) *Direct service.* As used in this subpart, direct service means the provision of service directly to the qualifying low-income consumer.

■ 4. Amend § 54.401 by revising paragraph (a) introductory text to read as follows:

§ 54.401 Lifeline defined.

(a) As used in this subpart, Lifeline means a non-transferable retail service offering provided directly to qualifying low-income consumers:

* * * * *

■ 5. Amend § 54.404 by adding paragraph (b)(11) to read as follows:

§ 54.404 The National Lifeline Accountability Database.

* * * * *

(b) * * *

(11) All eligible telecommunications carriers must securely retain subscriber documentation that the ETC reviewed to verify subscriber eligibility, for the purposes of production during audits or investigations or to the extent required by NLAD processes, which require, *inter alia,* verification of eligibility, identity, address, and age.

* * * * *

■ 6. Amend § 54.407 by revising paragraphs (a) and (b) to read as follows:

§ 54.407 Reimbursement for offering Lifeline.

(a) Universal service support for providing Lifeline shall be provided to an eligible telecommunications carrier, based on the number of actual qualifying low-income consumers it serves directly as of the first day of the month.

(b) For each qualifying low-income consumer receiving Lifeline service, the reimbursement amount shall equal the federal support amount, including the support amounts described in § 54.403(a) and (c). The eligible telecommunications carrier's universal service support reimbursement shall not exceed the carrier's rate for that offering, or similar offerings, subscribed to by consumers who do not qualify for Lifeline.

* * * * *

■ 7. Amend § 54.410 by revising paragraph (b)(1)(ii), by removing paragraph (b)(1)(iii), by adding

paragraph (b)(2)(iii), by revising paragraph (c)(1)(ii), by removing paragraph (c)(1)(iii), and by adding paragraph (c)(2)(iii).

The revisions and additions read as follows:

§ 54.410 Subscriber eligibility determination and certification.

* * * * *

(b) * * *

(1) * * *

(ii) Must securely retain copies of documentation demonstrating a prospective subscriber's income-based eligibility for Lifeline consistent with § 54.417.

(2) * * *

(iii) An eligible telecommunications carrier must securely retain all information and documentation provided by the state Lifeline administrator or other state agency consistent with § 54.417.

* * * * *

(c) * * *

(1) * * *

(ii) Must securely retain copies of the documentation demonstrating a subscriber's program-based eligibility for Lifeline services, consistent with § 54.417.

(2) * * *

(iii) An eligible telecommunications carrier must securely retain all information and documentation provided by the state Lifeline administrator or other state agency consistent with § 54.417.

* * * * *

■ 8. Revise § 54.417 to read as follows:

§ 54.417 Recordkeeping requirements.

(a) Eligible telecommunications carriers must maintain records to document compliance with all Commission and state requirements governing the Lifeline and Tribal Link Up program for the three full preceding calendar years and provide that documentation to the Commission or Administrator upon request. Eligible telecommunications carriers must maintain the documentation required in §§ 54.404 (b)(11), 54.410(b), 54.410 (c), 54.410(d), and 54.410(f) for as long as the subscriber receives Lifeline service from that eligible telecommunications carrier, but for no less than the three full preceding calendar years.

(b) Prior to the effective date of the rules, if an eligible telecommunications carrier provides Lifeline discounted wholesale services to a reseller, it must obtain a certification from that reseller that it is complying with all Commission requirements governing the Lifeline and Tribal Link Up program. Beginning on the effective date of the rules, the eligible telecommunications carrier must retain the reseller certification for the three full preceding calendar years and provide that documentation to the Commission or Administrator upon request.

(c) Non-eligible telecommunications carrier resellers that purchased Lifeline discounted wholesale services to offer discounted services to low-income consumers prior to the effective date of the rules, must maintain records to document compliance with all Commission requirements governing the Lifeline and Tribal Link Up program for the three full preceding calendar years and provide that documentation to the Commission or Administrator upon request.

[FR Doc. 2015–17186 Filed 7–13–15; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 140819687–5583–02]

RIN 0648–BE40

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources in the Gulf of Mexico and Atlantic Region; Framework Amendment

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

ACTION: Final rule.

SUMMARY: In this final rule, NMFS implements management measures described in Framework Amendment 2 to the Fishery Management Plan (FMP) for the Coastal Migratory Pelagic (CMP) Resources in the Gulf of Mexico and Atlantic Region (Framework Amendment 2), as prepared and submitted by the South Atlantic and Gulf of Mexico Fishery Management Councils (Councils). This final rule removes the unlimited commercial trip limit for Spanish mackerel in Federal waters off the east coast of Florida that began on weekdays beginning December 1 of each year. The modifications to the commercial trip limit system better fit the current fishery conditions and catch limits for Atlantic migratory group Spanish mackerel in the southern zone, while increasing social and economic benefits of the CMP fishery.

DATES: This final rule is effective August 13, 2015.

ADDRESSES: Framework Amendment 2 to the FMP, which includes an environmental assessment and a regulatory impact review, is available from *www.regulations.gov* or the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Karla Gore, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *karla.gore@noaa.gov.*

SUPPLEMENTARY INFORMATION: The CMP fishery of the South Atlantic and Gulf of Mexico (Gulf) includes Spanish mackerel and is managed under the CMP FMP. The FMP was prepared by the Councils and implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On April 9, 2015, NMFS published a proposed rule for the framework action and requested public comment (80 FR 19056). The proposed rule and the framework action set forth additional rationale for the actions contained in this final rule. A summary of the actions implemented by this final rule is provided below.

Management Measure Contained in This Final Rule

This final rule modifies the commercial trip limit system for Atlantic migratory group Spanish mackerel. Changes in fishery conditions, such as an increase of the commercial annual catch limit (ACL), have necessitated modifications to some elements of the trip limit system.

This final rule streamlines the commercial trip limit system for the Atlantic migratory group Spanish mackerel by eliminating the unlimited weekday Spanish mackerel trip limit in Federal waters off the eastern coast of Florida. The final rule retains the adjusted quota, which provides a buffer to help prevent the commercial sector from exceeding the commercial ACL.

This final rule establishes a commercial trip limit of 3,500 lb (1,588 kg) for Spanish mackerel in Federal waters offshore of South Carolina, Georgia, and eastern Florida, which is the area established as the southern zone by the final rule implementing Amendment 20B to the FMP (80 FR 4216, January 27, 2015). When 75 percent of the adjusted southern zone quota (2,417,330 lb (1,096,482 kg)) is met or is projected to be met, the commercial trip limit will be reduced to 1,500 lb (680 kg). When 100 percent of the adjusted southern zone commercial quota is met or projected to be met, the commercial trip limit will be reduced to

500 lb (227 kg) until the end of the fishing year or until the southern zone commercial quota is met or is projected to be met, at which time the commercial sector in the southern zone would be closed to harvest of Spanish mackerel. The modified system of trip limits described above would control harvest more effectively.

Comments and Responses

NMFS received two comments on the proposed rule, one from a fishing organization that expressed support of the proposed action, and one from a Federal agency that stated it had no comment. NMFS did not receive any substantive comments on the proposed rule.

Classification

The Regional Administrator, Southeast Region, NMFS determined that this final rule is necessary for the conservation and management of Atlantic migratory group Spanish mackerel and is consistent with Framework Amendment 2, the FMP, the Magnuson-Stevens Act, and other applicable laws.

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

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. NMFS received no comments regarding the certification and has not received any new information that would affect its determination. As a result, a final regulatory flexibility analysis was not required and none was prepared.

List of Subjects in 50 CFR Part 622

Annual catch limit, Fisheries, Fishing, Gulf of Mexico, Quotas, South Atlantic, Spanish mackerel.

Dated: July 8, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.385, paragraphs (b)(1) and (2) are revised to read as follows:

§ 622.385 Commercial trip limits.

* * * * *

(b) * * *

(1) *Atlantic migratory group.* The following trip limits apply to vessels for which commercial permits for Spanish mackerel have been issued, as required under § 622.370(a)(3).

(i) Northern zone. Spanish mackerel in or from the EEZ may not be possessed on board or landed in a day from a vessel for which a permit for Spanish mackerel has been issued, as required under § 622.370(a)(3), in amounts exceeding 3,500 lb (1,588 kg).

(ii) Southern zone. Spanish mackerel in or from the EEZ may not be possessed on board or landed in a day from a vessel for which a permit for Spanish mackerel has been issued, as required under § 622.370(a)(3)—

(A) From March 1 until 75 percent of the adjusted quota for the southern zone has been reached or is projected to be reached, in amounts exceeding 3,500 lb (1,588 kg).

(B) After 75 percent of the adjusted quota for the southern zone has been reached or is projected to be reached, in amounts exceeding 1,500 lb (680 kg).

(C) After 100 percent of the adjusted quota for the southern zone has been reached or is projected to be reached, and until the end of the fishing year or the southern zone's quota has been reached or is projected to be reached, in amounts exceeding 500 lb (227 kg). See § 622.384(e) for limitations regarding Atlantic migratory group Spanish mackerel after the southern zone's quota is reached.

(2) For the purpose of paragraph (b)(1)(ii) of this section, the adjusted quota for the southern zone is 2,417,330 lb (1,096,482 kg). The adjusted quota for the southern zone is the quota for the Atlantic migratory group Spanish mackerel southern zone reduced by an amount calculated to allow continued harvest of Atlantic migratory group Spanish mackerel at the rate of 500 lb (227 kg) per vessel per day for the remainder of the fishing year after the adjusted quota is reached. Total commercial harvest in the southern zone is still subject to the southern zone quota and accountability measures. By filing a notification with the Office of the Federal Register, the Assistant Administrator will announce when 75 percent and 100 percent of the adjusted quota are reached or are projected to be reached.

* * * * *

[FR Doc. 2015–17192 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 80, No. 134
Tuesday, July 14, 2015

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

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket Number EERE–2014–BT–STD–0048]

RIN 1904–AD37

Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Intent To Establish the Central Air Conditioners and Heat Pumps Working Group To Negotiate a Notice of Proposed Rulemaking (NOPR) for Energy Conservation Standards

AGENCY: Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

ACTION: Notice of intent and announcement of public meeting.

SUMMARY: The U.S. Department of Energy (DOE or the Department) is giving notice of a public meeting and that DOE intends to establish a negotiated rulemaking working group under the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC) in accordance with the Federal Advisory Committee Act (FACA) and the Negotiated Rulemaking Act (NRA) to negotiate proposed amended energy conservation standards for central air conditioners and heat pumps standards and to discuss certain aspects of the proposed Federal test procedure. The purpose of the working group will be to discuss and, if possible, reach consensus on a proposed rule for amended energy conservation standards for central air conditioners and heat pumps and provide recommendations to DOE regarding certain aspects of the proposed test procedure, as authorized by the Energy Policy and Conservation Act (EPCA) of 1975, as amended. The working group will consist of representatives of parties having a defined stake in the outcome of the proposed standards and amended test procedure, and will consult as appropriate with a range of experts on technical issues. The working group is expected to make a concerted effort to negotiate a final term sheet by December 31, 2015 and no extensions will be considered.

DATES: DOE will host a public meeting and webinar on Wednesday, August 26, 2015 from 9:00 a.m. to 4:00 p.m. in Washington, DC.

Written comments and applications (*i.e.,* cover letter and resume) to be appointed as members of the working group are welcome and should be submitted by July 28, 2015.

ADDRESSES: U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, Room 8E–089. Individuals will also have the opportunity to participate by webinar. To register for the webinar and receive call-in information, please register at *https://attendee.gotowebinar.com/register/7200494210145268481.*

Interested person may submit comments and an application for membership (including a cover letter and resume), identified by docket number EERE–2014–BT–STD–0048 any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
2. *Email: ASRAC@ee.doe.gov.* Include docket number EERE–2014–BT–STD–0048 in the subject line of the message.
3. *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.
4. *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586–2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted.

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

FOR FURTHER INFORMATION CONTACT: John Cymbalsky, U.S. Department of Energy, Office of Building Technologies (EE–2J), 950 L'Enfant Plaza SW., Washington, DC 20024. Phone: 202–287–1692. Email: *asrac@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Authority
II. Background
III. Proposed Negotiating Procedures
IV. Comments Requested
V. Public Participation
VI. Approval of the Office of the Secretary

I. Authority

DOE is announcing its intent to negotiate proposed energy conservation standards and certain aspects of the test procedure for central air conditioners and heat pumps, under the authority of sections 563 and 564 of the NRA (5 U.S.C. 561–570, Pub. L. 104–320). The regulation of central air conditioners and heat pumps standards and test procedure amendments that DOE is proposing to develop under a negotiated rulemaking will be developed under the authority of EPCA, as amended, 42 U.S.C. 6311(1) and 42 U.S.C. 6291 *et seq.*

II. Background

As required by the NRA, DOE is giving notice that it is establishing a working group under ASRAC to discuss certain test procedure amendments and potentially develop proposed energy conservation standards for central air conditioners and heat pumps.

A. Negotiated Rulemaking

DOE has decided to use the negotiated rulemaking process to discuss certain test procedure amendments and develop proposed energy conservation standards for central air conditioners and heat pumps. The primary reason for using the negotiated rulemaking process for this product is that stakeholders strongly support a consensual rulemaking effort. DOE believes such a regulatory negotiation process will be less adversarial and better suited to resolving complex technical issues. An important virtue of negotiated rulemaking is that it allows expert dialog that is much better than traditional techniques at getting the facts and issues right and will result in

a proposed rule that will effectively reflect Congressional intent.

A regulatory negotiation will enable DOE to engage in direct and sustained dialog with informed, interested, and affected parties when drafting the regulation, rather than obtaining input during a public comment period after developing and publishing a proposed rule. Gaining this early understanding of all parties' perspectives allows DOE to address key issues at an earlier stage of the process, thereby allowing more time for an iterative process to resolve issues. A rule drafted by negotiation with informed and affected parties is expected to be potentially more pragmatic and more easily implemented than a rule arising from the traditional process. Such rulemaking improvement is likely to provide the public with the full benefits of the rule while minimizing the potential negative impact of a proposed regulation conceived or drafted without the full prior input of outside knowledgeable parties. Because a negotiating working group includes representatives from the major stakeholder groups affected by or interested in the rule, the number of public comments on the proposed rule may be decreased. DOE anticipates that there will be a need for fewer substantive changes to a proposed rule developed under a regulatory negotiation process prior to the publication of a final rule.

B. The Concept of Negotiated Rulemaking

Usually, DOE develops a proposed rulemaking using Department staff and consultant resources. Congress noted in the NRA, however, that regulatory development may ''discourage the affected parties from meeting and communicating with each other, and may cause parties with different interests to assume conflicting and antagonistic positions * * *.'' 5 U.S.C. 561(2)(2). Congress also stated that ''adversarial rulemaking deprives the affected parties and the public of the benefits of face-to-face negotiations and cooperation in developing and reaching agreement on a rule. It also deprives them of the benefits of shared information, knowledge, expertise, and technical abilities possessed by the affected parties.'' 5 U.S.C. 561(2)(3).

Using negotiated rulemaking to develop a proposed rule differs fundamentally from the Department centered process. In negotiated rulemaking, a proposed rule is developed by an advisory committee or working group, chartered under FACA, 5 U.S.C. App. 2, composed of members chosen to represent the various interests that will be significantly affected by the rule. The goal of the advisory committee or working group is to reach consensus on the treatment of the major issues involved with the rule. The process starts with the Department's careful identification of all interests potentially affected by the rulemaking under consideration. To help with this identification, the Department publishes a notice of intent such as this one in the **Federal Register**, identifying a preliminary list of interested parties and requesting public comment on that list. Following receipt of comments, the Department establishes an advisory committee or working group representing the full range of stakeholders to negotiate a consensus on the terms of a proposed rule. Representation on the advisory committee or working group may be direct; that is, each member may represent a specific interest, or may be indirect, such as through trade associations and/or similarly-situated parties with common interests. The Department is a member of the advisory committee or working group and represents the Federal government's interests. The advisory committee or working group chair is assisted by a neutral mediator who facilitates the negotiation process. The role of the mediator, also called a facilitator, is to apply proven consensus-building techniques to the advisory committee or working group process.

After an advisory committee or working group reaches consensus on the provisions of a proposed rule, the Department, consistent with its legal obligations, uses such consensus as the basis of its proposed rule, which then is published in the **Federal Register**. This publication provides the required public notice and provides for a public comment period. Other participants and other interested parties retain their rights to comment, participate in an informal hearing (if requested), and request judicial review. DOE anticipates, however, that the pre-proposal consensus agreed upon by the advisory committee or working group will narrow any issues in the subsequent rulemaking.

C. Proposed Rulemaking for Energy Conservation Standards Regarding Central Air Conditioners and Heat Pumps

The NRA enables DOE to establish an advisory committee or working group if it is determined that the use of the negotiated rulemaking process is in the public interest. DOE intends to develop Federal regulations that build on the depth of experience accrued in both the public and private sectors in implementing standards and programs.

DOE has determined that the regulatory negotiation process will provide for obtaining a diverse array of in-depth input, as well as an opportunity for increased collaborative discussion from both private-sector stakeholders and government officials who are familiar with the test procedures and energy efficiency of central air conditioners and heat pumps.

D. Department Commitment

In initiating this regulatory negotiation process to develop amendments to the test procedure and energy conservation standards for central air conditioners and heat pumps, DOE is making a commitment to provide adequate resources to facilitate timely and successful completion of the process. This commitment includes making the process a priority activity for all representatives, components, officials, and personnel of the Department who need to be involved in the rulemaking, from the time of initiation until such time as a final rule is issued or the process is expressly terminated. DOE will provide administrative support for the process and will take steps to ensure that the advisory committee or working group has the dedicated resources it requires to complete its work in a timely fashion. Specifically, DOE will make available the following support services: Properly equipped space adequate for public meetings and caucuses; logistical support; word processing and distribution of background information; the service of a facilitator; and such additional research and other technical assistance as may be necessary.

To the maximum extent possible consistent with the legal obligations of the Department, DOE will use the consensus of the advisory committee or working group as the basis for the rule the Department proposes for public notice and comment.

E. Negotiating Consensus

As discussed above, the negotiated rulemaking process differs fundamentally from the usual process for developing a proposed rule. Negotiation enables interested and affected parties to discuss various approaches to issues rather than asking them only to respond to a proposal developed by the Department. The negotiation process involves a mutual education of the various parties on the practical concerns about the impact of standards. Each advisory committee or working group member participates in resolving the interests and concerns of

other members, rather than leaving it up to DOE to evaluate and incorporate different points of view.

A key principle of negotiated rulemaking is that agreement is by consensus of all the interests. Thus, no one interest or group of interests is able to control the process. The NRA defines consensus as the unanimous concurrence among interests represented on a negotiated rulemaking committee or working group, unless the committee or working group itself unanimously agrees to use a different definition. 5 U.S.C. 562. In addition, experience has demonstrated that using a trained mediator to facilitate this process will assist all parties, including DOE, in identifying their real interests in the rule, and thus will enable parties to focus on and resolve the important issues.

III. Proposed Negotiating Procedures

A. Key Issues for Negotiation

The following issues and concerns will underlie the work of the Negotiated Rulemaking Committee for Central Air Conditioners and Heat Pumps:

- Certain aspects of the proposed test procedure, including key test procedure conditions, as applicable; and
- Proposed energy conservation standards for central air conditioners and heat pumps, which may be nationally or regionally based.

To examine the underlying issues outlined above, and others not yet articulated, all parties in the negotiation will need DOE to provide data and an analytic framework complete and accurate enough to support their deliberations. DOE's analyses must be adequate to inform a prospective negotiation—for example, a notice of data availability containing a preliminary Technical Support Document or equivalent must be available and timely.

B. Formation of Working Group

A working group will be formed and operated in full compliance with the requirements of FACA and in a manner consistent with the requirements of the NRA. DOE has determined that the working group not exceeds 25 members. The Department believes that more than 25 members would make it difficult to conduct effective negotiations. DOE is aware that there are many more potential participants than there are membership slots on the working group. The Department does not believe, nor does the NRA contemplate, that each potentially affected group must participate directly in the negotiations; nevertheless, each affected interest can be adequately represented. To have a successful negotiation, it is important for interested parties to identify and form coalitions that adequately represent significantly affected interests. To provide adequate representation, those coalitions must agree to support, both financially and technically, a member of the working group whom they choose to represent their interests.

DOE recognizes that when it considers adding covered products and establishing energy efficiency standards for residential products and commercial equipment, various segments of society may be affected in different ways, in some cases producing unique ''interests'' in a proposed rule based on income, gender, or other factors. The Department will pay attention to providing that any unique interests that have been identified, and that may be significantly affected by the proposed rule, are represented.

FACA also requires that members of the public have the opportunity to attend meetings of the full committee and speak or otherwise address the committee during the public comment period. In addition, any member of the public is permitted to file a written statement with the advisory committee. DOE plans to follow these same procedures in conducting meetings of the working group.

C. Interests Involved/Working Group Membership

DOE anticipates that the working group will comprise no more than 25 members who represent affected and interested stakeholder groups, at least one of whom must be a member of the ASRAC. As required by FACA, the Department will conduct the negotiated rulemaking with particular attention to ensuring full and balanced representation of those interests that may be significantly affected by the proposed rule governing rules of residential central air conditioners energy conservation standards. Section 562 of the NRA defines the term interest as ''with respect to an issue or matter, multiple parties which have a similar point of view or which are likely to be affected in a similar manner.'' Listed below are parties the Department to date has identified as being ''significantly affected'' by a proposed rule regarding the energy efficiency of residential central air conditioners.

- The Department of Energy
- Trade Associations representing manufacturers of central air conditioners and heat pumps
- Manufacturers of central air conditioners and heat pumps and component manufacturers and related suppliers
- Distributors or contractors selling or installing central air conditioners and heat pumps
- Utilities
- Energy efficiency/environmental advocacy groups
- Consumers

One purpose of this notice of intent is to determine whether Federal regulations regarding central air conditioners and heat pumps will significantly affect interests that are not listed above. DOE invites comment and suggestions on its initial list of significantly affected interests.

Members may be individuals or organizations. If the effort is to be fruitful, participants on the working group should be able to fully and adequately represent the viewpoints of their respective interests. This document gives notice of DOE's process to other potential participants and affords them the opportunity to request representation in the negotiations. Those who wish to be appointed as members of the working group, should submit a request to DOE, in accordance with the public participation procedures outlined in the **DATES** and **ADDRESSES** sections of this notice of intent. Membership of the working group is likely to involve:

- Attendance at approximately eight (8), one (1) to two (2) day meetings (with the potential for two (2) additional one (1) or two (2) day meetings);
- Travel costs to those meetings; and
- Preparation time for those meetings.

Members serving on the working group will not receive compensation for their services. Interested parties who are not selected for membership on the working group may make valuable contributions to this negotiated rulemaking effort in any of the following ways:

- The person may request to be placed on the working group mailing list and submit written comments as appropriate.
- The person may attend working group meetings, which are open to the public; caucus with his or her interest's member on the working group; or even address the working group during the public comment portion of the working group meeting.
- The person could assist the efforts of a workgroup that the working group might establish.

A working group may establish informal workgroups, which usually are asked to facilitate committee deliberations by assisting with various technical matters (*e.g.,* researching or

preparing summaries of the technical literature or comments on specific matters such as economic issues). Workgroups also might assist in estimating costs or drafting regulatory text on issues associated with the analysis of the costs and benefits addressed, or formulating drafts of the various provisions and their justifications as previously developed by the working group. Given their support function, workgroups usually consist of participants who have expertise or particular interest in the technical matter(s) being studied. Because it recognizes the importance of this support work for the working group, DOE will provide appropriate technical expertise for such workgroups.

D. Good Faith Negotiation

Every working group member must be willing to negotiate in good faith and have the authority, granted by his or her constituency, to do so. The first step is to ensure that each member has good communications with his or her constituencies. An intra-interest network of communication should be established to bring information from the support organization to the member at the table, and to take information from the table back to the support organization. Second, each organization or coalition therefore should designate as its representative a person having the credibility and authority to ensure that needed information is provided and decisions are made in a timely fashion. Negotiated rulemaking can require the appointed members to give a significant sustained for as long as the duration of the negotiated rulemaking. Other qualities of members that can be helpful are negotiating experience and skills, and sufficient technical knowledge to participate in substantive negotiations.

Certain concepts are central to negotiating in good faith. One is the willingness to bring all issues to the bargaining table in an attempt to reach a consensus, as opposed to keeping key issues in reserve. The second is a willingness to keep the issues at the table and not take them to other forums. Finally, good faith includes a willingness to move away from some of the positions often taken in a more traditional rulemaking process, and instead explore openly with other parties all ideas that may emerge from the working group's discussions.

E. Facilitator

The facilitator will act as a neutral in the substantive development of the proposed standard. Rather, the facilitator's role generally includes:

- Impartially assisting the members of the working group in conducting discussions and negotiations; and
- Impartially assisting in performing the duties of the Designated Federal Official under FACA.

F. Department Representative

The DOE representative will be a full and active participant in the consensus building negotiations. The Department's representative will meet regularly with senior Department officials, briefing them on the negotiations and receiving their suggestions and advice so that he or she can effectively represent the Department's views regarding the issues before the working group. DOE's representative also will ensure that the entire spectrum of governmental interests affected by the standards rulemaking, including the Office of Management and Budget, the Attorney General, and other Departmental offices, are kept informed of the negotiations and encouraged to make their concerns known in a timely fashion.

G. Working Group and Schedule

After evaluating the comments submitted in response to this notice of intent and the requests for nominations, DOE will either inform the members of the working group that they have been selected or determine that conducting a negotiated rulemaking is inappropriate.

The working group is expected to make a concerted effort to negotiate a final term sheet by December 31, 2015 without further option for extensions.

DOE will advise working group members of administrative matters related to the functions of the working group before beginning. DOE will establish a meeting schedule based on the settlement agreement and produce the necessary documents so as to adhere to that schedule. While the negotiated rulemaking process is underway, DOE is committed to performing much of the same analysis as it would during a normal standards rulemaking process and to providing information and technical support to the working group.

IV. Comments Requested

DOE requests comments on which parties should be included in a negotiated rulemaking to develop draft language pertaining to the energy efficiency of residential central air conditioners and suggestions of additional interests and/or stakeholders that should be represented on the working group. All who wish to participate as members of the working group should submit a request for nomination to DOE.

V. Public Participation

Members of the public are welcome to observe the business of the meeting and, if time allows, may make oral statements during the specified period for public comment. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, email *asrac@ee.doe.gov.* In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed. Anyone attending the meeting will be required to present a government photo identification, such as a passport, driver's license, or government identification. Due to the required security screening upon entry, individuals attending should arrive early to allow for the extra time needed.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS) recent changes regarding ID requirements for individuals wishing to enter Federal buildings from specific states and U.S. territories. Driver's licenses from the following states or territory will not be accepted for building entry and one of the alternate forms of ID listed below will be required.

DHS has determined that regular driver's licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, Louisiana, New York, American Samoa, Maine, Oklahoma, Arizona, Massachusetts, Washington, and Minnesota.

Acceptable alternate forms of Photo-ID include: U.S. Passport or Passport Card; An Enhanced Driver's License or Enhanced ID-Card issued by the states of Minnesota, New York or Washington (Enhanced licenses issued by these states are clearly marked Enhanced or Enhanced Driver's License); A military ID or other Federal government issued Photo-ID card.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of today's notice of intent.

Issued in Washington, DC, on June 30, 2015.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency and Renewable Energy.

[FR Doc. 2015–17252 Filed 7–13–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–2461; Directorate Identifier 2013–NM–202–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2009–18–15 for all Airbus Model A300, A310, and A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). AD 2009–18–15 currently requires revising the Airworthiness Limitations section (ALS) of the Instructions for Continued Airworthiness (ICA) to require additional life limits and/or replacements for certain main landing gear and nose landing gear components. Since we issued AD 2009–18–15, we have determined that existing maintenance requirements and airworthiness limitations are inadequate to ensure the structural integrity of the airplane. This proposed AD would require revising the maintenance or inspection program to incorporate new maintenance requirements and airworthiness limitations. We are proposing this AD to prevent failure of certain system components, which could result in reduced structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by August 28, 2015.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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

You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2461; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–2461; Directorate Identifier 2013–NM–202–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On August 24, 2009, we issued AD 2009–18–15, Amendment 39–16011 (74 FR 48143, September 22, 2009). AD 2009–18–15 requires actions intended to address an unsafe condition for all Airbus Model A300, A310, and A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes).

Since we issued AD 2009–18–15, Amendment 39–16011 (74 FR 48143, September 22, 2009), we have determined that more restrictive maintenance requirements and airworthiness limitations are necessary.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2013–0248, dated October 14, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Model A300, A310, and A300–600 series airplanes. The MCAI states:

> The airworthiness limitations for Airbus aeroplanes are currently published in Airworthiness Limitations Section (ALS) documents.
>
> The mandatory instructions and airworthiness limitations applicable to the Aging Systems Maintenance (ASM) are specified in Airbus A310 or A300–600 ALS Part 4 documents, which are approved by the European Aviation Safety Agency (EASA). EASA AD 2007–0092 [*http://ad.easa.europa.eu/blob/easa_ad_2007_0092.pdf/AD_2007-0092]* [which corresponds to FAA AD 2009–06–06, Amendment 39–15842 (74 FR 12228, March 24, 2009)] was issued to require compliance to the requirements as specified in these documents.
>
> The revision 02 of Airbus A310 and Airbus A300–600 ALS Part 4 documents introduces more restrictive maintenance requirements and/or airworthiness limitations. Failure to comply with the instructions of ALS Part 4 could result in an unsafe condition [reduced structural integrity of the airplane.]
>
> For the reasons described above, this new [EASA] AD retains the requirements of EASA AD 2007–0092, which is superseded, and requires the implementation of the new or more restrictive maintenance requirements and/or airworthiness limitations as specified in Airbus A310 ALS Part 4, Revision 02, or Airbus A300–600 ALS Part 4, Revision 02, as applicable to aeroplane type/model.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2461.

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information, which describes procedures for revising the maintenance or inspection program to incorporate new maintenance requirements and airworthiness limitations.

• For Model A300 series airplanes: ''Sub-part 1–2: Life Limits,'' and ''Sub-part 1–3: Demonstrated fatigue lives'' of Part 1, ''Safe Life Airworthiness Limitation Items,'' Revision 01, dated September 5, 2013, of the Airbus Model A300 Airworthiness Limitations Section.

• For Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes): ''Sub-part 1–2: Life Limits,'' and ''Sub-part 1–3: Demonstrated fatigue lives'' of Part 1, ''Safe Life Airworthiness Limitation Items,'' Revision 01, dated September 5, 2013, of the Airbus Model A300–600 Airworthiness Limitations Section.

• For Model A310 series airplanes: ''Sub-part 1–2: Life Limits,'' and ''Sub-part 1–3: Demonstrated fatigue lives'' of Part 1, ''Safe Life Airworthiness Limitation Items,'' Revision 01, dated September 5, 2013, of the Airbus Model A310 Airworthiness Limitations Section.

This service information is reasonably available because the interested parties have access to it through their normal course of business, or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 177 airplanes of U.S. registry.

The ALS revision required by AD 2009–18–15, Amendment 39–16011 (74 FR 48143, September 22, 2009), takes about 1 work-hour per product, at an average labor rate of $85 per work-hour. Based on these figures, the estimated cost of the actions that were required by AD 2009–18–15 is $85 per product.

We also estimate that it would take about 1 work-hour per product to comply with the new ALS revision of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $15,045, or $85 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive AD 2009–18–15, Amendment 39–16011 (74 FR 48143, September 22, 2009), and adding the following new AD:

Airbus: Docket No. FAA–2015–2461; Directorate Identifier 2013–NM–202–AD.

(a) Comments Due Date

We must receive comments by August 28, 2015.

(b) Affected ADs

This AD replaces AD 2009–18–15, Amendment 39–16011 (74 FR 48143, September 22, 2009).

(c) Applicability

This AD applies to Airbus Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes; Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes; Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R and F4–622R, and A300 C4–605R Variant F airplanes; and Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes; certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America 32, Landing Gear.

(e) Reason

This AD was prompted by a determination that existing maintenance requirements and airworthiness limitations are inadequate to ensure the structural integrity of the airplane. We are issuing this AD to prevent failure of certain system components, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of Airworthiness Limitation Section (ALS)

This paragraph restates the requirements of paragraph (h) of AD 2009–18–15, Amendment 39–16011 (74 FR 48143, September 22, 2009). For Model A300, A310, and A300–600 series airplanes: Within 3 months after October 27, 2009 (the effective date of AD 2009–18–15), revise the ALS of the instructions for continued airworthiness (ICA) to incorporate the applicable document

listed in paragraph (g)(1), (g)(2), or (g)(3) of this AD. Accomplishing the actions specified in the applicable document satisfies the requirements of paragraph A. of AD 84–02–04, Amendment 39–4795.

(1) For Model A300 series airplanes: Incorporate the applicable document listed in paragraph (g)(1)(i) or (g)(1)(ii) of this AD.

(i) Section 05–10–00, Revision 28, dated February 27, 1998, of Chapter 05, ''Service Life Limits and Maintenance Checks,'' of the Airbus A300 Aircraft Maintenance Manual, except that the parts listed in table 1 to paragraph (g) of this AD are subject to the life limits defined in the document listed in paragraph (g)(1)(ii) of this AD.

(ii) ''Sub-part 1–2: Life Limits,'' and ''Sub-part 1–3: Demonstrated Fatigue Lives'' of Part 1, ''Safe Life Airworthiness Limitation Items,'' dated September 6, 2007, of the Airbus A300 ALS.

TABLE 1 TO PARAGRAPH (g) OF THIS AD—PARTS SUBJECT TO THE LIFE LIMITS SPECIFIED IN THE DOCUMENT IDENTIFIED IN PARAGRAPH (g)(1)(ii) OF THIS AD

Part No. (P/N)	Part name
P/N C61643–2, P/N C61643–4, P/N C61643–5.	Main landing gear (MLG) shock absorber end fitting.
P/N A32210001205xx	Nose landing gear (NLG) pintle pin.
P/N C62037–1	NLG shock absorber bottom.
P/N 196–0328–501 ...	Cross beam (Pratt & Whitney forward engine mount).

(2) For Model A310 series airplanes: Incorporate ''Sub-part 1–2: Life Limits,'' and ''Sub-part 1–3: Demonstrated Fatigue Lives'' of Part 1, ''Safe Life Airworthiness Limitation Items,'' dated December 21, 2006, of the Airbus A310 ALS.

(3) For Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes): Incorporate ''Sub-part 1–2: Life Limits,'' and ''Sub-part 1–3: Demonstrated Fatigue Lives'' of Part 1, ''Safe Life Airworthiness Limitation Items,'' dated December 21, 2006, of the Airbus A300–600 ALS.

(h) Retained Initial Compliance Times and Repetitive Inspections

This paragraph restates the requirements of paragraph (i) of AD 2009–18–15, Amendment 39–16011 (74 FR 48143, September 22, 2009). Do the replacement at the applicable time specified in paragraph (h)(1) or (h)(2) of this AD, except as provided by paragraph (i) of this AD. The replacement must be done thereafter within the interval specified in the applicable document identified in paragraph (g)(1), (g)(2), or (g)(3) of this AD.

(1) For any life limitation/task that has been complied with before October 27, 2009 (the effective date of AD 2009–18–15, Amendment 39–16011), in accordance with the applicable document listed in paragraph (g)(1), (g)(2), or (g)(3) of this AD, or in accordance with paragraph (g) of AD 2009–18–15, use the last accomplishment of each limitation/task as a starting point for accomplishing each corresponding limitation/task required by this AD.

(2) For any life limitation/task that has not been complied with before October 27, 2009 (the effective date of AD 2009–18–15, Amendment 39–16011), in accordance with the applicable document listed in paragraphs (g)(1), (g)(2), and (g)(3) of this AD, or in accordance with paragraph (g) of AD 2009–18–15, the initial compliance time starts from the date of initial entry into service as defined in the applicable document.

(i) Retained Special Compliance Times

This paragraph restates the requirements of paragraph (j) of AD 2009–18–15, Amendment 39–16011 (74 FR 48143, September 22, 2009). For any airplane on which the history of accumulated landings is partial or unknown, or where the history of application details (airplane type, model, weight variant, etc.) is partial or unknown, with or without using the information in Airbus Service Information Letter 32–118, Revision 02, dated October 24, 2007: Parts listed in figure 1 to paragraph (i) of this AD must be replaced at the associated compliance time. The replacement must be done thereafter at the interval specified in the applicable document(s) specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD.

Note 1 to paragraph (i) of this AD: Airbus Service Information Letter 32–118, Revision 02, dated October 24, 2007, provides operators with guidance on the means to assign a conservative calculated life to parts whose history of accumulated landings is partial or unknown; and to select the limitations applicable to parts whose history of application details (aircraft type, aircraft model, weight variant, etc.) is partial or unknown.

FIGURE 1 TO PARAGRAPH (i) OF THIS AD—SPECIAL COMPLIANCE TIMES

Designation	Aircraft type applicability				Start date	Compliance time (whichever occurs first after the ''start date'')	
	A300	A310	A300–600	P/N		Landings	Calendar time
	X	X	X				
MAIN LANDING GEAR							
	A32140032200xx	X			December 13, 2007	13,500	9 years.
	A32140056200xx	X			December 13, 2007	13,500	9 years.
	A32140056202xx	X			December 13, 2007	13,500	9 years.
Aft pintle pin	A32140057200xx	X			December 13, 2007	13,500	9 years.
	A32140057202xx	X		X	December 13, 2007	13,500	9 years.
	A32140062000xx	X			December 13, 2007	13,500	9 years.
	A32140063000xx	X		X	December 13, 2007	13,500	9 years.
	A32140036200xx	X			December 13, 2007	13,500	9 years.
	A32140036202xx	X			December 13, 2007	13,500	9 years.
	A32140036204xx	X			December 13, 2007	13,500	9 years.
	A32140036206xx	X			December 13, 2007	13,500	9 years.
Half ball housing (Fwd pintle bearing).	A32140042200xx	X		X	December 13, 2007	13,500	9 years.
	A32140042202xx	X		X	December 13, 2007	13,500	9 years.
	A32140068002xx	X			December 13, 2007	13,500	9 years.
	A32140068004xx	X			December 13, 2007	13,500	9 years.
	A32140069002xx	X		X	December 13, 2007	13,500	9 years.
	A32140069004xx	X		X	December 13, 2007	13,500	9 years.
Ball (Fwd pintle pin)	A32140012202xx	X			December 13, 2007	13,500	9 years.
	A32140043202xx	X		X	December 13, 2007	13,500	9 years.

FIGURE 1 TO PARAGRAPH (i) OF THIS AD—SPECIAL COMPLIANCE TIMES—Continued

Designation	Aircraft type applicability				Start date	Compliance time (whichever occurs first after the "start date")	
	A300	A310	A300–600	P/N		Landings	Calendar time
	X	X	X				
Pin (Multiple link/Frame 50).	A53833451200xx	X			December 13, 2007	13,500	9 years..
	A53833451206xx	X			December 13, 2007	13,500	9 years.
	A53834451200xx	X			December 13, 2007	13,500	9 years.
	A53834451202xx	X		X	April 25, 2007	13,500	9 years.
Pin (Drop link/Frame 50).	A53811122200xx		X		April 25, 2007	18,000	9 years.
MLG Barrel Assembly							
Upper torque link pin nut.	00–200–402	X			December 13, 2007	N/A	30 months.
	SL40089	X			December 13, 2007	N/A	30 months.
	SL40089P	X			December 13, 2007	N/A	30 months.
	SL40123	X			December 13, 2007	N/A	30 months.
	SL40123P	X	X	X	April 25, 2007	N/A	30 months.
Torque link medium pin nut.	00–200–358	X			December 13, 2007	N/A	30 months.
	SL40114P	X	X		April 25, 2007	N/A	30 months.
	SL40132	X			December 13, 2007	N/A	30 months.
	SL40132P	X		X	April 25, 2007	N/A	30 months.
Attaching fitting pin	C62311–1	X			December 13, 2007	13,500	9 years.
	C62311–20	X		X	April 25, 2007	13,500	9 years.
Pin (Connecting rod/Upper rod).	C65815	X			December 13, 2007	13,500	9 years.
	C65815–1	X			December 13, 2007	13,500	9 years.
	C65815–20	X			December 13, 2007	13,500	9 years.
	C66472	X			December 13, 2007	13,500	9 years.
	C66472–1	X			December 13, 2007	13,500	9 years.
	C66472–20	X		X	April 25, 2007	13,500	9 years.
	D52751		X		April 25, 2007	18,000	9 years.
MLG Shock Absorber Assembly							
Lower torque link pin nut.	00–200–402	X			December 13, 2007	N/A	30 months.
	SL40089	X			December 13, 2007	N/A	30 months.
	SL40089P	X			December 13, 2007	N/A	30 months.
	SL40123	X			December 13, 2007	N/A	30 months.
	SL40123P	X	X	X	April 25, 2007	N/A	30 months.
Bogie beam pivot pin nut.	SL40054	X			December 13, 2007	at next removal/installation.[1 2]	
	SL40054P	X		X	April 25, 2007	at next removal/installation.[1 2]	
	SL40413P		X		April 25, 2007	at next removal/installation.[1 2]	
MLG Lock Link Assembly							
Lock link medium pin	C61485–1	X			December 13, 2007	N/A	30 months.
	C61485–20	X		X	April 25, 2007	N/A	30 months.
NOSE LANDING GEAR							
Pintle pin	A32210079200xx	X	X	X	April 25, 2007	13,500	9 years.
NLG Telescopic Strut Assembly							
Nut (Cylinder/Locking cylinder).	C61375	X	X		April 25, 2007	13,500	9 years.
	D55955	X	X	X	April 25, 2007	13,500	9 years.
Locking sleeve	C61389	X	X		December 13, 2007	13,200	9 years.
	C61389–1	X	X	X	April 25, 2007	13,500	9 years.
NLG Barrel Assembly							
Pin (Clevis/Telescopic strut).	C62231–1	X			December 13, 2007	13,200	9 years.
	C62231–2	X			December 13, 2007	13,200	9 years.

FIGURE 1 TO PARAGRAPH (i) OF THIS AD—SPECIAL COMPLIANCE TIMES—Continued

Designation	Aircraft type applicability				Start date	Compliance time (whichever occurs first after the "start date")	
	A300	A310	A300–600	P/N		Landings	Calendar time
	X	X	X				
	C62231–20	X	X	X	April 25, 2007	13,500	9 years.
	D56530	X	X	X	April 25, 2007	13,500	9 years.
Lower pin (Link/Clevis).	C62268–1	X			December 13, 2007	13,200	9 years.
	C62268–2	X			December 13, 2007	13,200	9 years.
	C62268–20	X	X	X	April 25, 2007	13,500	9 years.
Link (Clevis/Barrel)	C62230–1	X	X	X	April 25, 2007	13,500	9 years.
	D56526	X	X	X	April 25, 2007	13,500	9 years.
Upper pin (Link/Barrel).	C62267–1	X			December 13, 2007	13,200	9 years.
	C62267–2	X			December 13, 2007	13,200	9 years.
	C62267–20	X	X	X	April 25, 2007	13,500	9 years.
End fitting pin nut	D68062	X	X	X	December 13, 2007	at next removal/installation.[2]	
	MS17825–6	X	X	X	December 13, 2007	at next removal/installation.[2]	
End fitting pin	AN6–17	X	X	X	December 13, 2007	at next removal/installation.[2]	
	D61183	X	X	X	December 13, 2007	at next removal/installation.[2]	
	D68063	X	X	X	December 13, 2007	at next removal/installation.[2]	
	NAS1306–22D	X	X	X	December 13, 2007	at next removal/installation.[2]	
End fitting	C62032	X	X	X	April 25, 2007	13,500	9 years.
	C62032–1	X	X	X	April 25, 2007	13,500	9 years.
Rack	C61453	X			December 13, 2007	13,200	9 years.
	C61453–1	X	X	X	April 25, 2007	13,500	9 years.
	C61453–20	X	X	X	April 25, 2007	13,500	9 years.
	C61453–40	X	X	X	April 25, 2007	13,500	9 years.
	C61453–41	X	X	X	April 25, 2007	13,500	9 years.
Torque link pin (Upper & Lower).	C62223–1	X			December 13, 2007	13,200	9 years.
	C62223–20	X	X	X	April 25, 2007	13,500	9 years.
Torque link medium pin nut.	SL40110P	X	X	X	April 25, 2007	N/A	30 months.
NLG Shock Absorber Assembly							
Wheel axle nut	C62879	X	X	X	April 25, 2007	4,000	24 months.
Upper cam dowel	C62270	X	X	X	December 13, 2007	at next removal/installation.	
Upper cam	C62034–1	X	X	X	April 25, 2007	13,500	9 years.
Lower cam	C62035	X	X	X	April 25, 2007	13,500	9 years.
Restrictor	C62036	X			December 13, 2007	13,200	9 years.
	C62036–1	X			December 13, 2007	13,200	9 years.
	C62036–2	X			December 13, 2007	13,200	9 years.
	C67863	X			December 13, 2007	13,200	9 years.
	C67863–1	X	X	X	April 25, 2007	13,500	9 years.
	C67863–2	X	X	X	April 25, 2007	13,500	9 years.
	C67863–3	X			December 13, 2007	13,500	9 years.
	C67863–4	X	X	X	April 25, 2007	13,500	9 years.
Lower cam dowel	C62866	X	X	X	December 13, 2007	at next removal/installation.[2]	
Nut (S/A/Barrel)	C64040	X			December 13, 2007	at next removal/installation.[1 2]	
	C64040–1	X	X	X	December 13, 2007	at next removal/installation.[1 2]	

[1] When the nut is temporarily removed and reinstalled for the purpose of performing maintenance outside a workshop, no replacement is required provided the nut's removal and reinstallation are performed on the same assembly and neither the assembly nor the nut accumulates time in service during the period between the removal and reinstallation.

[2] If the removal/installation was done after the start date, but before the effective date of this AD, the compliance time is within 3 months. after October 27, 2009 (the effective date of AD 2009–18–15, Amendment 39–16011 (74 FR 48143, September 22, 2009)).

(j) New Requirements of This AD: Maintenance Program Revision

Within 3 months after the effective date of this AD: Revise the maintenance or inspection program, as applicable, to incorporate the applicable limitation, replacement, or inspection specified in paragraph (j)(1), (j)(2), or (j)(3) of this AD, as applicable. Doing any task required by this paragraph terminates the corresponding task required by paragraph (g), (h), and (i) of this AD.

(1) For Model A300 series airplanes: Incorporate ''Sub-part 1–2: Life Limits,'' and ''Sub-part 1–3: Demonstrated Fatigue Lives'' of Part 1, ''Safe Life Airworthiness Limitation Items,'' Revision 01, dated September 5, 2013, of the Airbus A300 ALS.

(2) For Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4 605R Variant F airplanes (collectively

called Model A300–600 series airplanes): Incorporate ''Sub-part 1–2: Life Limits,'' and ''Sub-part 1–3: Demonstrated Fatigue Lives'' of Part 1, ''Safe Life Airworthiness Limitation Items,'' Revision 01, dated September 5, 2013, of the Airbus A300–600 ALS.

(3) For Model A310 series airplanes: Incorporate ''Sub-part 1–2: Life Limits,'' and ''Sub-part 1–3: Demonstrated Fatigue Lives'' of Part 1, ''Safe Life Airworthiness Limitation Items,'' dated Revision 01, September 5, 2013, of the Airbus A310 ALS.

(k) New Limitation: No Alternative Actions or Intervals

After accomplishment of the revision required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l) of this AD.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

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

(2) Contacting the Manufacturer: As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2013–0248, dated October 14, 2013, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2461.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on June 25, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–17201 Filed 7–13–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–2714; Directorate Identifier 2014–SW–052–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Airbus Helicopters Model AS332C1, AS332L1, AS332L2, EC225LP, AS–365N2, AS 365 N3, EC 155B, and EC155B1 helicopters with an energy absorbing seat (seat). This proposed AD would require inspecting for the presence of labels that prohibit stowing anything under the seat. If a label is missing or not clearly visible to each occupant, installing a label would be required. This proposed AD is prompted by the discovery that required labels had not been systematically installed. The proposed actions are intended to prevent objects from being stowed under the seat as these objects could reduce the energy-absorbing function of the seat, resulting in injury to the seat occupants during an accident.

DATES: We must receive comments on this proposed AD by September 14, 2015.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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 proposed AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact Airbus Helicopters, Inc., 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.airbushelicopters.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.

FOR FURTHER INFORMATION CONTACT: Robert Grant, Aviation Safety Engineer, Safety Management Group, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *robert.grant@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will

consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, issued EASA AD No. 2014–0204, dated September 11, 2014, followed by a correction dated September 12, 2014, to correct an unsafe condition for Airbus Helicopters Model AS332C1, AS332L1, AS332L2, EC225LP, AS–365N2, AS 365 N3, EC 155B, and EC155B1 helicopters. EASA advises that during certification of an energy absorbing seat with a new part number, it was observed that the label that requires keeping the space under the seat free of any object was not systematically installed in a helicopter. EASA states that this condition, if not corrected, could prompt occupants to stow objects under an energy absorbing seat, which would reduce the effectiveness of the seat and the occupants' chance of surviving an accident. The EASA AD consequently requires a one-time inspection for the presence of labels and, if they are missing or unreadable, making and installing labels prohibiting the placing of an object under an energy absorbing seat.

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 its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

Airbus Helicopters issued Alert Service Bulletin (ASB) No. AS332–01.00.85 for Model AS332C1, AS332L1, AS332L2 helicopters; ASB No. AS365–01.00.66 for Model AS–365N2 and AS 365 N3 helicopters; ASB No. EC155–04A013 for EC 155B and EC155B1 helicopters; and ASB No. EC225–04A012 for Model EC225LP helicopters. All ASBs are Revision 0 and dated August 26, 2014. The ASBs state that during certification of an energy absorbing seat with a new part number, it was observed that the label, which indicates that the space under the seats must remain free of objects, was not systematically installed. Objects stowed under these seats reduce the energy absorbing function and thus jeopardize the occupant's survival in the event of a crash, the ASBs state. Pending a definitive solution, Airbus Helicopters calls for affixing a label that states that nothing can be stored under the seats.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this proposed AD.

Proposed AD Requirements

Within 110 hours time in service this proposed AD would require:

- For Model AS332C1, AS332L1, AS332L2, and EC225LP helicopters: Inspecting the cabin and cockpit for labels, placards, or markings that prohibit stowing anything under the seats. If a label, placard, or marking is not located in every required location or is not visible and legible to every occupant, before further flight, installing a placard.
- For Model AS–365N2, AS 365 N3, EC 155B, and EC155B1 helicopters: Inspecting each seat leg in the cabin and cockpit for labels, placards, or markings that prohibit stowing anything under the seats. If a label, placard, or marking does not exist on one leg of each seat or is not visible and legible, before further flight, installing a placard.

Costs of Compliance

We estimate that this proposed AD would affect 52 helicopters of U.S. Registry and that labor costs average $85 a work-hour. Based on these estimates, we expect that the inspection for the presence of a label would take a quarter work hour for a labor cost of about $21. The cost of parts and time for installing a label would be minimal, for a total cost of $21 per helicopter and $1,092 for the U.S. fleet.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska 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 proposed 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.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive

(AD): Airbus Helicopters: Docket No. FAA–2015–2714; Directorate Identifier 2014–SW–052–AD.

(a) Applicability

This AD applies to Airbus Helicopters Model AS332C1, AS332L1, AS332L2,

EC225LP, AS–365N2, AS 365 N3, EC 155B, and EC155B1 helicopters with an energy absorbing seat (seat) listed in Figure 1 to paragraph (a) of this AD, certificated in any category.

FIGURE 1 TO PARAGRAPH (a)

Seat manufacturer	Seat type	Generic part number
Fischer + Entwicklungen	H110	9606-()-()-()
	H140	0520-()-()-()
	H160	0718-()-()-()-()
	185/410	9507-()-()-()
	236/406	9608-()-()-()
SICMA Aero Seat or Zodiac Seats France	Sicma 192	192xx-xx-xx
	Sicma 159	1591718-xx
		159110
Socea Sogerma	ST102	2510102-xx-xx
	ST107	2010107-xx-xx
	ST120	2520120-xx

Note 1 to Figure 1 to paragraph (a) of this AD: ''xx'' can be any two alphanumeric characters and ''()'' can be any number of alphanumeric characters.

(b) Unsafe Condition

This AD defines the unsafe condition as an object stowed under an energy-absorbing seat. This condition could reduce the efficiency of the energy-absorbing function of the seat, resulting in injury to the seat occupants during an accident.

(c) Comments Due Date

We must receive comments by September 14, 2015.

(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

Within 110 hours time in service:

(1) For Model AS332C1, AS332L1, AS332L2, and EC225LP helicopters:

(i) Inspect the cabin and cockpit for labels, placards, or markings that prohibit stowing anything under the seats in the locations shown in the figure in the Appendix of Airbus Helicopters Alert Service Bulletin No. AS332–01.00.85 (ASB AS332–01.00.85) or No. EC225–04A012 (ASB EC225–04A012), both Revision 0 and dated August 26, 2014, as applicable for your model helicopter.

(ii) If a label, placard, or marking is not located in every location depicted in the figure in the Appendix or is not visible and legible to every occupant, before further flight, install a placard in accordance with the Accomplishment Instructions, paragraph 3.B., of ASB AS332–01.00.85 or ASB EC225–04A012, as applicable for your model helicopter.

(2) For Model AS–365N2, AS 365 N3, EC 155B, and EC155B1 helicopters:

(i) Inspect each seat leg in the cabin and cockpit for labels, placards, or markings that prohibit stowing anything under the seats.

(ii) If a label, placard, or marking does not exist on one leg of each seat or is not visible and legible, before further flight, install a placard in accordance with the Accomplishment Instructions, paragraph 3.B., and the Appendix of Airbus Helicopters Alert Service Bulletin No. AS365–01.00.66 or No. EC155–04A013, both Revision 0 and dated August 26, 2014, as applicable for your model helicopter.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Robert Grant, Aviation Safety Engineer, Safety Management Group, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *robert.grant@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

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2014–0204, dated September 11, 2014, and corrected September 12, 2014. You may view the EASA AD on the Internet at *http://www.regulations.gov* in Docket No. FAA–2015–2714.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 1100, Placards and Markings.

Issued in Fort Worth, Texas, on July 2, 2015.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2015–16940 Filed 7–13–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–2775; Directorate Identifier 2015–CE–021–AD]

RIN 2120–AA64

Airworthiness Directives; PILATUS AIRCRAFT LTD. Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for PILATUS AIRCRAFT LTD. Model PC–12, PC–12/45, and PC–12/47E airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as a malfunction of the universal joint. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by August 28, 2015.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room

W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact PILATUS AIRCRAFT LTD, Customer Support Manager, CH–6371 STANS, Switzerland; phone: +41 (0)41 619 33 33; fax: +41 (0)41 619 73 11; email: *SupportPC12@pilatus-aircraft.com;* internet: *http://www.pilatus-aircraft.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2775; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–2775; Directorate Identifier 2015–CE–021–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No.: 2015–0111, dated June 16, 2015 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> A case of malfunctioning was reported of a universal joint installed between the control tube assembly and the control column on a PC–12/47E aeroplane.
>
> Investigation determined that the malfunction was caused by an incorrectly manufactured universal joint. Universal joints from the same manufacturing batch were provided to operators between 01 March 2014 and 28 February 2015, and are thus potentially affected.
>
> This condition, if not corrected, could lead to other cases of malfunctioning of a universal joint, possibly resulting in reduced control of the aeroplane.
>
> To address this potential unsafe condition, Pilatus Aircraft Ltd. issued Service Bulletin (SB) No. 27–022 to provide instructions for replacement of the universal joints in the flight controls.
>
> For the reason described above, this AD requires removal from service of the potentially incorrectly manufactured universal joints.

You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2775.

Related Service Information Under 1 CFR Part 51

Pilatus Aircraft Limited has issued PILATUS PC–12 Service Bulletin No: 27–022, dated March 17, 2015. The PILATUS PC–12 Service Bulletin No: 27–022, dated March 17, 2015, describes procedures for replacement of the universal joint on the aileron control system. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD will affect 55 products of U.S. registry. We also estimate that it would take about 3 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $1,000 per product.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $69,025 or $1,255 per product.

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

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

PILATUS AIRCRAFT LTD.: Docket No. FAA–2015–2775; Directorate Identifier 2015–CE–021–AD.

(a) Comments Due Date

We must receive comments by August 28, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to PILATUS AIRCRAFT LTD. Models PC–12, PC–12/45, and PC–12/47E airplanes, manufacturer serial numbers 244, 307, 409, 646, 1447 through 1450, 1461, 1462, 1466 through 1514, 1516 through 1520, and 1523, certificated in any category.

(d) Subject

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

(e) Reason

This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as a malfunction of the universal joint. We are issuing this proposed AD to replace defective aileron control system universal joints.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) through (f)(2) of this AD:

(1) For airplanes equipped with aileron control system universal joints part number (P/N) 944.61.73.012 or P/N 527.10.12.195, purchased between March 1, 2014, and February 28, 2015; or universal joints installed in service through an aileron control system inspection kit P/N 500.50.12.314, purchased between March 1, 2014, and February 28, 2015, do one of the following actions as applicable:

(i) *For airplanes with less than 200 flight cycles since first flight of the airplane or less than 200 flight cycles since installation of an affected universal joint or inspection kit, whichever applies:* Within 10 flight cycles after the effective date of this AD or 3 months after the effective date of this AD, whichever occurs first, replace with a new universal joint P/N 527.10.12.195 purchased after March 1, 2015, and marked with a placard ''RT iO'' following the Accomplishment Instructions in PILATUS PC–12 Service Bulletin No: 27–022, dated March 17, 2015.

(ii) *For airplanes with 200 flight cycles or more since first flight of the airplane or 200 flight cycles or more since installation of an affected universal joint or inspection kit, whichever applies:* Within 12 months after the effective date of this AD, replace with a new universal joint P/N 527.10.12.195 purchased after March 1, 2015, and marked with a placard ''RT iO'' following the Accomplishment Instructions in PILATUS PC–12 Service Bulletin No: 27–022, dated March 17, 2015.

(iii) *For all airplanes where total flight cycles are not tracked:* The conversion formula is one flight cycle equals one flight hour.

(2) *For all airplanes:* After the effective date of this AD, do not install the following parts on any airplane after the modification of the airplane as required in paragraphs (f)(1)(i) and (f)(1)(ii) of this AD or any airplane that does not have an affected part installed:

(i) A universal joint P/N 944.61.73.012 or P/N 527.10.12.195 (except for a P/N 527.10.12.195 marked with a placard ''RT iO'').

(ii) Inspection kit P/N 500.50.12.314 purchased between March 1, 2014, and February 28, 2015.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

(3) Reporting Requirements: For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not 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 current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2015–0111, dated June 16, 2015. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2775. For service information related to this AD, contact PILATUS AIRCRAFT LTD, Customer Support Manager, CH–6371 STANS, Switzerland; phone: +41 (0)41 619 33 33; fax: +41 (0)41 619 73 11; email: *SupportPC12@pilatus-aircraft.com;* internet: *http://www.pilatus-aircraft.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on July 7, 2015.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–17205 Filed 7–13–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF STATE

22 CFR Part 171

[Public Notice: 9187]

RIN 1400–AD86

Privacy Act; STATE–09, Records Maintained by the Office of Civil Rights

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: The Department of State is giving concurrent notice of a publication for a system of records pursuant to the Privacy Act of 1974 for the Records Maintained by the Office of Civil Rights, STATE–09; and this proposed rulemaking, which proposes to exempt portions of this system of records from one or more provisions of the Privacy Act of 1974.

DATES: Comments on this proposed rule are due by August 24, 2015.

FOR FURTHER INFORMATION CONTACT: John Hackett, Acting Director; Office of Information Programs and Services, A/GIS/IPS; Department of State, SA–2; 515 22nd Street NW., Washington, DC 20522–8001, or at *Privacy@state.gov.*

SUPPLEMENTARY INFORMATION: The Department of State maintains the Records Maintained by the Office of Civil Rights system of records. The primary purpose of this system of records is for the investigation, processing, and resolution of informal and formal complaints of discrimination filed against the Department of State in accordance with 29 CFR part 1614 and the Department's internal procedures for addressing Equal Employment Opportunity (EEO) complaints; and for the investigation, processing and resolution of complaints of discrimination under 42 U.S.C. 2000d and complaints under 20 U.S.C. 1681, 29 U.S.C. 794 and 794d, 42 U.S.C. 6101, 29 U.S.C. 621, and 36 CFR chapter XI.

The Department of State is issuing this document as a proposal to amend 22 CFR part 171 to exempt portions of the Records Maintained by the Office of Civil Rights system of records from the Privacy Act subsections (c)(3);(d); (e)(1); (e)(4)(G), (H), and (I); and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(5) to the extent that the system contains investigatory material compiled for law enforcement purposes, and (k)(6) to the extent that it contains testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service.

List of Subjects in 22 CFR Part 171

Privacy.

For the reasons stated in the preamble, 22 CFR part 171 is proposed to be amended as follows:

PART 171—AVAILABILITY OF INFORMATION AND RECORDS TO THE PUBLIC

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 5 U.S.C. 552, 552a; 22 U.S.C. 2651a; Pub. L. 95–521, 92 Stat. 1824, as amended; E.O. 13526, 75 FR 707; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235.

§ 171.36 [Amended]

■ 2. Section 171.36 is amended by adding an entry, in alphabetical order, for ''Records Maintained by the Office of Civil Rights, State-09'' to the lists in paragraphs (b)(5) and (6).

Joyce A. Barr,

Assistant Secretary for Administration, U.S. Department of State.

[FR Doc. 2015–17227 Filed 7–13–15; 8:45 am]

BILLING CODE 4710–10–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2014–0916; FRL–9930–46–Region–8]

Approval and Promulgation of Air Quality Implementation Plans; South Dakota; Revisions to South Dakota Administrative Code

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of South Dakota on July 29, 2013. This SIP submission revises the Administrative Rules of South Dakota (ARSD) Article 74:36—Air Pollution Control Program. These revisions include grammatical changes, renumbering, revisions to the date of incorporation by reference of the federal regulations referenced throughout ARSD Article 74:36, and removal of obsolete language regarding variance provisions and clean units. A cross-walk table, which details each individual rule revision in Article 74:36, and the actions EPA is proposing on those revisions, is included in the docket for this rulemaking. EPA is also proposing to clarify a final rule issued on January 29, 2015 pertaining to South Dakota's infrastructure SIP. This action is being taken in accordance with section 110 of the Clean Air Act (CAA).

DATES: Comments must be received on or before August 13, 2015.

ADDRESSES: The EPA has established a docket for this action under Docket Identification Number EPA–R08–OAR–2014–0916. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in the hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at EPA Region 8, Office of Partnership and Regulatory Assistance, Air Program, 1595 Wynkoop Street, Denver, Colorado, 80202–1129. The EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. The Regional Office's official hours of business are Monday through Friday, 8:00 a.m.–4:00 p.m., excluding federal holidays. An electronic copy of the state's SIP compilation is also available at *http://www.epa.gov/region8/air/sip.html.*

FOR FURTHER INFORMATION CONTACT: Adam Clark, Air Program, U.S. Environmental Protection Agency, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–7104, *clark.adam@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

What should I consider as I prepare my comments for EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit CBI to EPA through *www.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:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- 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.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at

your estimate in sufficient detail to allow for it to be reproduced.

- Provide specific examples to illustrate your concerns and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. Background

South Dakota's June 29, 2013, submittal covers the following rule changes: (1) Removal of obsolete language regarding variance provisions and clean units, and renumbering to reflect the deletions; and (2) Revisions to the date of federal regulations referenced throughout ARSD Article 74:36 to July 1, 2012. A cross-walk table, which identifies the proposed rule revisions in Article 74:36 specifically, and the action EPA is proposing to take on those revisions, is included in the docket for this rulemaking.

South Dakota's June 29, 2013 submittal also requests EPA approval of rule revisions for provisions that are not required to be included in SIPs under section 110 of the Clean Air Act (CAA), most notably additions to the State's New Source Performance Standards (NSPS) and National Emissions Standards for Hazardous Air Pollutants (NESHAPs). These revisions, which EPA is not proposing action on, are outlined in the cross-walk table located in the docket for this rulemaking.

III. What action is EPA taking?

EPA is proposing to approve most revisions of South Dakota's July 29, 2013 submittal as outlined in Section II. of this rulemaking that were not acted on previously. An overview of EPA's proposed approval of each section is described below. The excepted revisions, on which EPA will not take action, are also described below.

74:36:01:01 (Definitions)

EPA is proposing to approve all changes in this section as outlined in the crosswalk table (see docket). These changes specifically remove the term ''variance'' previously included in the definitions of ''existing source'' and ''new source,'' and removes the definition of ''variance.'' The removal of the variance will strengthen the environmental protection provided by the SIP, and therefore EPA proposes to approve these changes. EPA is also proposing to approve all remaining changes in this section, which update the date of incorporation by reference of the federal regulations to July 1, 2012.

74:36:02 (Ambient Air Quality)

EPA is proposing to approve all changes in this section, which update the date of incorporation by reference of the federal regulations to July 1, 2012.

74:36:04 (Operating Permits for Minor Sources)

EPA is proposing to approve all changes in this section, which remove citations to repealed provisions of South Dakota's legal code regarding variances from the General Authorities and Implemented Laws provided. It also updates the date of incorporation by reference of the federal regulations to July 1, 2012.

74:36:05 (Operating Permits for Part 70 Sources)

EPA is proposing to approve the changes in this section, which update the date of incorporation by reference of the federal regulations to July 1, 2012 and remove citations to repealed provisions of South Dakota's legal code regarding variances from the General Authorities and Implemented Laws provided.

74:36:07 (New Source Performance Standards)

EPA is not taking action on this section because NSPS are not required to be included in a SIP per section 110 of the CAA.

74:36:08 (National Emission Standards for Hazardous Air Pollutants)

EPA is not taking action on this section because NESHAPs are not required to be included in a SIP per section 110 of the CAA.

74:36:09 (Prevention of Significant Deterioration)

EPA is not taking action on this section of South Dakota's July 29, 2013 submittal because it was acted upon by EPA in a final rulemaking dated January 29, 2015. (80 FR 4799)

74:36:10 (New Source Review)

EPA is proposing to approve all changes in this section that were not acted upon in an EPA final rule issued on June 27, 2014, with one exception. The provisions that EPA is proposing to act upon in this rulemaking are 74:36:10:09 and 74:36:10:10. These provisions remove obsolete language regarding clean units. EPA is not taking action on 74:36:10:06, which proposes to add $PM_{2.5}$ to the ''Pollutant and Significant Levels'' table and to renumber other pollutants in the table. On January 22, 2013, the United States Court of Appeals for the District of Columbia vacated and remanded portions of EPA's 2010 $PM_{2.5}$ Increment Rule (75 FR 64864) addressing the Significant Impact Levels (SILs) for $PM_{2.5}$. On December 9, 2013, EPA amended its regulations to remove the $PM_{2.5}$ SILs (78 FR 73698). Therefore, South Dakota's incorporation of the $PM_{2.5}$ SILs into its SIP no longer reflects the current regulations.

74:36:11 (Performance Testing)

EPA is proposing to approve changes in this section, which update the date of incorporation by reference of the federal regulations to July 1, 2012.

74:36:12 (Control of Visible Emissions)

EPA is proposing to approve the changes to 74:36:12:01 and 74:36:12:03 in the submittal, which update the date of incorporation by reference of the federal regulations to July 1, 2012 and update the General Authorities and Laws Implemented. EPA is not taking action on the language change in 74:36:12:02(3). On February 22, 2013, EPA (among other things) made a finding of substantial inadequacy and issued a SIP call for certain provisions related to start-up, shutdown, and malfunction in current SIPs for specific states. For South Dakota the affected provision is 74:36:12:02(3). EPA is not taking action on this provision, because it will be addressed in the proposed SIP call.

74:36:13 (Continuous Emissions Monitoring)

EPA is proposing to approve changes in this section, which update the date of incorporation by reference of the federal regulations to July 1, 2012.

74:36:16 (Acid Rain Program)

EPA is not taking action on this section because the Acid Rain Program is not required to be included in a SIP per section 110 of the CAA.

74:36:18 (Regulations for State Facilities in the Rapid City Area)

EPA is proposing to approve changes in this section, which update the date of incorporation by reference of the federal regulations for the visible emission test method to EPA Method 9 in 40 CFR part 60, Appendix A to July 1, 2012 and delete references to repealed provisions of the South Dakota Legal Code regarding variances.

74:36:20 (Construction Permits for New Sources or Modifications)

EPA is proposing to approve the changes in this section, which update the date of incorporation by reference of the federal regulations to July 1, 2012 and delete references to repealed

provisions of the South Dakota Legal Code regarding variances. It also includes a change to 74:36:20:05 to ensure air pollution dispersion modeling used to determine compliance with that requirement is performed in accordance with 40 CFR part 51, Appendix W to July 1, 2012.

74:36:21 (Regional Haze Program)

EPA is proposing to approve changes in this section, which update the date of incorporation by reference of the federal regulations to July 1, 2012.

IV. Proposed Clarification of January 29, 2015 Final Action

Under CAA sections 110(a)(1) and (2), states are required to submit infrastructure SIPs to ensure their SIPs provide for implementation, maintenance, and enforcement of the NAAQS. As noted, on January 29, 2015, EPA took final action on the infrastructure submittals which addressed several different NAAQS from the State of South Dakota. (80 FR 4799). As part of the January 29, 2015 action, EPA approved South Dakota's 1997 $PM_{2.5}$ NAAQS interstate transport infrastructure sub-element (CAA section 110(a)(2)(D)(i)(II)). However, EPA had already approved this sub-element in a final rulemaking on May 8, 2008. (73 FR 26019, effective July 7, 2008). Therefore, in this action EPA is proposing to clarify that no action was required on this sub-element for this NAAQS in the January 29, 2015 approval of CAA section 110(a)(2)(D)(i)(II) for the 1997 $PM_{2.5}$ NAAQS and the effective date of approval remains July 7, 2008.

V. Summary of Proposed Action

In this proposed rulemaking, we are proposing approval of most remaining portions of South Dakota's July 29, 2013 submittal as outlined in section III. above and in the crosswalk table located in the docket. We are proposing not to take action on certain portions of this submittal as described in section III. Finally, we are proposing to clarify our January 29, 2015 final action (80 FR 4799) regarding the effective date of approval for South Dakota's SIP regarding CAA section 110(a)(2)(D)(i)(II) for the 1997 $PM_{2.5}$ NAAQS.

VI. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the rules in ARSD 74:36 submitted by South Dakota for action which are identified within this notice of proposed rulemaking. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this rule's preamble for more information).

VII. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state actions, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law provisions as meeting federal requirements and does not propose 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 Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not proposed to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

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

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

Dated: June 25, 2015.

Debra H. Thomas,

Acting Regional Administrator, Region 8.

[FR Doc. 2015–17257 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2014–0626; FRL–9930–26-Region 6]

Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$) Prevention of Significant Deterioration (PSD) Permitting Program State Implementation Plan (SIP)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve portions of two revisions to the New Mexico SIP for the permitting of $PM_{2.5}$ emissions submitted on May 23, 2011, and August 6, 2014. Together, these submittals revise the New Mexico PSD program to be consistent with the federal PSD regulations regarding the use of a significant impact level (SIL) or significant monitoring concentration (SMC) for $PM_{2.5}$ emissions. We are proposing to approve these SIP revisions to regulate $PM_{2.5}$ emissions in accordance with requirements of section 110 and part C of the Clean Air Act.

DATES: Written comments must be received on or before August 13, 2015.

ADDRESSES: Comments may be mailed to Ms. Adina Wiley, Air Planning Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Ste. 1200, Dallas, TX 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Adina Wiley, 214–665–2115, *wiley.adina@epa.gov*.

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register,** EPA is approving the State's SIP submittals as a direct rule without prior proposal because the Agency views this as noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action no further activity is contemplated. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: June 30, 2015.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2015–17059 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0345; FRL–9929–59–Region 9]

Revisions to the California State Implementation Plan, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP). This revision concerns volatile organic compound (VOC) emissions from graphic arts facilities. The EPA is proposing to approve a local rule to regulate these emission sources under the Clean Air Act (CAA or the Act).

DATES: Any comments on this proposal must arrive by August 13, 2015.

ADDRESSES: Submit comments, identified by docket number [EPA–R09–OAR–2015–345, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.
2. *Email: steckel.andrew@epa.gov.*
3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. *www.regulations.gov* is an ''anonymous access'' system, and the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to the EPA, your email address will be automatically captured and included as part of the public comment. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: 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 94105–3901. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), 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: Vanessa Graham, EPA Region IX, (415) 947–4120, *graham.vanessa@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposal addresses the following local rule: SCAQMD 1130, Graphic Arts. In the Rules and Regulations section of this **Federal Register**, the EPA is approving this local rule in a direct final action without prior proposal because the EPA believes this SIP revision is not controversial. If the EPA receives adverse comments, however, the EPA will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule.

The EPA does not plan to open a second comment period, so anyone interested in commenting should do so at this time. If the EPA does not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: June 9, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2015–17062 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2015–0241; FRL–9930–34–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Low Emissions Vehicle Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve two State Implementation Plan (SIP) revisions submitted by the State of Maryland for the purpose of amending Maryland's prior approved Low Emission Vehicles (LEV), or Clean Car Program. Maryland adopted California's emission standards applicable to newly manufactured light and medium-duty motor vehicles in 2007, effective beginning with 2011 and newer vehicles sold in Maryland. EPA approved Maryland's Clean Car Program in prior SIP approval rulemakings. However, since then California revised its LEV program regulations on several occasions, and Maryland subsequently amended its own rules to be consistent with those of California. Maryland then submitted these regulatory amendments to EPA as a revision to its SIP. Maryland submitted two such Clean Car Program SIP revisions in July 2014 and April 2015.

In the Final Rules section of this **Federal Register**, EPA is approving the

State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by August 13, 2015.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2015–0241 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: Fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2015–0241, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2015–0241. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means 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 *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Brian Rehn, (215) 814–2176, or by email at *rehn.brian@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action to approve Maryland's amended Clean Car Program, with the same title, which is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

List of Subjects in 40 CFR Part 52

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

Dated: June 26, 2015.

William C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2015–17063 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 69

[WC Docket No. 05–25, RM–10593; DA 15–737]

Wireline Competition Bureau Further Extends Comment Deadlines in Special Access Proceeding

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment and reply deadlines.

SUMMARY: In this document, the Federal Communications Commission's (Commission's) Wireline Competition Bureau (Bureau) further extends deadlines for interested parties to submit comments and reply comments in response to Section IV.B of the Further Notice of Proposed Rulemaking (*Special Access FNPRM*), 78 FR 2600, January 11, 2013, in the special access proceeding.

DATES: The comment period for the proposed rule published January 11, 2013 (78 FR 2600), has been further extended. Comments are due on or before September 25, 2015; reply comments are due on or before October 16, 2015.

ADDRESSES: You may submit comments on the *Special Access FNPRM,* 78 FR 2600, January 11, 2013, identified by WC Docket No. 05–25, RM–10593, by any of the following methods:

- *Electronic Filers:* Federal Communication Commission's Electronic Comments Filing System (ECFS): *http://apps.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *Paper Filers:* All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. Eastern Time (ET). 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, DC 20554.
- *People with Disabilities:* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, or 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).

FOR FURTHER INFORMATION CONTACT: Christopher Koves, Pricing Policy Division, Wireline Competition Bureau, (202) 418–8209 or *Christopher.Koves@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, WC Docket No. 05–25, RM–10593; DA 15–737, released June 24, 2015. This document does not contain 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[s] for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002. The complete text of this document is available for public inspection and copying from 8:00 a.m. to 4:30 p.m. ET Monday through Thursday or from 8:00 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text is also available on the Commission's Web site at *http://wireless.fcc.gov*, or by using the search function on the ECFS Web page at *http://www.fcc.gov/cgb/ecfs/.*

Background

On June 24, 2015, the Commission released a public notice extending the deadlines for filing comments and reply comments in response to Section IV.B of the *Special Access FNPRM* (78 FR 2600, January 11, 2013) in the Commission's special access rulemaking proceeding until September 25, 2015 and October 16, 2015, respectively. Previous comment period extensions have been published in the **Federal Register**. The latest comment period extension was published in the **Federal Register** on April 27, 2015 (80 FR 23248), to extend the comment and reply comment deadlines to July 1 and July 22, 2015, respectively. On December 11, 2012, the Commission adopted an order requiring providers and purchasers of special access service and certain entities providing ''best efforts'' service to submit data and information for a comprehensive evaluation of the special access market. In Section IV.B of the *Special Access FNPRM* accompanying that order, the Commission sought comment on potential changes to its rules governing the special access services provided by incumbent local exchange carriers in price cap areas. The Bureau is in the process of allowing access to the data collected for interested parties to review pursuant to restrictions found in the previously issued protective order, but has yet to make the data available. As a result, interested parties will not have adequate time to access and review the information collected prior to the current July 1 and July 22, 2015 comment and reply comment deadlines.

Accordingly, the Bureau hereby further extends the deadline for filing comments to September 25, 2015, and for filing reply comments to October 16, 2015.

Federal Communications Commission.

Pamela Arluk,

Chief, Pricing Policy Division, Wireline Competition Bureau.

[FR Doc. 2015–16821 Filed 7–13–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[GN Docket No. 12–268; MB Docket No. 15–137; FCC 15–67]

Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions; Channel Sharing by Full Power and Class A Stations Outside the Broadcast Television Spectrum Incentive Auction Context

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this *Notice of Proposed Rulemaking* (*NPRM*), the Commission tentatively concludes that we should authorize channel sharing by full power and Class A stations outside the incentive auction context, including ''second generation'' agreements in which one or both entities were parties to an auction-related CSA whose term has expired or that has otherwise been terminated. By providing greater flexibility and certainty regarding CSAs, our objective is to encourage voluntary participation by broadcasters in the incentive auction.

DATES: Comments may be filed on or before August 13, 2015, and reply comments may be filed August 28, 2015. Written comments on the proposed information collection requirements, subject to the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13, should be submitted on or before September 14, 2015.

ADDRESSES: You may submit comments, identified by MB Docket No. 15–137, 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://fjallfoss.fcc.gov/ecfs2/*. Follow the instructions for submitting comments.
- *Mail:* 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.
- *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.

In addition to filing comments with the Secretary, a copy of any comments on the Paperwork Reduction Act proposed information collection requirements contained herein should be submitted to the Federal Communications Commission via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov* and also to Nicholas A. Fraser, Office of Management and Budget, via email to *Nicholas-A.-Fraser@omb.eop.gov*. 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: Kim Matthews, Media Bureau, Policy Division, 202–418–2154, or email at *kim.matthews@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking,* FCC 15–67, adopted on June 11, 2015 and released on June 12, 2015. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, 445 12th Street SW., Room CY–B402, Washington, DC 20554. This document will also be available via ECFS at *http://fjallfoss.fcc.gov/ecfs/*. Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format) by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202)

418–0530 (voice), (202) 418–0432 (TTY).

Paperwork Reduction Act of 1995 Analysis

The *NPRM* contains proposed new and modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Comments should address: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain*, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

The information collections are as follows:

OMB Control Number: 3060–0027.

Title: Application for Construction Permit for Commercial Broadcast Station, FCC Form 301; FCC Form 2100, Application for Media Bureau Audio and Video Service Authorization, Schedule A.

Form Number: FCC Form 301; FCC Form 2100, Schedule A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or Tribal governments.

Number of Respondents and Responses: 3,825respondents; 7,361 responses.

Estimated Time per Response: 1–8 hours.

Frequency of Response: On occasion and one-time reporting requirements; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is contained in Sections 154(i), 303 and 308 of the Communications Act of 1934, as amended and the Middle Class Tax Relief and Job Creation Act of 2012 (''Spectrum Act'').

Total Annual Burden: 18,022 hours.

Total Annual Cost: $69,634,713.

Nature and Extent of Confidentiality: There is no need for confidentiality with this information collection.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On June 12, 2015, the Commission released a *First Order on Reconsideration and Notice of Proposed Rulemaking, In the Matter of Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* GN Docket No. 12–268 and MB Docket No. 15–137, FCC 15–67. This document contains proposed rules for channel sharing by and between full power and Class A television stations outside the context of the incentive auction. The proposed rules would allow full power stations to share a single channel with other full power or Class A stations. Full power stations will use FCC Form 2100, Schedule A to apply for a construction permit for the technical facilities it proposes to share with another station. The application for a construction permit to channel share must include a copy of the channel sharing agreement (''CSA'') between the stations Each CSA must include provisions governing certain key aspects of the stations' operations including: access to facilities; allocation of bandwidth within the shared channel; operation maintenance, repair, and modification of facilities; and termination or transfer/assignment of rights to the shared license. We propose to treat applications to channel share outside the auction context as minor change applications—that is, they would not be subject to local public notice requirements or a 30-day petition to deny filing window.

The Commission's proposed rules would also require stations participating in CSAs to provide notice to MVPDs that: (1) No longer will be required to carry the station because of the relocation of the station; (2) currently carry and will continue to be obligated to carry a station that will change channels; or (3) will become obligated to carry the station due to a channel sharing relocation. We propose that the notice contain the following information: (1) Date and time of any channel changes; (2) the channel occupied by the station before and after implementation of the CSA; (3) modification, if any, to antenna position, location, or power levels; (4) stream identification information; and (5) engineering staff contact information. We propose that stations be able to elect whether to provide notice via a letter notification or provide notice electronically, if pre-arranged with the relevant MVPD. We also propose to require that sharee stations provide notice at least 30 days prior to terminating operations on the sharee's channel and that both sharer and sharee stations provide notice at least 30 days prior to initiation of operations on the sharer channel. Should the anticipated date to either cease operations or commence channel sharing operations change, we propose to require that the station(s) send a further notice to affected MVPDs informing them of the new anticipated date(s).

No changes to FCC Form 2100, Schedule A are required for it to be used to file applications for channel sharing outside the auction context; this collection is being changed to reflect the proposed use of the form for a new purpose—to propose channel sharing outside the context of the incentive auction. This collection is also being changed to reflect the burden associated with preparing a CSA in connection with channel sharing as well as the burden associated with providing the required notification to MVPDs.

OMB Control Number: 3060–0932.

Title: FCC Form 2100, Application for Media Bureau Audio and Video Service Authorization, Schedule E (Former FCC Form 301–CA); 47 CFR 74.793(d).

Form Number: FCC Form 2100, Schedule E.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or Tribal governments.

Number of Respondents and Responses: 450 respondents; 500 responses.

Estimated Time per Response: 1–8 hours.

Frequency of Response: On occasion reporting requirement, One time reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is contained in Sections 154(i), 307, 308, 309, and 319 of the Communications Act of 1934, as amended, the Community Broadcasters Protection Act of 1999, and the Middle Class Tax Relief and Job Creation Act of 2012 (''Spectrum Act'').

Total Annual Burden: 4,050 hours.

Total Annual Cost: $2,879,200.

Nature and Extent of Confidentiality: There is no need for confidentiality for this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On June 12, 2015, the Commission released a *First Order on Reconsideration and Notice of Proposed Rulemaking, In the Matter of Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* GN Docket No. 12–268 and MB Docket No. 15–137, FCC 15–67. This document contains proposed rules for channel sharing by and between full power and Class A television stations outside the context of the incentive auction. The proposed rules would allow Class A television stations to share a single channel with other full power or Class A stations. Class A stations will use FCC Form 2100, Schedule E (formerly FCC Form 301–CA) to apply for a construction permit for the technical facilities it proposes to share with another station.

The application for a construction permit to channel share must include a copy of the channel sharing agreement (''CSA'') between the stations Each CSA must include provisions governing certain key aspects of the stations' operations including: access to facilities; allocation of bandwidth within the shared channel; operation maintenance, repair, and modification of facilities; and termination or transfer/assignment of rights to the shared license. We propose to treat applications to channel share outside the auction context as minor change applications—that is, they would not be subject to local public notice requirements or a 30-day petition to deny filing window.

The Commission's proposed rules would also require stations participating in CSAs to provide notice to multichannel video programming distributors (MVPDs) that: (1) No longer will be required to carry the station because of the relocation of the station; (2) currently carry and will continue to be obligated to carry a station that will change channels; or (3) will become obligated to carry the station due to a channel sharing relocation. We propose that the notice contain the following information: (1) Date and time of any channel changes; (2) the channel occupied by the station before and after implementation of the CSA; (3) modification, if any, to antenna position, location, or power levels; (4) stream identification information; and (5) engineering staff contact information. We propose that stations be able to elect whether to provide notice via a letter notification or provide notice electronically, if pre-arranged with the relevant MVPD. We also propose to require that sharee stations provide notice at least 30 days prior to terminating operations on the sharee's channel and that both sharer and sharee stations provide notice at least 30 days prior to initiation of operations on the sharer channel. Should the anticipated date to either cease operations or commence channel sharing operations change, we propose to require that the station(s) send a further notice to affected MVPDs I nforming them of the new anticipated date(s).

No changes to FCC Form 2100, Schedule E are required for it to be used to file applications for channel sharing outside the auction context; this collection is being changed to reflect the proposed use of the form for a new purpose—to propose channel sharing outside the context of the incentive auction. This collection is also being changed to reflect the burden associated with preparing a CSA in connection with channel sharing as well as the burden associated with providing the required notification to MVPDs.

OMB Control Number: 3060–0837.

Title: FCC Form 2100, Application for Media Bureau Audio and Video Service Authorization, Schedule B (Former FCC Form 302–DTV).

Form Number: FCC Form 2100, Schedule B

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents and Responses: 350 respondents; 400 responses.

Estimated Time per Response: 0.5–2 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is contained in Sections 154(i), 303 and 308 of the Communications Act of 1934, as amended, and the Middle Class Tax Relief and Job Creation Act of 2012 (Spectrum Act).

Total Annual Burden: 725 hours.

Total Annual Cost: $160,375.

Nature and Extent of Confidentiality: There is no need for confidentiality for this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On June 12, 2015, the Commission released a *First Order on Reconsideration and Notice of Proposed Rulemaking, In the Matter of Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* GN Docket No. 12–268 and MB Docket No. 15–137, FCC 15–67. This document contains proposed rules for channel sharing by and between full power and Class A television stations outside the context of the incentive auction. The proposed rules would allow full power stations to share a single channel with other full power or Class A stations. After sharing stations have obtained the necessary construction permits, implemented their shared facility, and initiated shared operations, full power sharing stations will use FCC Form 2100, Schedule B (formerly FCC Form 302–DTV) to apply for a license.

In addition, after sharing stations have obtained the necessary construction permits, implemented their shared facility, and initiated shared operations, a station relinquishing its channel would notify the Commission that it has terminated operation on that channel at the same time that the sharing stations file applications for license.

No changes to FCC Form 2100, Schedule B are required for it to be used to file applications for license for channel sharing outside the auction context; this collection is being changed to reflect the proposed use of the form for a new purpose—to apply for a license to channel share outside the context of the incentive auction. This collection is also being changed to reflect the burden associated notifying the Commission that a station relinquishing its channel has terminated operation on that channel.

OMB Control Number: 3060–0928.

Title: FCC Form 2100, Application for Media Bureau Audio and Video Service Authorization, Schedule F (Formerly FCC 302–CA); 47 CFR 73.3572(h) and 47 CFR 73.3700.

Form Number: FCC Form 2100, Schedule F .

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or Tribal governments.

Number of Respondents and Responses: 571 respondents; 621 responses.

Estimated Time per Response: 0.50–2 hours.

Frequency of Response: On occasion reporting requirement and one time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is contained in Sections 154(i), 307, 308, 309, and 319 of the Communications Act of 1934, as amended, the Community Broadcasters Protection Act of 1999, and the Middle Class Tax Relief and Job Creation Act of 2012 (''Spectrum Act'').

Total Annual Burden: 1,167 hours.

Total Annual Cost: $162,735.

Nature and Extent of Confidentiality: There is no need for confidentiality for this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On June 12, 2015, the Commission released a *First Order on Reconsideration and Notice of Proposed Rulemaking, In the Matter of Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* GN Docket No. 12–268 and MB Docket No. 15–137, FCC 15–67. This document contains proposed rules for channel sharing by and between full power and Class A television stations outside the context of the incentive auction. The proposed rules would allow Class A stations to share a single channel with other full power or Class A stations. After sharing stations have obtained the necessary construction permits, implemented their shared facility, and initiated shared operations, Class A sharing stations will use FCC Form 2100, Schedule F (formerly FCC Form 302–CA) to apply for a license.

In addition, after sharing stations have obtained the necessary construction permits, implemented their shared facility, and initiated shared operations, a station relinquishing its channel would notify the Commission that it has terminated operation on that channel at the same time that the sharing stations file applications for license.

No changes to FCC Form 2100, Schedule F are required for it to be used to file applications for license for channel sharing outside the auction context; this collection is being changed to reflect the proposed use of the form for a new purpose—to apply for a license to channel share outside the context of the incentive auction. This collection is also being changed to reflect the burden associated notifying the Commission that a station relinquishing its channel has terminated operation on that channel.

Discussion of Notice of Proposed Rulemaking

I. Notice of Proposed Rulemaking

1. In this *NPRM,* we propose to adopt rules to permit channel sharing by and between full power and Class A television stations outside the context of the incentive auction, including by one or both parties to auction-related CSAs with other entities after those auction-related agreements terminate. Below we propose a regulatory framework for these agreements. We do not propose to distinguish between the ''second generation'' CSAs that EOBC requested, and which would succeed a CSA executed in connection with the auction, and new CSAs between stations that did not channel share in connection with the auction. Accordingly, there is no need to determine whether ''second generation'' CSAs would fall under the Spectrum Act's carriage rights protection because the sharee station '''voluntarily relinquishe[d] spectrum usage rights' under the Spectrum Act 'in order to share a television channel.''' Instead, we propose to authorize non-auction-related CSAs without regard to their relationship to incentive auction-related CSAs. As discussed below, we believe that the carriage rights of parties to such CSAs would be protected under the Communications Act. In the companion *First Order on Reconsideration,* the Commission refines the rules it adopted in the Incentive Auction Report and Order and the preceding Channel Sharing Report and Order to provide greater flexibility and certainty regarding channel sharing agreements (''CSAs'').

A. Public Interest and Legal Authority

2. While the Commission declined in the *Channel Sharing R&O,* 77 FR 30423 (May 23, 2012), to address channel sharing outside the auction context, we now believe it is appropriate to do so. We tentatively conclude that authorizing channel sharing outside the auction context will encourage auction participation by giving prospective channel sharing bidders the knowledge that they can pursue future CSAs when their auction-related agreements expire. But the public interest benefits of channel sharing by full power and Class A stations are likely to extend beyond the auction. When it adopted a general framework for channel sharing by full power and Class A stations in the context of the incentive auction, the Commission concluded that channel sharing will help broadcasters, including existing small, minority-owned, and niche stations, to reduce operating costs and provide broadcasters with additional net income to strengthen operations and improve programming services. We also believe that authorizing channel sharing by full power and Class A stations outside the context of the incentive auction will promote spectral efficiency. We seek comment on our tentative conclusion that authorizing channel sharing by full power and Class A stations outside the context of the action will serve the public interest.

3. We tentatively conclude that the authority conferred on the Commission by Title III of the Communications Act of 1934, as amended, permits us to adopt channel sharing rules for full power and Class A television stations, and seek comment on this tentative conclusion.

B. Carriage Rights

4. We tentatively conclude that the Communications Act provides stations that elect to channel share outside the aegis of the Spectrum Act the same satellite and cable carriage rights on their new shared channels that the stations would have at the shared location if they were not channel sharing. We seek comment on this tentative conclusion. We note that this is consistent with the approach to channel sharing must-carry rights established by Congress in the Spectrum Act.

5. The Communications Act establishes slightly different thresholds for carriage, depending on whether the station is full power or low-power, or commercial or noncommercial, and also depending on whether carriage is sought on a cable or DBS system. The must-carry rights of full-power commercial stations on cable systems are set forth in Section 614 of the Act. Pursuant to Section 614(a), ''[e]ach cable operator shall carry, on the cable system of that operator, the signals of local commercial television stations . . . as provided by this section.'' The term ''local commercial television station'' means ''any full power television broadcast station, other than a qualified noncommercial educational television station . . . licensed and operating on a channel regularly assigned to its community by the Commission that,

with respect to a particular cable system, is within the same television market as the cable system.'' ''Television market'' is defined by Commission's rules as a Designated Market Area (''DMA'').

6. The must-carry rights of full power noncommercial stations on cable systems are set forth in Section 615 of the Act. Section 615(a) provides that ''each cable operator of a cable system shall carry the signals of qualified noncommercial educational television stations in accordance with the provisions of this section.'' A qualified noncommercial educational station can be considered ''local,'' and thus eligible for mandatory carriage on a cable system, in one of two ways. It may either be licensed to a principal community within 50 miles of the system's headend, or place a ''Grade B'' signal over the headend.

7. The must-carry rights of low power stations, including Class A stations, on cable systems are set forth in Section 614(c) of the Act. Under very narrow circumstances, such stations can become ''qualified'' and eligible for must carry. Among the several requirements for reaching ''qualified'' status with respect to a particular cable operator, the station must be ''located no more than 35 miles from the cable system's headend.''

8. The must-carry rights of full power stations (both commercial and noncommercial) on DBS providers are set forth in Section 338 of the Act. A full power ''television broadcast station'' is entitled to request carriage by a DBS provider any time that provider relies on the statutory copyright license to retransmit the signal of any other ''local'' station (*i.e.,* one located in the same DMA). A ''television broadcast station'' is defined as ''an over-the-air commercial or noncommercial television broadcast station licensed by the Commission.'' Low-power stations, including Class A stations do not have DBS carriage rights.

9. Under the foregoing Communications Act provisions, carriage rights are accorded to licensees without regard to whether they occupy a full six megahertz channel or share a channel with another licensee. Nothing in the Communications Act requires a station to occupy an entire six megahertz channel in order to be eligible for must carry rights; rather, the station must simply be a licensee eligible for carriage under the applicable provision of the Communications Act. Thus, the carriage rights conferred by Sections 614, 615, and 338 of the Act apply to channel sharees as they do to any other licensee.

10. Based on these provisions, we tentatively conclude that a sharee station participating in a CSA that moves to a different frequency (that of the ''sharer'' station) remains entitled to must carry rights, but at the sharer's location. For example, in the case of a full power commercial station asserting mandatory cable carriage rights, both before and after the CSA, the station will be a ''full power television broadcast station . . . licensed and operating on a channel regularly assigned to its community by the Commission that, with respect to a particular cable system, is within the same television market as the cable system.'' The same analysis applies with respect to broadcasters qualifying for cable must-carry rights as ''qualified local noncommercial educational television stations,'' and ''qualified low power stations,'' and to broadcasters qualifying for DBS must-carry rights as ''television broadcast stations.''

11. We tentatively conclude that, under the statutory definitions outlined above, the sharee station's carriage rights would be determined at the new shared location. Carriage rights in this situation would be determined under Sections 338, 614, and 615 of the Communications Act in the same manner as they would outside the context of channel sharing, such as where stations change transmitter location, community of license, or DMA. We seek comment on this interpretation.

12. We tentatively conclude that each broadcaster participating in a CSA will continue to be entitled to must-carry rights for a single, primary video stream. Section 614(b)(3) of the Communications Act provides that ''[a] cable operator shall carry in its entirety, on the cable system of that operator, the primary video . . . of each of the local commercial television stations carried on the cable system. . . .'' Although digital technology enables broadcasters to transmit multiple program streams simultaneously on each six MHz channel, the Commission has determined that the must-carry provisions require only that a cable operator carry a single programming stream. We tentatively conclude that a sharee station's transmission of its signal on a different channel following implementation of a CSA does not alter the station's must-carry right to carriage of a single ''primary video'' programming stream.

13. Section 1452(a)(4) provides that sharee stations resulting from the incentive auction have the same carriage rights on the shared channel that each station would have on that channel and from that location if it were not sharing, but this provision by its terms addresses only auction-related CSAs. For this reason, as noted above, we conclude that the carriage rights of sharees outside the context of the incentive auction are determined not by the Spectrum Act but by the carriage provisions of the Communications Act.

14. Notably, however, Section 1452(a)(4) does not simply affirm carriage rights under the Communications Act, it also limits the carriage rights of sharee stations in connection with the incentive auction to those that possessed such rights on November 30, 2010. The date of November 30, 2010 refers to the Commission's issuance of the *2010 Channel Sharing NPRM,* 76 FR 5521 (February 1, 2011), proposing to allow television stations to channel share. In the *2010 Channel Sharing NPRM,* the Commission proposed to ''limit channel sharing to television stations with existing applications, construction permits or licenses as of [November 30, 2010].'' In response, MVPDs expressed concern that allowing new stations that have not yet built facilities to become sharee stations would be a shortcut to obtaining MVPD carriage and thereby artificially increase the number of stations MVPDs are required to carry under the must carry regime. In the Spectrum Act, Congress adopted a different approach than the one proposed in the *2010 Channel Sharing NPRM* by requiring a sharee station resulting from the incentive auction to have ''possessed carriage rights'' on November 30, 2010 in order have carriage rights at its shared location. Consistent with the concerns expressed by MVPDs, this approach precluded stations that were not licensed as of November 30, 2010 from the entitlement to carriage under Section 1452(a)(4) because they did not ''possess[ ] carriage rights'' on that date.

15. Consistent with Section 1452(a)'s objective of avoiding artificially creating new stations that can demand MVPD carriage, we propose that a full power or Class A station will be eligible to become a sharee station outside of the auction context only if it possessed carriage rights under sections 338, 614, or 615 of the Communications Act through an auction-related channel sharing agreement, pursuant to Section 1452(a)(4), or because it was operating on its own non-shared channel immediately prior to entering into a channel sharing agreement. We also seek comment on any alternative approaches that would address Congress's concern that channel sharing not be used as a means to artificially

increase the number of stations that MVPDs are required to carry, including the adoption of November 30, 2010, or some later date certain for the possession of carriage rights as a condition precedent to becoming a sharee. Another approach would be to extend eligibility of a sharee station for carriage rights outside of the auction context only to a station that has constructed and licensed facilities without relying on sharing with another station, regardless of when that station possessed carriage rights. How would this approach apply to a station that entered into an auction-related sharing agreement for a limited term and subsequently seeks to enter into a new sharing agreement outside the auction context with the same or different sharer? Are there any other alternative approaches that we should consider?

16. We do not propose, however, to restrict full power and Class A stations from becoming sharer stations outside of the auction context, regardless of when or whether such stations have obtained carriage rights. We believe this approach is consistent with Section 1452(a)(4), which pertains to the carriage rights of only sharee stations, not sharer stations. Because a sharer station necessarily would have already constructed and licensed its facilities, there is no apparent concern that such stations could use sharing as a shortcut to obtaining MVPD carriage. Moreover, we believe the ability of such stations to serve as sharers would benefit other stations, including those participating in the incentive auction, by increasing the number of potential sharers. We seek comment on this approach.

C. Voluntary and Flexible Channel Sharing

17. We propose to adopt rules and procedures for channel sharing for full power and Class A stations outside the auction context that are generally similar to those we adopted in connection with the incentive auction, as modified in the companion First Order on Reconsideration. We propose that channel sharing be voluntary and flexible, that stations be permitted to choose their channel sharing partners, that channel sharing agreements be required to outline stations' rights with respect to certain matters, and that stations be permitted to assign or transfer their rights under a CSA. We do not intend to be involved in the process of matching licensees interested in channel sharing with potential partners. Instead, full power and Class A stations would decide for themselves whether and with whom to enter into a CSA.

18. In addition, consistent with our approach toward channel sharing in the auction context, we propose to require all stations involved in channel sharing to retain spectrum usage rights sufficient to ensure at least enough capacity to operate one standard definition (''SD'') programming stream at all times. This requirement will ensure that each station has sufficient channel capacity to meet our requirement to ''transmit at least one over-the-air video broadcast signal provided at no direct charge to viewers. . . .'' We propose, however, to allow stations flexibility beyond this ''minimum capacity'' requirement to tailor their agreements and allow a variety of different types of spectrum sharing to meet the individualized programming and economic needs of the parties involved. We do not propose to prescribe a fixed split of the capacity of the six megahertz channel between the stations from a technological or licensing perspective. We propose that all channel sharing stations be licensed for the entire capacity of the six megahertz channel and that the stations be allowed to determine the manner in which that capacity will be divided among themselves subject only to the minimum capacity requirement.

19. In the companion First Order on Reconsideration, we determined that CSAs need not be permanent in nature and modified our rules to permit broadcasters to choose the length of their CSAs. Similarly, we propose to permit term-limited CSAs outside the auction context. We also invite comment on whether we should establish a minimum term for CSAs that are unrelated to the auction. Our goal in permitting term-limited CSAs is to provide flexibility for broadcasters that choose to end the channel sharing relationship while maintaining the opportunity to continue to operate. We are concerned, however, about the potential disruption to viewers that could occur if channel sharing stations enter into short-term CSAs or terminate CSAs early, resulting in frequent channel moves. In addition, we note that MVPDs could experience carriage-related disruptions should there be a multitude of short-term CSAs. Given this, should we establish a minimum term for CSAs, or would this unduly constrain channel sharing partners who may prefer a short-term agreement or want to terminate a CSA early? If we were to establish a minimum term for CSAs, what minimum term would be appropriate (*e.g.,* three years)?

D. Licensing Procedures

20. We also propose to extend to non-auction-related sharing agreements our existing policy framework for the licensing and operation of channel sharing stations. Under this policy, despite sharing a single channel and transmission facility, each full power and Class A station would continue to be licensed separately. Each station would have its own call sign, and each licensee would separately be subject to all of the Commission's obligations, rules, and policies. We seek comment on these proposals.

21. We propose to adopt a two-step process for implementing non-auction-related channel sharing by and between full power and Class A stations outside the auction context. If no technical changes are necessary for sharing, a channel sharing station relinquishing its channel first would file an application for digital construction permit for the same technical facilities as the sharer station. That application would include a copy of the CSA as an exhibit and cross reference the other sharing station(s). The sharer station would not need to take action at this time unless the CSA required technical changes to the sharer station's facilities. If changes to the sharer station facilities were required, each sharing station would file an application for construction permit for identical technical facilities proposing to share the channel, along with the CSA. As a second step, after the sharing stations have obtained the necessary construction permits, implemented their shared facility, and initiated shared operations, a station relinquishing its channel would notify the Commission that it has terminated operation on that channel. At the same time, sharing stations would file applications for license to complete the licensing process. We seek comment on these proposed procedures.

22. We propose to treat applications for a construction permit in order to channel share as minor change applications, similar to the approach we adopted for auction-related channel sharing. We believe that the use of minor change applications is appropriate to facilitate CSAs, particularly if we prohibit sharee stations from relocating outside their community of license in order to channel share, as discussed below. We seek comment on this approach.

23. We also seek comment on an appropriate length of time for channel sharing full power and Class A stations to implement their agreements. In the *Incentive Auction Report & Order,* 79 FR 48442 (August 15, 2014) (IA R&O), we

required that CSAs be implemented within three months after the relinquishing station receives its reverse auction proceeds. In the companion First Order on Reconsideration, we modify our rules to permit post-auction CSAs, and to permit a successful license relinquishment bidder who in its application expresses a present intent to enter a post-auction CSA up to three months from the receipt of auction proceeds to execute and implement a sharing agreement. The exigencies of the auction process do not apply in setting a deadline for stations to implement their CSAs outside the auction context. In the *LPTV Channel Sharing NPRM,* 79 FR 70824 (November 28, 2014), we sought comment on whether to allow channel sharing stations the standard three-year construction period under the rules to implement their sharing deals. Should we also give full power and Class A stations the standard three-year construction period in which to implement CSAs? Is there another timeframe that would be more appropriate?

24. We also seek comment on the degree of flexibility we should provide to potential sharee stations seeking to relocate to take advantage of channel sharing. In the *IA R&O,* we stated that we would permit a sharee to change its community of license only in situations where the sharee cannot meet community of license signal requirements operating from the sharer's transmission site and provided that the sharee chooses a new community of license that, at a minimum, meets the same allotment priorities as its current community. In addition, the Commission stated that it would not allow a bidder to propose a community of license change that would change its DMA. The Commission adopted this restriction on changes in community of license in the auction context in order to promote the goals underlying Section 307(b) of the Communications Act while at the same time avoiding any detrimental impact on the speed and certainty of the auction, as well as on broadcaster participation, that would result from application of the Commission's usual analysis of community of license changes. Outside the auction context, we propose to preclude sharee stations from changing their community of license, and to limit these stations to CSAs with a sharer from whose transmitter site the sharee will continue to meet the community of license signal requirement over its current community of license. Precluding relocation that would require a community of license change would advance our interest in ensuring the provision of service to local communities, avoid viewer disruption, and avoid any potential impact on MVPDs that might result from community of license changes.

25. In the event that we permit sharee stations to propose a change in community of license in order to channel share, we invite comment on how we should evaluate such requests. Should we use our traditional television allotment rules and policies, pursuant to which a proposed full power television sharee would have to file a petition for rulemaking and demonstrate that the requested change in community would result in a preferential arrangement of television allotments under Section 307(b) and the Commission's allotment priorities? Alternatively, should we adopt a more streamlined approach that would dispense with a rulemaking? Outside the auction context, the concerns we expressed in the IA R&O about the potential impact on the auction of our usual analysis of community of license changes are not relevant. We seek comment on these possible approaches to community of license changes.

E. Channel Sharing Operating Rules

26. We propose to adopt channel sharing operating rules similar to those adopted for full power and Class A television stations in the IA R&O, as modified by the First Order on Reconsideration. In the IA R&O, we determined that CSAs for full power and Class A stations must include provisions governing certain key aspects of their operations: (1) Access to facilities, including whether each licensee will have unrestrained access to the shared transmission facilities; (2) allocation of bandwidth within the shared channel; (3) operation, maintenance, repair, and modification of facilities, including a list of all relevant equipment, a description of each party's financial obligations, and any relevant notice provisions; and (4) termination or transfer/assignment of rights to the shared licenses, including the ability of a new licensee to assume the existing CSA. We propose to require full power and Class A CSAs outside the auction context to contain the same key information. We also propose to reserve the right to review CSA provisions and require modification of any that do not comply with these requirements or the Commission's rules. We seek comment on these proposals.

27. *Termination, Assignment/Transfer, and Relinquishment of Channel Sharing Licenses.* We propose to apply to full power and Class A CSAs entered into outside the auction context the same rules regarding termination, assignment/transfer, and voluntary relinquishment of channel sharing rights that we adopted in the IA R&O, as modified by the First Order on Reconsideration. Under this proposed approach we would allow rights under a CSA to be assigned or transferred, subject to the requirements of Section 310 of the Communications Act, our rules, and the requirement that the assignee or transferee undertake to comply with the applicable CSA. In the event a channel sharing party's license is terminated due to voluntary relinquishment, revocation, or failure to renew, consistent with the approach we adopt in the First Order on Reconsideration we propose that the relinquished spectrum usage rights in the shared channel revert to the other sharing parties. Further, where only one sharing partner remains on a channel after its partner relinquishes its license, it may request that its channel return to non-shared status. We seek comment on this approach.

F. Channel Sharing Between Full Power and Class A Stations

28. In the IA R&O, we allowed channel sharing between full power and Class A television stations despite the fact that each operate with different technical rules. We concluded that the Class A television station sharing a full power television station's channel after the incentive auction would be permitted to operate under the part 73 rules governing power levels and interference. Similarly, we concluded that a full power station sharing a Class A station's channel after the incentive auction would be permitted to operate under the Part 74 power level and interference rules. We propose herein to permit channel sharing between full power and Class A stations outside the auction context and to apply to such agreements the same rules we adopted in the IA R&O. We seek comment on this approach.

G. Reimbursement

29. With respect to CSAs entered into outside the auction context, we do not propose to adopt rules regarding reimbursement of costs imposed on MVPDs as a result of CSAs. We note that our current rules do not require reimbursement of MVPD costs in connection with channel changes or other changes that modify carriage obligations outside the auction context. Further, the reimbursement provisions of the Spectrum Act apply only to CSAs made in connection with the incentive auction. Thus, by the plain language of

Section 1452, reimbursement under the Spectrum Act applies only to costs associated with channel sharing bids; reimbursement does not extend to CSAs unrelated to the auction.

30. Accordingly, costs associated with channel sharing outside the auction context will be borne by broadcasters and MVPDs in the same manner as these parties are traditionally responsible for costs associated with television station channel moves. For example, to obtain carriage, a local commercial television station must be capable of delivering a good quality signal to a cable system headend or bear responsibility for the cost of delivering such a good quality signal. A television station that cannot deliver a good quality signal to a cable system headend it previously could reach with its over-the-air signal may bear costs associated with use of alternative means, such as fiber or microwave, to deliver a good quality signal to the headend. In addition, a television station that relocates may gain carriage on a different cable or satellite system(s), which may incur costs for new equipment or other changes associated with adding the channel.

H. Notice to MVPDs

31. Similar to the requirement we adopted in the IA R&O, we propose to require stations participating in CSAs to provide notice to those MVPDs that: (1) No longer will be required to carry the station because of the relocation of the station; (2) currently carry and will continue to be obligated to carry a station that will change channels; or (3) will become obligated to carry the station due to a channel sharing relocation. We propose that the notice contain the following information: (1) Date and time of any channel changes; (2) the channel occupied by the station before and after implementation of the CSA; (3) modification, if any, to antenna position, location, or power levels; (4) stream identification information; and (5) engineering staff contact information. We propose that stations be able to elect whether to provide notice via a letter notification or provide notice electronically, if pre-arranged with the relevant MVPD. We also propose to require that sharee stations provide notice at least 30 days prior to terminating operations on the sharee's channel and that both sharer and sharee stations provide notice at least 30 days prior to initiation of operations on the sharer channel. Should the anticipated date to either cease operations or commence channel sharing operations change, we propose to require that the station(s) send a further notice to affected MVPDs informing them of the new anticipated date(s). We seek comment on these proposals.

II. Procedural Matters

A. Initial Regulatory Flexibility Act Analysis

1. As required by the Regulatory Flexibility Act of 1980, as amended (''RFA''), the Commission has prepared this Initial Regulatory Flexibility Analysis (''IRFA'') concerning the possible significant economic impact on small entities of the policies and rules proposed in the *Notice of Proposed Rulemaking* (''*NPRM*''). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided on the first page of the *NPRM.* The Commission will send a copy of the *NPRM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (''SBA''). In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.

2. The *NPRM* proposes to adopt rules to permit channel sharing by and between full power and Class A television stations outside the context of the incentive auction, including by one or both parties to auction-related CSAs with other entities after those auction-related agreements terminate. Our goal is to provide clarification regarding the scope of channel sharing outside the context of the incentive auction in order to encourage auction participation. In addition, our goal is to extend the public interest benefits of channel sharing to full power and Class A stations that are not participating in the auction. The Commission has previously concluded that channel sharing can help broadcasters, including existing small, minority-owned, and niche stations, to reduce operating costs and provide broadcasters with additional net income to strengthen operations and improve programming services. Thus, extending channel sharing to full power and Class A stations outside the auction context would permit these stations to take advantage of the potential benefits of channel sharing.

3. The proposed action is authorized pursuant to Sections 1, 4, 301, 303, 307, 308, 309, 310, 316, 319, 338, 403, 614, and 615 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, 301, 303, 307, 308, 309, 310, 316, 319, 338, 403, 614 and 615.

4. 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, 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. Below, we provide a description of such small entities, as well as an estimate of the number of such small entities, where feasible.

5. Wired Telecommunications Carriers. The North American Industry Classification System (''NAICS'') defines ''Wired Telecommunications Carriers'' as follows: ''This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services; wired (cable) audio and video programming distribution; and wired broadband Internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' The SBA has developed a small business size standard for wireline firms for the broad economic census category of ''Wired Telecommunications Carriers.'' Under this category, a wireline business is small if it has 1,500 or fewer employees. Census data for 2007 shows that there were 3,188 firms that operated for the entire year. Of this total, 3,144 firms had fewer than 1,000 employees, and 44 firms had 1,000 or more employees. Therefore, under this size standard, we estimate that the majority of businesses can be considered small entities.

6. Cable Television Distribution Services. Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers, which category is defined above. The SBA has developed a small business size standard for this category, which is: All

such businesses having 1,500 or fewer employees. Census data for 2007 shows that there were 3,188 firms that operated for the entire year. Of this total, 3,144 firms had fewer than 1,000 employees, and 44 firms had 1,000 or more employees. Therefore, under this size standard, we estimate that the majority of businesses can be considered small entities.

7. Cable Companies and Systems. The Commission has developed its own small business size standards for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers nationwide. Industry data shows that there are currently 660 cable operators. Of this total, all but ten cable operators nationwide are small under this size standard. In addition, under the Commission's rate regulation rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Current Commission records show 4,629 cable systems nationwide. Of this total, 4,057 cable systems have less than 20,000 subscribers, and 572 systems have 20,000 or more subscribers, based on the same records. Thus, under this standard, we estimate that most cable systems are small entities.

8. Cable System Operators (Telecom Act Standard). The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' There are approximately 54 million cable video subscribers in the United States today. Accordingly, an operator serving fewer than 540,000 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that all but ten incumbent cable operators are small entities under this size standard. We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed $250,000,000, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

9. Direct Broadcast Satellite (DBS) Service. DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic ''dish'' antenna at the subscriber's location. DBS, by exception, is now included in the SBA's broad economic census category, Wired Telecommunications Carriers, which was developed for small wireline businesses. Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees. Census data for 2007 shows that there were 3,188 firms that operated for that entire year. Of this total, 2,940 firms had fewer than 100 employees, and 248 firms had 100 or more employees. Therefore, under this size standard, the majority of such businesses can be considered small entities. However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled ''Cable and Other Program Distribution.'' As of 2002, the SBA defined a small Cable and Other Program Distribution provider as one with $12.5 million or less in annual receipts. Currently, only two entities provide DBS service, which requires a great investment of capital for operation: DIRECTV and DISH Network. Each currently offers subscription services. DIRECTV and DISH Network each report annual revenues that are in excess of the threshold for a small business. Because DBS service requires significant capital, we believe it is unlikely that a small entity as defined under the superseded SBA size standard would have the financial wherewithal to become a DBS service provider.

10. Television Broadcasting. This economic census category ''comprises establishments primarily engaged in broadcasting images together with sound.'' The SBA has created the following small business size standard for such businesses: Those having $38.5 million or less in annual receipts. The 2007 U.S. Census indicates that 808 firms in this category operated in that year. Of that number, 709 had annual receipts of $25,000,000 or less, and 99 had annual receipts of more than $25,000,000. Because the Census has no additional classifications that could serve as a basis for determining the number of stations whose receipts exceeded $38.5 million in that year, we conclude that the majority of television broadcast stations were small under the applicable SBA size standard.

11. Apart from the U.S. Census, the Commission has estimated the number of licensed commercial television stations to be 1,390 stations. Of this total, 1,221 stations (or about 88 percent) had revenues of $38.5 million or less, according to Commission staff review of the BIA Kelsey Inc. Media Access Pro Television Database (BIA) on July 2, 2014. In addition, the Commission has estimated the number of licensed noncommercial educational (NCE) television stations to be 395. NCE stations are non-profit, and therefore considered to be small entities. Therefore, we estimate that the majority of television broadcast stations are small entities.

12. We note, however, that in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, an element of the definition of ''small business'' is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply does not exclude any television station from the definition of a small business on this basis and is therefore possibly over-inclusive to that extent.

13. Class A TV Stations. The same SBA definition that applies to television broadcast stations would apply to licensees of Class A television stations. As noted above, the SBA has created the following small business size standard for this category: Those having $38.5 million or less in annual receipts. The Commission has estimated the number of licensed Class A television stations to be 405. Given the nature of these services, we will presume that these licensees qualify as small entities under the SBA definition.

14. The *NPRM* proposes several regulatory requirements that will require either new information collections or revisions to existing collections. The *NPRM* proposes to require full power and Class A stations seeking to channel share outside the auction context to follow a two-step licensing process—first filing an application for construction permit and then an application for license. These existing collections will need to be revised to reflect these new channel-sharing related filings and the

associated burden estimates. In addition, the *NPRM* proposes that channel sharing stations submit their channel sharing agreements (CSAs) with the Commission and be required to include certain provisions in their CSAs. The existing collection concerning the execution and filing of CSAs will need to be revised. Finally, the *NPRM* proposes to require channel sharing stations to notify affected MVPDs.

15. 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, standard; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

16. The *NPRM* proposes to permit channel sharing by and between full power and Class A television stations outside the context of the incentive auction and seeks comment on that proposal as well as a proposed regulatory framework for such agreements. The Commission has previously concluded that channel sharing can help broadcasters, including existing small, minority-owned, and niche stations, to reduce operating costs and provide broadcasters with additional net income to strengthen operations and improve programming services. Thus, the proposals in the *NPRM* may help smaller broadcasters conserve resources. In addition, the *NPRM* proposes licensing and operating rules for channel sharing by and between full power and Class A stations that are designed to minimize impact on small entities. The rules provide a streamlined method for reviewing and licensing channel sharing for these stations and seek comment on whether to adopt a streamlined approach for reviewing proposals for a change in community of license of sharee stations. The Commission will consider all comments submitted in connection with the *NPRM,* including any suggested alternative approaches to channel sharing by full power and Class A stations that would reduce the burden and costs on smaller entities.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

17. None.

B. Paperwork Reduction Act Analysis

18. This *NPRM* contains proposed new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, *see* 44 U.S.C. 3507. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), we seek specific comment on how we might further reduce the information collection burden for small business concerns with fewer than 25 employees.

C. Ex Parte Presentations

19. The proceeding this *NPRM* initiates shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules.[1] 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.

[1] 47 CFR 1.1200.

D. Comment Filing Procedures

20. Pursuant to sections 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 8:00 a.m. to 7:00 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 DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format),

send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

21. Additional Information: For additional information on this *NPRM,* please contact Kim Matthews of the Media Bureau, Policy Division, *Kim.Matthews@fcc.gov*, (202) 418–2154.

III. Ordering Clauses

22. IT IS ORDERED that, pursuant to the authority contained in Sections 1, 4, 301, 303, 307, 308, 309, 310, 316, 319, 338, 403, 614, and 615 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, 301, 303, 307, 308, 309, 310, 316, 319, 338, 403, 614 and 615, this Notice of Proposed Rulemaking IS ADOPTED.

23. IT IS FURTHER ORDERED that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this NPRM, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 73

Broadcast radio.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336 and 339.

■ 2. Add § 73.3800 to read as follows:

§ 73.3800 Full power television channel sharing outside the auction context.

(a) *Channel sharing generally.* (1) Subject to the provisions of this section, full power television stations may voluntarily seek Commission approval to share a single six megahertz channel with other full power television and Class A television stations.

(2) Each station sharing a single channel pursuant to this section shall continue to be licensed and operated separately, have its own call sign, and be separately subject to all applicable Commission obligations, rules, and policies.

(b) *Licensing of channel sharing stations.* A full power television channel sharing station relinquishing its channel must file an application for the initial channel sharing construction permit (FCC Form 2100), include a copy of the channel sharing agreement as an exhibit, and cross reference the other sharing station(s). Any engineering changes necessitated by the channel sharing agreement may be included in the station's application. Upon initiation of shared operations, the station relinquishing its channel must notify the Commission that it has terminated operation pursuant to § 73.1750 and each sharing station must file an application for license (FCC Form 2100).

(c) *Deadline for implementing channel sharing agreements.* Channel sharing agreements submitted pursuant to this section must be implemented within three years of the grant of the initial channel sharing construction permit.

(d) *Channel sharing agreements (CSAs).* (1) Channel sharing agreements submitted under this section must contain provisions outlining each licensee's rights and responsibilities regarding:

(i) Access to facilities, including whether each licensee will have unrestrained access to the shared transmission facilities;

(ii) Operation, maintenance, repair, and modification of facilities, including a list of all relevant equipment, a description of each party's financial obligations, and any relevant notice provisions; and

(iii) Transfer/assignment of a shared license, including the ability of a new licensee to assume the existing CSA; and

(iv) Termination of the license of a party to the CSA, including reversion of spectrum usage rights to the remaining parties to the CSA.

(2) Channel sharing agreements submitted under this section must include a provision affirming compliance with the channel sharing requirements in this section including a provision requiring that each channel sharing licensee shall retain spectrum usage rights adequate to ensure a sufficient amount of the shared channel capacity to allow it to provide at least one Standard Definition (SD) program stream at all times.

(e) *Termination and assignment/transfer of shared channel.* Upon termination of the license of a party to a CSA, the spectrum usage rights covered by that license may revert to the remaining parties to the CSA. Such reversion shall be governed by the terms of the CSA in accordance with paragraph (d)(1)(iv) of this section. If upon termination of the license of a party to a CSA only one party to the CSA remains, the remaining licensee may file an application to change its license to non-shared status using FCC Form 2100, Schedule B (for a full power licensee) or F (for a Class A licensee).

(f) *Notice to MVPDs.* (1) Stations participating in channel sharing agreements must provide notice to MVPDs that:

(i) No longer will be required to carry the station because of the relocation of the station;

(ii) Currently carry and will continue to be obligated to carry a station that will change channels; or

(iii) Will become obligated to carry the station due to a channel sharing relocation.

(2) The notice required by this section must contain the following information:

(i) Date and time of any channel changes;

(ii) The channel occupied by the station before and after implementation of the CSA;

(iii) Modification, if any, to antenna position, location, or power levels;

(iv) Stream identification information; and

(v) Engineering staff contact information.

(3) Sharee stations (those relinquishing a channel in order to share) must provide notice as required by this section at least 30 days prior to terminating operations on the sharee's channel. Sharer stations (those hosting a sharee as part of a channel sharing agreement) and sharee stations must provide notice as required by this section at least 30 days prior to initiation of operations on the sharer channel. Should the anticipated date to either cease operations or commence channel sharing operations change, the stations must send a further notice to affected MVPDs informing them of the new anticipated date(s).

(4) Notifications provided to cable systems pursuant to this section must be either mailed to the system's official address of record provided in the cable system's most recent filing in the FCC's Cable Operations and Licensing System (COALS) Form 322, or emailed to the system if the system has provided an email address. For all other MVPDs, the letter must be addressed to the official corporate address registered with their State of incorporation.

■ 3. Add § 73.6028 to read as follows:

§ 73.6028 Class A Television channel sharing outside the auction context.

(a) *Channel sharing generally.* (1) Subject to the provisions of this section, Class A television stations may voluntarily seek Commission approval

to share a single six megahertz channel with other Class A and full power television stations.

(2) Each station sharing a single channel pursuant to this section shall continue to be licensed and operated separately, have its own call sign, and be separately subject to all of the Commission's obligations, rules, and policies.

(b) *Licensing of channel sharing stations.* A full power television channel sharing station relinquishing its channel must file an application for the initial channel sharing construction permit (FCC Form 2100), include a copy of the channel sharing agreement as an exhibit, and cross reference the other sharing station(s). Any engineering changes necessitated by the channel sharing agreement may be included in the station's application. Upon initiation of shared operations, the station relinquishing its channel must notify the Commission that it has terminated operation pursuant to § 73.1750 and each sharing station must file an application for license (FCC Form 2100).

(c) *Deadline for implementing channel sharing agreements.* Channel sharing agreements submitted pursuant to this section must be implemented within three years of the grant of the initial channel sharing construction permit.

(d) *Channel sharing agreements (CSAs).* (1) Channel sharing agreements submitted under this section must contain provisions outlining each licensee's rights and responsibilities regarding:

(i) Access to facilities, including whether each licensee will have unrestrained access to the shared transmission facilities;

(ii) Operation, maintenance, repair, and modification of facilities, including a list of all relevant equipment, a description of each party's financial obligations, and any relevant notice provisions; and

(iii) Termination or transfer/assignment of rights to the shared licenses, including the ability of a new licensee to assume the existing CSA.

(2) Channel sharing agreements submitted under this section must include a provision affirming compliance with the channel sharing requirements in this section including a provision requiring that each channel sharing licensee shall retain spectrum usage rights adequate to ensure a sufficient amount of the shared channel capacity to allow it to provide at least one Standard Definition (SD) program stream at all times.

(e) *Termination and assignment/transfer of shared channel.* Upon termination of the license of a party to a CSA, the spectrum usage rights covered by that license may revert to the remaining parties to the CSA. Such reversion shall be governed by the terms of the CSA in accordance with paragraph (d)(1)(iv) of this section. If upon termination of the license of a party to a CSA only one party to the CSA remains, the remaining licensee may file an application to change its license to non-shared status using FCC Form 2100, Schedule B (for a full power licensee) or F (for a Class A licensee).

(f) *Notice to MVPDs.* (1) Stations participating in channel sharing agreements must provide notice to MVPDs that:

(i) No longer will be required to carry the station because of the relocation of the station;

(ii) Currently carry and will continue to be obligated to carry a station that will change channels; or

(iii) Will become obligated to carry the station due to a channel sharing relocation.

(2) The notice required by this section must contain the following information:

(i) Date and time of any channel changes;

(ii) The channel occupied by the station before and after implementation of the CSA;

(iii) Modification, if any, to antenna position, location, or power levels;

(iv) Stream identification information; and

(v) Engineering staff contact information.

(3) Sharee stations (those relinquishing a channel in order to share) must provide notice as required by this section at least 30 days prior to terminating operations on the sharee's channel. Sharer stations (those hosting a sharee as part of a channel sharing agreement) and sharee stations must provide notice as required by this section at least 30 days prior to initiation of operations on the sharer channel. Should the anticipated date to either cease operations or commence channel sharing operations change, the station(s) must send a further notice to affected MVPDs informing them of the new anticipated date(s).

(4) Notifications provided to cable systems pursuant to this section must be either mailed to the system's official address of record provided in the cable system's most recent filing in the FCC's Cable Operations and Licensing System (COALS) Form 322, or emailed to the system if the system has provided an email address. For all other MVPDs, the letter must be addressed to the official corporate address registered with their State of incorporation.

[FR Doc. 2015–16537 Filed 7–13–15; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 4, 9, 17, 22, and 52

[FAR Case 2014–025; Docket No. 2014–0025; Sequence No. 1]

RIN 9000–AM81

Federal Acquisition Regulation; Fair Pay and Safe Workplaces; Extension of Time for Comments

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: DoD, GSA, and NASA issued a proposed rule (FAR Case 2014–025) on May 28, 2015, amending the Federal Acquisition Regulation (FAR) to implement Executive Order (E.O.) 13673, ''Fair Pay and Safe Workplaces,'' which is designed to improve contractor compliance with labor laws and increase efficiency and cost savings in Federal contracting. The deadline for submitting comments is being extended from July 27, 2015, to August 11, 2015, to provide additional time for interested parties to provide comments on the FAR case. The due date for comments on DOL's Guidance for Executive Order 13673, ''Fair Pay and Safe Workplaces'', which also implements the E.O., is being extended to August 11, 2015 as well.

DATES: The comment period for the proposed rule published on May 28, 2015 (80 FR 30548), is extended. Submit comments by August 11, 2015.

ADDRESSES: Submit comments in response to FAR Case 2014–025 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''FAR Case 2014–025''. Select the link ''Comment Now'' that corresponds with ''FAR Case 2014–025.'' Follow the instructions provided at the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2014–025'' on your attached document.

• *Mail:* General Services Administration, Regulatory Secretariat (MVCB), ATTN: Ms. Flowers, 1800 F Street NW., 2nd Floor, Washington, DC 20405.

Instructions: Please submit comments only and cite FAR Case 2014–025, in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov*, including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, Procurement Analyst, at 202–501–0650, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite FAR Case 2014–025.

SUPPLEMENTARY INFORMATION:

Background

DoD, GSA, NASA published a proposed rule in the **Federal Register** at 80 FR 30548, May 28, 2015. The comment period is extended to provide additional time for interested parties to submit comments on the FAR case until August 11, 2015.

List of Subjects in 48 CFR Parts 1, 4, 9, 17, 22, and 52

Government procurement.

Dated: July 9, 2015.

Edward Loeb,

Acting Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2015–17282 Filed 7–13–15; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 224

[Docket No. 150506424–5424–01]

RIN 0648–XD940

Endangered and Threatened Wildlife and Plants; 12-Month Finding and Proposed Rule To List Three Angelshark Species as Endangered Under the Endangered Species Act

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

ACTION: Proposed rule; 12-month petition finding; request for comments.

SUMMARY: We, NMFS, have completed a comprehensive status review under the Endangered Species Act (ESA) for three foreign marine angelshark species in response to a petition to list those species. These three species are the sawback angelshark (*Squatina aculeata*), smoothback angelshark (*Squatina oculata*), and common angelshark (*Squatina squatina*). Based on the best scientific and commercial information available, including the status review report (Miller 2015), and after taking into account efforts being made to protect these species, we have determined that these three angelshark species warrant listing as endangered under the ESA. We are not proposing to designate critical habitat because the geographical areas occupied by these species are entirely outside U.S. jurisdiction, and we have not identified any unoccupied areas that are currently essential to the conservation of any of these species. We are soliciting comments on our proposal to list these three angelshark species.

DATES: Comments on this proposed rule must be received by September 14, 2015. Public hearing requests must be made by August 28, 2015.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2015–0084, by either of the following methods:

• *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0084.* Click the ''Comment Now'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Maggie Miller, NMFS Office of Protected Resources (F/PR3), 1315 East West Highway, Silver Spring, MD 20910, USA.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

You can find the petition, status review report, **Federal Register** notices, and the list of references electronically on our Web site at *http://www.nmfs.noaa.gov/pr/species/petition81.htm.*

FOR FURTHER INFORMATION CONTACT: Maggie Miller, NMFS, Office of Protected Resources (OPR), (301) 427–8403.

SUPPLEMENTARY INFORMATION:

Background

On July 15, 2013, we received a petition from WildEarth Guardians to list 81 marine species or subpopulations as threatened or endangered under the Endangered Species Act (ESA). This petition included species from many different taxonomic groups, and we prepared our 90-day findings in batches by taxonomic group. We found that the petitioned actions may be warranted for 24 of the species and 3 of the subpopulations and announced the initiation of status reviews for each of the 24 species and 3 subpopulations (78 FR 63941, October 25, 2013; 78 FR 66675, November 6, 2013; 78 FR 69376, November 19, 2013; 79 FR 9880, February 21, 2014; and 79 FR 10104, February 24, 2014). This document addresses the findings for 3 of those 24 species: the sawback angelshark (*Squatina aculeata*), smoothback angelshark (*Squatina oculata*), and the common angelshark (*Squatina squatina*). The status of the findings and relevant **Federal Register** notices for the other 21 species and 3 subpopulations can be found on our Web site at *http://www.nmfs.noaa.gov/pr/species/petition81.htm.*

We are responsible for determining whether species are threatened or endangered under the ESA (16 U.S.C. 1531 *et seq.*). To make this determination, we consider first whether a group of organisms constitutes a ''species'' under the ESA, then whether the status of the species qualifies it for listing as either threatened or endangered. Section 3 of the ESA defines a ''species'' to include ''any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.'' On February 7, 1996, NMFS and the U.S. Fish and Wildlife Service (USFWS; together, the Services) adopted a policy describing what constitutes a distinct population segment (DPS) of a taxonomic species (the DPS Policy; 61 FR 4722). The DPS Policy identified two elements that must be considered when identifying a DPS: (1) The discreteness of the population segment in relation to the remainder of the species (or subspecies) to which it belongs; and (2) the significance of the population segment to the remainder of the species

(or subspecies) to which it belongs. As stated in the DPS Policy, Congress expressed its expectation that the Services would exercise authority with regard to DPSs sparingly and only when the biological evidence indicates such action is warranted. Based on the scientific information available, we determined that the sawback angelshark (*Squatina aculeata*), smoothback angelshark (*Squatina oculata*), and common angelshark (*Squatina squatina*) are ''species'' under the ESA. There is nothing in the scientific literature indicating that any of these species should be further divided into subspecies or DPSs.

Section 3 of the ESA defines an endangered species as ''any species which is in danger of extinction throughout all or a significant portion of its range'' and a threatened species as one ''which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' We interpret an ''endangered species'' to be one that is presently in danger of extinction. A ''threatened species,'' on the other hand, is not presently in danger of extinction, but is likely to become so in the foreseeable future (that is, at a later time). In other words, the primary statutory difference between a threatened and endangered species is the timing of when a species may be in danger of extinction, either presently (endangered) or in the foreseeable future (threatened).

When we consider whether a species might qualify as threatened under the ESA, we must consider the meaning of the term ''foreseeable future.'' It is appropriate to interpret ''foreseeable future'' as the horizon over which predictions about the conservation status of the species can be reasonably relied upon. The foreseeable future considers the life history of the species, habitat characteristics, availability of data, particular threats, ability to predict threats, and the reliability to forecast the effects of these threats and future events on the status of the species under consideration. Because a species may be susceptible to a variety of threats for which different data are available, or which operate across different time scales, the foreseeable future is not necessarily reducible to a particular number of years.

Section 4(a)(1) of the ESA requires us to determine whether any species is endangered or threatened due to any one or a combination of the following five threat factors: the present or threatened destruction, modification, or curtailment of its habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; the inadequacy of existing regulatory mechanisms; or other natural or manmade factors affecting its continued existence. We are also required to make listing determinations based solely on the best scientific and commercial data available, after conducting a review of the species' status and after taking into account efforts being made by any state or foreign nation to protect the species.

Status Review

The status review for the three angelshark species addressed in this finding was conducted by a NMFS biologist in the Office of Protected Resources (Miller 2015). In order to complete the status review, information was compiled on each species' biology, ecology, life history, threats, and conservation status from information contained in the petition, our files, a comprehensive literature search, and consultation with experts. We also considered information submitted by the public in response to our petition finding. In assessing extinction risk of these three species, we considered the demographic viability factors developed by McElhany *et al.* (2000). The approach of considering demographic risk factors to help frame the consideration of extinction risk has been used in many of our status reviews, including for Pacific salmonids, Pacific hake, walleye pollock, Pacific cod, Puget Sound rockfishes, Pacific herring, scalloped and great hammerhead sharks, and black abalone (see *http://www.nmfs.noaa.gov/pr/species/* for links to these reviews). In this approach, the collective condition of individual populations is considered at the species level according to four demographic viability factors: abundance, growth rate/productivity, spatial structure/connectivity, and diversity. These viability factors reflect concepts that are well-founded in conservation biology and that individually and collectively provide strong indicators of extinction risk.

The draft status review report (Miller 2015) was submitted to independent peer reviewers; comments and information received from peer reviewers were addressed and incorporated as appropriate before finalizing the draft report. The status review report is available on our Web site (see **ADDRESSES** section) and the peer review report is available at *http://www.cio.noaa.gov/services_programs/prplans/PRsummaries.html.* Below we summarize information from the report and our analysis of the status of the three angelshark species. Further details can be found in Miller (2015).

Species Descriptions

Angelsharks belong to the family Squatinidae (Order: Squatiniformes) and are recognized by their batoid shape. Species identification of angelsharks is mainly conducted through the examination of external characteristics (such as dorsal spines, nasal barbels, color, etc.), but the taxonomy is often considered to be problematic since several species are morphologically similar, with overlapping characteristics (Vaz and de Carvalho 2013). In 1984, Compagno (1984) identified and described 12 *Squatina* species. Since 1984, 11 additional *Squatina* species have been recognized (Froese and Pauly 2014), bringing the present total to 23 identified *Squatina* species. Recent research suggests there are currently undescribed species, indicating that the taxonomy of the angelsharks may still be unresolved (Stelbrink *et al.* 2010; Vaz and de Carvalho 2013).

Angelsharks can be found worldwide in temperate and tropical waters. The three species proposed for listing are found in coastal and outer continental shelf sediment habitats in the Mediterranean Sea and eastern Atlantic. These species are bottom dwellers and prefer to spend most of their time buried in the sand or mud (Compagno 1984). To feed, they generally lie in wait for prey to approach before attacking (ambush predators), and, based on their diet, they are considered to be high trophic level predators (trophic level = 4.0; Cortés 1999). In terms of reproduction, all three angelshark species are ovoviviparous, meaning embryos develop inside eggs that hatch within the female's body, with young born live. However, according to Sunye and Vooren (1997), *Squatina* species also have a uterine–cloacal chamber (the chamber where embryos complete their final development stage) that is open to the external environmental through a cloacal vent. This anatomical configuration is thought to be the reason why *Squatina* species are observed easily aborting embryos during capture or handling (Sunye and Vooren 1997; Capapé *et al.* 2005). Additional species-specific descriptions are provided below.

Squatina aculeata (Cuvier, 1829), the sawback angelshark, is distinguished from other angelsharks by its row of dorsal spines (sword-like bony structure) down the middle of its body, with spines also located on the snout and above the eyes. The sawback angelshark also has fringed nasal barbels and anterior nasal flaps on its body

(Compagno 1984). It can be found on the continental shelf and upper slope in depths of 30 m to 500 m, and feeds on small sharks, jacks, and benthic invertebrates, including cephalopods and crustaceans (Compagno 1984; Corsini and Zava 2007). Gestation for the species likely lasts around a year, with litter sizes ranging from 8 to 12 pups and size at birth estimated to be around 30 cm–35 cm total length (TL) (Capapé *et al.* 2005). *Squatina aculeata* displays sexual dimorphism, with males maturing at around 120 cm–124 cm TL and reaching maximum sizes of around 152 cm TL, and females maturing at larger sizes, around 137 cm–143 cm TL, and attaining larger maximum sizes (175 cm–180 cm TL) (Capapé *et al.* 2005; Serena 2005).

Squatina oculata (Bonaparte, 1840), the smoothback angelshark, is distinguished from other angelsharks by its big thorns (sharp, tooth-like structures on the skin) that are present on the snout and above the eyes, a first dorsal fin that originates well behind the pelvic rear tips, and noticeable white spots in symmetrical patterns on the pectoral fins and body (Compagno 1984). The species occurs in depths of 20 m to 560 m on the continental shelf and upper slopes, but is more commonly found in depths between 50 and 100 m (Compagno 1984; Serena 2005). *Squatina oculata* generally feeds on small fishes, including goatfishes, and reaches sizes of at least 145 cm TL (males) and 160 cm TL (females) (Compagno 1984). Gestation likely lasts, at a minimum, around a year, with litter sizes ranging from 5 to 8 pups and size at birth around 23 cm–27 cm TL (Capapé *et al.* 1990, 2002). Maturity is attained at around 71 cm TL for males and around 90 cm TL for females (Compagno 1984; Capapé *et al.* 1990, 2002).

Squatina squatina (Linnaeus, 1758), the common angelshark, is distinguished from other angelsharks by its simple and conical nasal barbels, high and wide pectoral fins, small spines that are present on snout and above eyes and may also be present down middle of back, and lateral trunk denticles that are very narrow with sharp-cusped crowns (Compagno 1984). Unlike the other two angelshark species, *S. squatina* is generally found in shallower water, from inshore areas out to the continental shelf in depths of 5 m to 150 m (OSPAR Commission 2010). It may also be observed in estuaries and brackish waters (OSPAR Commission 2010). *Squatina squatina* has a diet that consists mostly of bony fishes, especially flatfishes, and other demersal animals (skates, crustaceans, molluscs), with the occasional eelgrass and seabird (Day 1880; Compagno 1984; Ellis *et al.* 1996; Agri-Food & Biosciences Institute 2009; Narváez 2012). Gestation for *S. squatina* in the Canary Islands is estimated to be ±6 months with a 3-year reproductive cycle (Osaer 2009). Elsewhere in its range, gestation period is unknown but possibly lasts from 8 to 12 months, with potentially a 2-year reproductive cycle (Tonachella 2010; ICES 2014). Litter sizes range from 7 to 25 pups, with size at birth from 24 cm–30 cm TL (Osaer 2009; Tonachella 2010). Males mature between 80 cm and 132 cm TL, with maximum sizes attained at 183 cm TL, and females mature between 126 cm and 169 cm TL and attain maximum sizes of up to 244 cm TL (Compagno 1984; Capapé *et al.* 1990; Quigley 2006; Tonachella 2010). In the Canary Islands, Osaer (2009) found length at first maturity (Lm50) for males to be 100.9 cm TL and for females to be 102.1 cm TL, which is a bit smaller than the values estimated elsewhere. Weight of *S. squatina* has been recorded up to 80 kg (Quigley 2006).

Historical and Current Distribution and Population Abundance

Squatina aculeata

The sawback angelshark was historically found in central and western Mediterranean waters and in the eastern Atlantic, from Morocco to Angola. According to Capapé *et al.* (2005), it has never been recorded in Atlantic waters north of the Strait of Gibraltar. It was previously assumed to be very rare or absent from the eastern Mediterranean (Capapé *et al.* 2005; Psomadakis *et al.* 2009); however, a number of recent studies have documented its presence in this region, suggesting possible misidentification of the species in historical records. For example, in 2007, Corsini and Zava (2007) reported the first record of the species in Hellenic waters of the Southeast Aegean Sea (around Rhodes and the Dodecanese Islands). Catch of *S. aculeata* has also been reported from the Çanakkale Strait off Turkey (Ünal *et al.* 2010) and from Gökova Bay in the southern Aegean Sea (Filiz *et al.* 2005). The species was also listed as occurring in the Levantine Sea by Golani (1996) (as reported in Capapé *et al.* (2005)), with the first actual description of a specimen caught in this area from Iskenderun Bay in 1997 (Basusta 2002); however, by 2004, Golani (personal communication cited in Capapé *et al.* (2005)) noted that the species was no longer reported in the area. In their updated checklist of marine fishes of Turkey, Bilecenoğlu *et al.* (2014) recorded *S. aculeata* as occurring in the Aegean Sea and Levantine Sea, and between 2001 and 2004, Saad *et al.* (2005) captured the species along the Syrian coast.

The species is currently reported as ''doubtful'' or rare in many areas in the central and western Mediterranean Sea, such as off the Spanish and French coasts, within Italian waters, and off Algeria (Barrull *et al.* 1999; Capapé *et al.* 2005). In the central Mediterranean, specifically the Gulf of Gabès (Tunisia), the species was noted as being abundant in 1978 (Quignard and Ben Othman 1978) and ''regularly observed'' in 2006 (Bradai *et al.* 2006); however, more recent studies suggest the species has significantly declined in this region and is now a rare occurrence in Mediterranean Tunisian waters (Scacco *et al.* 2002; Capapé *et al.* 2005; Ragonese *et al.* 2013). Although the species had been previously included in inventories of sharks and ray species from the Maltese Islands (based on unconfirmed records; Schembri *et al.* 2003), recent surveys conducted in these waters (Scacco *et al.* 2002; Ragonese *et al.* 2013) cannot confirm its presence.

Squatina aculeata has also seen significant declines in neighboring Mediterranean waters, such as in the Tyrrhenian Sea and Adriatic Sea. Based on historical commercial landings data and recent survey data, Ferretti *et al.* (2005) concluded that the species has been extirpated from the northern Tyrrhenian Sea since the early 1970s. Similarly, Capapé *et al.* (2005) noted past records of *S. aculeata* in the Adriatic Sea (dated to 1975); however, more recent and extensive bottom trawl surveys conducted from 1994–2005 throughout the Adriatic Sea have failed to locate the species (Jukic-Peladic *et al.* 2001; Ferretti *et al.* 2013). In contrast, in waters off Libya, the species was described as relatively common by the United National Environment Programme (UNEP) in 2005 (UNEP-Mediterranean Action Plan Regional Activity Centre For Specially Protected Areas (UNEP–MAP RAC/SPA) 2005); however, the data on which this statement was based, and present abundance, are unknown.

In the western Mediterranean, the only information concerning the distribution and abundance of *S. aculeata* is the mention of a few specimens held in Spanish and French museums (The Global Biodiversity Information Facility (GBIF) 2013) and a discussion of the Balearic Islands (Spain) population in the International Union for Conservation of Nature (IUCN) Red List assessment of the species by Morey *et al.* (2007a).

Specifically, Morey *et al.* (2007a) suggest that *Squatina* species (presumably *S. aculeata* or *S. oculata* based on fishing depths) were commonly caught in the Balearic Islands until the 1970s, after which captures became more sporadic. By the mid-1990s, the species was no longer observed or recorded from the area (Morey *et al.* 2007a).

In the eastern Atlantic, observed population declines appear to have occurred within the past 40 years, particularly in waters off West Africa. According to a personal communication in the Morey *et al.* (2007a) assessment (from F. Litvinov in 2006), *S. aculeata* was commonly reported in Russian surveys off the coast of West Africa during the 1970s and 1980s. Similarly, in their 1973 checklist of marine fishes, Hureau and Monod (1973) also referred to the species as common in these waters. By the early 1980s, however, there were signs of decline based on observations of the species. In fact, by 1985, Muñoz-Chapuli (1985) considered the species to be rare in the eastern Atlantic. This characterization was based on data from 181 commercial trawls conducted in 0 m–550 m depths from 1980–1982 along the northwestern African coast (27° N–37° N) and Alboran Sea. Only 28 *S. aculeata* sharks were captured, with 25 of them caught off the coast of Morocco (between 31° N and 34° N). In waters farther south, Morey *et al.* (2007a) indicate that the species was frequently caught by artisanal Senegalese fishermen 30 years ago (mid-1970s), with catches now very rare according to artisanal fishermen and observers of the industrial demersal trawl fleets (Morey *et al.* (2007a) citing a personal communication from M. Ducrocq). Similarly, Capapé *et al.* (2005) noted that the species was relatively abundant off the coast of Senegal and was landed throughout the year; but, in recent years, Senegalese fishermen have reported fewer observations of all squatinid species (Dr. Christian Capapé, Professor at Université Montpellier 2, personal communication 2015). In Sierra Leone, Morey *et al.* (2007a), citing a personal communication from M. Seisay, state that the species was ''periodically caught by demersal trawlers in the 1980s, but are now caught very infrequently.'' These observations tend to support the available survey data, although data are only available through the year 2002. From 1962 to 2002, species recorded from 246 surveys conducted along the west coast of Africa were reported in two databases: Trawlbase and Statbase, as part of the Système d'Information et d'Analyse des Pêches (SIAP) project (Mika Diop, Program Officer at Sub-Regional Fisheries Commission, personal communication 2015). Based on the information from these databases, *S. aculeata* was recorded rather sporadically and in low abundance in the surveys since the 1970s, the exception being a 1997 survey conducted off Senegal, which recorded 24 individuals. However, in the surveys that followed (conducted from 1999–2002; with surveys off Senegal conducted in 1999 and 2000), no *S. aculeata* individuals were caught, with the last record of the species from the database dating back to 1998.

Squatina Oculata

The smoothback angelshark was historically found throughout the Mediterranean Sea and in the eastern Atlantic from Morocco to Angola. The current distribution and abundance of the species is not well known. In the western Mediterranean, it is possible that the species has been extirpated from the Balearic Islands (see discussion for *S. aculeata* above). Similarly, in the central Mediterranean, Ferretti *et al.* (2005) noted the disappearance of the entire *Squatina* genus from the northern Tyrrhenian Sea in the early 1970s. Between the Maltese Islands and Tunisia, Ragonese *et al.* (2013) noted *S. oculata's* sporadic occurrence based on shelf and slope trawl data from 1997, 1998, and 2006, whereas Bradai *et al.* (2006) ''regularly observed'' the species in the Gulf of Gabès. Prior to these surveys, Capapé *et al.* (1990) had suggested that the Gulf of Tunis (Tunisia) was likely a nursery area for *S. oculata* based on trawl catch data. In 2005, UNEP reported the species as being relatively common in Libyan waters but provided no corresponding citation or data to support this statement or further information regarding abundance in the Mediterranean Sea (UNEP–MAP RAC/SPA 2005). The species has also been reported in the Adriatic Sea (Arapi *et al.* 2006; Soldo 2006), although, extensive bottom trawl surveys conducted from 1994–2005 throughout the Adriatic Sea failed to locate the species in these waters (Jukic-Peladic *et al.* 2001; Ferretti *et al.* 2013).

In the eastern Mediterranean, its present distribution appears to be patchy, with few observations of the species. In 2004, one female *S. oculata* individual was caught by a trawl net in depths of 60 m–70 m in Trianda Gulf off the northwest coast of Rhodes, Greece. This marked the first record of the species in Hellenic waters of the Southeastern Aegean Sea (Corsini and Zava 2007). The species also appears to be rare in the central Aegean Sea as Damalas and Vassilopolou (2011) recorded only one individual during their analysis of 335 records of bottom trawl hauls conducted between 1995 and 2006. On the other hand, the species is characterized as ''prevalent'' by Golani (2006) along the Mediterranean coast of Israel, although the data upon which this characterization was based and the present abundance are unknown. *S. oculata* is also reported as occurring in the Sea of Marmara (Bilecenoğlu *et al.* 2014) and off the Mediterranean Syrian coast (based on survey data from 2001–2004; Saad *et al.* 2006). In 2015, an individual was landed near Akyaka (Turkey) by local fishermen (Joanna Barker, UK & Europe Project Manager of Conservation Programmes at Zoological Society of London, personal communication 2015).

There is very little available information on the abundance of this species in the eastern Atlantic. The IUCN Red List assessment of the species by Morey *et al.* (2007b) also cites to the same personal communication from M. Ducrocq and F. Litvinov, found in the assessment of *S. aculeata* (Morey *et al.* 2007a), that indicates the species was frequently caught by artisanal Senegalese fishermen as well as commonly reported in Russian surveys off the coast of West Africa 30 years ago. Hureau and Monod (1973) also referred to the species as ''rather common'' in the eastern Atlantic, from Morocco to Angola. During 1981–1982, a Norwegian research vessel conducted trawl surveys off West Africa, from Aghadir to Ghana, to examine the composition and biomass of fish resources in this region. *Squatina oculata* was the only *Squatina* species caught during these surveys, with catch rates of 45.6 kg/hour off the coast of Gambia, 13.4 kg/hour off Sierra Leone, and 12.4 kg/hour off Liberia (Strømme 1984). In 2001, *S. oculata* was also reported as occurring off the coast of Ghana, with individuals usually caught between November and December but rarely landed (Edwards *et al.* 2001). No other data on abundance or frequency of occurrence were provided. Based on personal communication, Morey *et al.* (2007b) report that catches of the species in this region are now very rare, and Senegalese fishermen have noted a decrease in observations of all squatinid species in recent years (C. Capapé, pers. comm. 2015). Based on the information from the SIAP databases, *S. oculata* was recorded rather sporadically in the surveys, with a few years reporting >20 individuals, primarily from surveys

conducted off the coast of Senegal. The last record of the species from the data dates back to 2002.

Squatina Squatina

The common angelshark is the most northerly distributed of the three angelshark species discussed in this finding. Its historical range extended along the eastern Atlantic, from Scandinavia to Mauritania, including the Canary Islands, and the Mediterranean and Black Seas. Throughout most of the northeastern Atlantic, *S. squatina* was historically frequently encountered. As Day (1880) reported, the species was common within the North Sea and English Channel, especially along the southern coasts of Kent, Sussex, and Hampshire. It was also regularly observed in the Firth of Clyde after gales (Day 1880). Hureau and Monod (1973) noted its occurrence from the western and southern North Sea, and in Scandinavian waters in the Skagerrak and Kattegat. The authors characterized the species as common over 40 years ago, except in the most northern and eastern parts of its range. Pethon (1979) also documented the presence of the species in waters off Norway (first record in 1929; second record in 1979), describing the species as rare in Scandinavian waters but regularly observed in the southern part of the North Sea and around the British Isles. However, comparisons of historical and current catch and survey data on *S. squatina* suggest significant declines in abundance of the species throughout its range in the northeastern Atlantic, with possible extirpations of the species from the western English Channel (near Plymouth), North Sea, and Baltic Sea (although adult *S. squatina* were always considered to be rare in these waters; HELCOM 2013) (Morey *et al.* 2006; OSPAR Commission 2010; McHugh *et al.* 2011; ICES 2014).

In Irish waters, historical records (dating back to 1772) suggest the species was regularly observed off the southern and western coasts of Ireland (Dr. Declan Quigley, Sea Fisheries Protection Authority, personal communication 2015). In fact, in the1960s, *S. squatina* were caught in large numbers off the west coast of Ireland, in Tralee Bay (County Kerry), by recreational anglers competing in fishing tournaments. Data from a marine sport fish tagging program in Ireland also suggests the species was rather common in these waters, with 320 angelsharks caught, tagged, and released in Tralee and Clew Bays (Ireland) from 1987–1991. However, by the late 1990s, data from angler catches and the tagging program indicate that abundance started to decline. Specifically, annual numbers of *S. squatina* (weighing >22.68 kg) caught by rod and line gear significantly decreased when compared to the previous 50 years, and from 1997–2001, only 16 angelsharks were caught by the tagging program, despite no change in tagging effort (Quigley 2006; ICES 2014). Since 2006, only one individual has been caught and tagged (ICES 2014). The species is now extremely rare off the west coast of Ireland, with no reported recaptures of tagged sharks since 2004. However, in October 2013, an angler reported catching (and releasing) an angelshark in Tralee Bay, confirming that the species still exists in these waters.

Similarly, in other areas of the northeastern Atlantic, survey data on *S. squatina* suggest very low present abundance. For example, Ellis *et al.* (1996) analyzed data from 550 bottom trawls conducted throughout the northeastern Atlantic (with survey focus in the Irish Sea) between 1981 and 1983 and found only 19 *S. squatina* sharks, comprising 0.6 percent of the total elasmobranch catch. Analysis of more extensive bottom-trawl survey datasets, covering the period of 1967–2002 and with sampling in the North Sea (1967–1990; 2001–2002), Celtic Sea (1982–2002), Eastern English Channel (1989–2002), Irish Sea (1988–2001), and Western English Channel (1990–2001), failed to record any *S. squatina* individuals (Ellis *et al.* 2004). However, in 2009, one *S. squatina* shark was captured in Cardigan Bay, four sharks were collected off Pembrokeshire (Wales) near the entrance to St. George's Channel (two in 2007 and two in 2010), and recent (2015) reports on social media networks of *S. squatina* catches provide some evidence of the contemporary presence of the species in the Irish Sea and nearby waters (ICES 2013; ICES 2014; J. Barker, pers. comm. 2015).

Similar to the trend in the northeastern Atlantic, *S. squatina* populations have declined throughout the Mediterranean Sea, with possible local extirpations in the Black Sea, Adriatic Sea, and northern Tyrrhenian Sea (Jukic-Peladic *et al.* 2001; Ferretti *et al.* 2005; Morey *et al.* 2006; OSPAR Commission 2010; Ferretti *et al.* 2013). In the central Mediterranean, *S. squatina* was commonly recorded in historical faunistic lists (Giusto and Ragonese 2014). The species was reported in the Gulf of Naples in historical records dating back to 1871 through at least 1956 (Tortonese 1956; Psomadakis *et al.* 2009) and in the Adriatic Sea (Tortonese 1956). However, Ferretti *et al.* (2005) noted the disappearance of the entire *Squatina* genus from the northern Tyrrhenian Sea in the early 1970s. In 2005, UNEP reported the species as being relatively common in Libyan waters; however, the data on which this statement was based are unknown. Bradai *et al.* (2006) also reported that the species was ''regularly observed'' in the Gulf of Gabès; however, the only available data from this region comes from surveys conducted off the southern coasts of Sicily and northern coasts of Tunisia and Libya. In contrast to the Bradai *et al.* (2006) characterization of the abundance of the species, trawl surveys conducted from 1995–1999 in the Strait of Sicily recorded *S. squatina* near Cape Bon, Tunisia with a biomass that comprised only 1 percent of the total elasmobranch catch (Scacco *et al.* 2002). Ragonese *et al.* (2013) confirmed the rarity of this species, reporting only one captured individual from their analysis of extensive survey data collected between the southern coasts of Sicily and northern coasts of Africa (Tunisia and Libya) from 1994 to 2009. The fish was caught at a depth of 128 m in 2005, close to the Maltese Islands. More recently, in 2011, an artisanal fishing vessel caught an *S. squatina* shark in a trammel net off the coast of Mazara del Vallo (southwestern Sicily), marking the first documented occurrence of *S. squatina* in over 30 years off the coast of southern Sicily (Giusto and Ragonese 2014).

In the eastern Mediterranean, *S. squatina* is rare but present. In 2008, three *S. squatina* individuals were recorded in Egypt from commercial landings in western Alexandrian waters (Moftah 2011). Within Turkish Seas, Kabasakal and Kabasakal (2014) report that *S. squatina* comprised 1.1 percent of the total number of elasmobranchs (n = 4632) caught between 1995 and 1999, and 0.46 percent of the total shark catches (n = 1068) between 1995 and 2004 in the northern Aegean Sea. In their updated checklist of marine fishes of Turkey, Bilecenoğlu *et al.* (2014) record *S. squatina* as occurring in the Black Sea (although the reference dates back to 1999), Sea of Marmara, Aegean Sea, and Levantine Sea. Kabasakal and Kabasakal (2014) also confirmed the presence of *S. squatina* in the Sea of Marmara but remarked on its rarity in these waters. In the Levantine Sea, Bulguroğlu *et al.* (2014) reported the capture of an *S. squatina* individual in 2013 by a commercial trawl vessel from a depth of 50 m in Antalya Bay (southern Turkey), Hadjichristophorou (2006) characterized the species as

occasionally occurring in Cyprus fishery records, and Saad *et al.* (2006) captured the species along the Syrian coast during surveys conducted from 2001–2004. Additionally, Soldo (2006) notes the presence of the species in the Adriatic Sea but the information used to support this assertion is unclear, as the species has not been reported in survey data from these waters since 1958 (Ferretti *et al.* 2013).

Presently, the only part of its range where *S. squatina* is confirmed as still relatively common is off the Canary Islands (Muñoz-Chapuli 1985; OSPAR Commission 2010). Much of the information on *S. squatina* presence and abundance from this area is derived from diver observational data. In 2013, the Zoological Society of London (ZSL), Universidad de Las Palmas de Gran Canaria (ULPGC) and Zoological Research Museum Alexander König (ZFMK) created the ''Angel Shark Project'' (ASP), which has gathered public sighting data of angelsharks through the creation of a citizen science sighting scheme called Poseidon (*www.programaposeidon.eu*) (Joanna Barker, UK & Europe Coordinator Conservation Programmes, ZSL, personal communication 2014). Since the launch of the Poseidon portal in April 2014, there have been 624 validated records (sightings of angelsharks), covering areas with no previous records such as El Hierro and La Palma (Meyers *et al.* 2014; Meyers, pers. comm. 2015; also see reported sightings on the ASP Web site, available at *http://angelsharkproject.com/*). Currently, 22 dive centers are actively reporting angelsharks (J. Barker, pers. comm. 2014); however, a few dive centers have been collecting observational data even prior to the creation of the Poseidon portal. For example, the ''Davy Jones Diving'' dive center, in Gran Canaria, has collected data on angelshark sightings in the ''El Cabron'' or Arinaga Marine Reserve since 2006. Narváez *et al.* (2008) analyzed these dive data for the period of May 2006 through August 2008 and found that 271 angelsharks were sighted over the course of 1,709 dives. Sightings included both females and males (with a sex ratio of 1:1.6) as well as juveniles (9 percent of the sightings) and adults.

The Davy Jones Diving dive center continues to log sightings of angelsharks and other species on its Web site. Analysis of the log data from January 1, 2011 through December 29, 2014 shows that angelsharks are still frequently observed in the Arinaga Marine Reserve, with sightings recorded on 35 percent of the dive trips off Gran Canaria over the past 3 years (n = 1,253 total trips) (Miller 2015).

Summary of Factors Affecting the Three Angelshark Species

Available information regarding historical, current, and potential threats to these three angelshark species was thoroughly reviewed (Miller 2015). We find that the main threat to these species is overutilization for commercial and recreational purposes. We consider the severity of this threat to be exacerbated by the species' natural biological vulnerability to overexploitation, which has led to declines in abundance and subsequent extirpations and range curtailment. We find current regulatory measures inadequate to protect these species from further overutilization. Hence, we identify these factors as additional threats contributing to the species' risk of extinction. We summarize information regarding these threats and their interactions below, with species-specific information where available, and according to the factors specified in section 4(a)(1) of the ESA. Available information does not indicate that disease, predation or other natural or manmade factors are operative threats on these species; therefore, we do not discuss these factors further in this finding. See Miller (2015) for a full discussion of all ESA Section 4(a)(1) threat categories.

The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Based on the evidence of *S. squatina* extirpations in many parts of its range (see discussion in Historical and Current Distribution and Population Abundance), there has been a significant curtailment of the species' historical range, most notably in the northeastern Atlantic. In 2008, the International Council for the Exploration of the Sea (ICES) acknowledged that *S. squatina* was extirpated in the North Sea (although stated it may still occur in parts of the English Channel) and from parts of the Celtic Seas (ICES 2014), defining the term ''extirpated'' as ''loss of the species from part of the main geographical range or habitat, and therefore . . . distinguished from a contraction in the range of a species, where it has been lost from the fringes of its distribution or suboptimal habitat.'' The species is also believed to be extirpated from the Baltic Sea and western English Channel in the northeastern Atlantic, from the Adriatic, Ligurian and Tyrrhenian Seas in the Mediterranean, and from the Black Sea (Rogers and Ellis 2000; Jukic-Peladic *et al.* 2001; Dulvy *et al.* 2003; Ferretti *et al.* 2005; OSPAR Commission 2010; EVOMED 2011).

In the northern parts of its range, *S. squatina* is thought to undertake seasonal migrations, sometimes of large distances, moving inshore for the summer and out to deeper water in the winter (Day 1880; OSPAR Commission 2010; ICES 2014). However, for the most part, results from tagging studies conducted in the northeastern Atlantic indicate these sharks remain in waters close to their initial tagging location (Quigley 2006). Similarly, in Mediterranean waters, *S. squatina* do not appear to stray far from a core area, with tagged fish recaptured 10–44 km from their release site (Quignard and Capapé 1971; Capapé *et al.* 1990). This available tagging information suggests that *S. squatina* exhibit potentially high site fidelity, which increases their susceptibility to local extirpations and has likely led to the observed loss of populations throughout large portions of its range. At this time, there is no genetic information available that could provide insight into natural rates of dispersal and genetic exchange among populations. However, based on information that *S. squatina* are ovoviviparous (lacking a dispersive larval phase) and likely exist as potentially isolated populations in a highly fragmented landscape, re-colonization of the extirpated areas mentioned above may not be possible. This curtailment of historical range ultimately translates to a significant loss of suitable habitat for the species and greatly increases the species' risk of extinction.

A curtailment of historical range is much less evident for the other two species, where data are severely limited. The IUCN Red List reviews of *S. aculeata* and *S. oculata* suggest these two species are now rare or even absent from most of the northern Mediterranean coastline (Morey *et al.* 2007a, b). Many historical records simply document the presence of these species in certain locations, with no corresponding information on abundance or distribution. Only a few references provide subjective descriptions of historical abundance, and only from select areas (*i.e.,* Balearic Islands, Gulf of Gabès, Libya, Israel, and Senegal; see Historical and Current Distribution and Population Abundance section). However, based on the absence of the species in relatively recent and repeated surveys in areas where they were once historically documented, it is possible that both species may have experienced a curtailment of their historical range. For *S. aculeata,* the available information suggests it may no

longer be found in the Adriatic Sea (Jukic-Peladic *et al.* 2001; Ferretti *et al.* 2013) or central Aegean Sea (where the species was likely historically rare; Damalas and Vassilopolou 2011), and is also missing from the Ligurian and Tyrrhenian Seas (where it was caught by local fishermen and also part of commercial landings in the 1970s; Ferretti *et al.* 2005; EVOMED 2011), and off the Balearic Islands (where angelsharks were historically common; Morey *et al.* 2007a). For *S. oculata,* the species may no longer be found in the Aegean Sea (Damalas and Vassilopolou 2011), Ligurian and Tyrrhenian Seas (Ferretti *et al.* 2005; EVOMED 2011), and off the Balearic Islands (Morey *et al.* 2007a), where its historical abundance in these areas mirrors that of *S. aculeata.* Similar to the case with *S. squatina,* these local extirpations and population declines have likely resulted in patchy distributions of both *S. aculeata* and *S. oculata* populations with low connectivity and loss of suitable habitat, increasing the species' risks of further extirpations and possibly leading to complete extinction.

We investigated additional habitat-specific threats to the three angelshark species, including the impacts of demersal trawling on habitat modification, deep-water oil exploration projects, and climate change; however, we found no information to indicate these are operative threats that are increasing the species' risks of extinction. Although significant demersal trawling occurred and continues to occur throughout the range of the *Squatina* species (Sacchi 2008; FAO 2013), and has likely altered seafloor morphology (Puig *et al.* 2012), there is no information that this habitat modification has had a direct effect on the abundance of these three species, or is specifically responsible for the curtailment of range of any of the *Squatina* species. The species' broad diets of benthic invertebrates and fishes from soft-sediment habitats means they are likely relatively resistant and resilient to changes in their habitats.

In 2012, there was concern regarding potential oil spill impacts on the *S. squatina* habitat around the Canary Islands because the Spanish government had approved a deep-water oil exploration project off the coasts of Fuerteventura and Lanzarote (Navío 2013). However, based on the 2014 exploratory drilling in the region, Repsol (the Spanish oil company in charge of the project) determined that the area ''lacked the necessary volume and quality [of methane and hexane gases] to consider future extraction'' and abandoned drilling off the Canary Islands in January 2015 (Bjork 2015).

Predicted impacts to angelshark habitats from climate change were also evaluated. The effects of climate change are a growing concern for fisheries management, as the distributions of many marine organisms are shifting in response to their changing environment. Factors having the most potential to affect marine species are changes in water temperature, salinity, ocean acidification, ocean circulation, and sea level rise. However, based on a study published by Jones *et al.* (2013), it appears that angelsharks, at least in United Kingdom (UK) waters, may not be especially vulnerable to these impacts. According to the authors' climate model projections, any negative impacts from a range shift due to climate change would likely be offset by an increase in availability of protected habitat areas for the common angelshark. In addition, the range shift would also shrink the angelshark's overlap with other commercially-targeted species, thus potentially decreasing their occurrence as bycatch during commercial fishery operations. We found no other information regarding the response of *Squatina* species to the impacts of climate change. Therefore, at this time, the best available information does not suggest that habitat modification or destruction by demersal trawling activities, deep-water oil exploration projects, or climate change contributes significantly to the extinction risk of these species.

Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Based on catch records and anecdotal reports, the *Squatina* species were historically regularly observed and landed in many areas of their respective ranges. For example, *S. squatina* (which was historically called ''monkfish'' before anglerfish entered the market) was commonly recorded on the southern and eastern English coasts, western and southern coasts of Ireland, within the North Sea, on the Dogger Bank, in the Bristol Channel, in the Firth of Clyde, and in the Mediterranean Sea during the 19th and early 20th centuries (Day 1880; Ferretti *et al.* 2005; Morey *et al.* 2006; D. Quigley, pers. comm. 2015). In UK waters in the late 19th century, Day (1880) noted that the species was taken off the coasts of Kent, Sussex, Hampshire, and Swansea, frequent in Cornwall, and common ''at all times'' along the southern coast of Devon, documenting a personal observation of finding 26 common angelsharks that had been pulled in by seine net from Start Bay and left to die on shore. In Italy, historical fishing gear called ''squaenara'' or ''squadrara'' were purposely built to catch angelsharks (EVOMED 2011), suggesting a level of abundance that would warrant specialized gear and targeting of the species. Similarly, in French waters, angelsharks were so common that Arcachon fishermen would also use a special net designed specifically for catching them. These fishermen, who fished on the continental shelf in Arcachon Bay and the Bay of Biscay, would rope the tails of the species with a string attached to a type of wooden buoy and would bring the live shark back to shore. By the mid-19th century, annual catches of *S. squatina* totaled around 25,000 kg per year (Laporte 1853 cited by Quéro and Cendrero 1996 and Quéro 1998). The angelshark was historically marketed for its flesh (which was consumed or used for a variety of purposes, including: Medicine, bait, polish for wood and ivory, cover for hilts of swords, and sheaths for knives), liver for oil, and carcass for fishmeal (Day 1880; Edwards *et al.* 2001; Saad *et al.* 2006; Shark Trust 2010; ICES 2014; D. Quigley, pers. comm. 2015 citing Rutty (1772)). This exploitation continued for much of the 19th and early 20th centuries, during the time when demersal trawl fisheries saw significant expansion in the northeast Atlantic and Mediterranean. Because angelsharks are sedentary, bottom-dwelling species, they are highly susceptible to being caught in trawl fisheries. Consequently, as demersal trawling activities expanded with the use of steam-powered trawlers in the 1890s, angelshark populations began to experience significant declines.

For *S. squatina,* the comparison of historical and current catch and survey data provide evidence of this clear decline from overutilization. In Arcachon Bay and the Bay of Biscay, for example, where *S. squatina* was once commonly caught in the mid-19th century, annual landings have decreased by over 95 percent compared to historical landings data, with only 291 kg of the species recorded caught in 1996 (Quéro 1998). Similarly, in the western English Channel, where Day (1880) noted the species was frequently captured by trawls and taken in trammel and seine nets in the late 19th century, *S. squatina* has since seemingly disappeared. Based on data from multiple research trawl surveys, conducted from 1989–1997 and 2008–2009 and in waters where historical surveys previously recorded the species, *S. squatina* was notably absent (Rogers

and Ellis 2000; McHugh *et al.* 2011). Numerous other surveys provide similar evidence of declines and disappearances (see Historical and Current Distribution and Population Abundance section), indicating that *S. squatina* has essentially declined to the point where it is now extirpated in a number of areas of its historical range where it was previously common, and is rarely observed or caught throughout the rest of its range (Barrull *et al.* 1999; Ferretti *et al.* 2005; Morey *et al.* 2006; Psomadakis *et al.* 2009; McHugh *et al.* 2011; Dell'Apa *et al.* 2012).

It is likely that *S. aculeata* and *S. oculata* were also negatively impacted by these demersal trawlers, given their similar behavior and overlapping ranges; however, information regarding their relative historical abundance and/or frequency throughout their respective ranges, which could provide insight into population trends and impacts of this utilization, is less certain. Instead, much of the information, at least from Mediterranean waters, is primarily in the form of presence/absence on shark inventory lists for different countries or general characterizations of the species (with the most recent characterizations dated almost 10 years ago), with no corresponding data or information on abundance, the rationale behind the characterization, or recent updates on the status or presence of these species from those areas. However, with this information, we at least have evidence of the presence of these species in certain areas in the past and can rely on survey data for indications as to the present status of these species. Examining the extent of coverage of recent surveys and evaluating the potential impact of historical fishing effort can allow for reasonable conclusions to be drawn regarding utilization of these species. For example, Ferretti *et al.* (2005) concluded that the *Squatina* species have been extirpated from off the Tuscan coast since the early 1970s. This conclusion was based on the fact that the *Squatina* species (specifically *S. aculeata* and *S. squatina*) were formerly present in commercial landings data (although of unknown magnitude) and all three species were absent in recent trawl surveys. The trawl surveys were extensive, covering the continental shelf and upper slope of the Tuscan coast, from 0 to 800 meters depth, with 88 tows conducted from 1972–1974 and 1,614 tows between 1985 and 2004 (Ferretti *et al.* 2005). In terms of historical fishing effort, the Tuscan fishery had been active for many years prior to the 20th century; however, it was not until the beginning of the 20th century when fishermen began focusing on exploiting demersal resources (Ferretti *et al.* 2005). As technology advanced in the 1930s, the fishery improved, and by 1960, Ferretti *et al.* (2005) estimated that the fleet was exploiting approximately 90 percent of the Tuscan Archipelago (~ 13,000 km^2), with the majority of trawl effort concentrated in depths less than 400 m. Although the historical abundance of the *Squatina* species in this region is unknown (which could provide insight into the likelihood of the species in landings and survey data), given the history of the fishery, area of operation of the Tuscan fleets, and coverage of the recent trawl surveys, it is likely that historical overutilization of the angelshark species has occurred as a result of the expansion of the trawl fisheries. This overutilization has ultimately led to the observed extirpation of the *Squatina* species from the region. The decline and subsequent extirpation is further corroborated by interviews with fishermen who used to trawl in the Ligurian and Tyrrhenian Seas. According to their personal observations, the *Squatina spp.* were already reduced in numbers by the 1960s and 1970s (during the surge in fishing effort and capacity), with the last catches of the species from these seas remembered as occurring in the early 1980s (EVOMED 2011). Fishermen that trawled off the Sardinian coast also noted the progressive decline in abundance of the *Squatina spp.* during these years of fishery expansion, with the disappearance of the species from Sardinian waters occurring in the mid-1980s (EVOMED 2011).

Similar conclusions can be made regarding the present status of the *Squatina* species off the Balearic Islands by comparing historical characterizations of these species and fishing effort to recent fishery-independent survey data. Historically, Morey *et al.* (2007a) suggested that *Squatina* species (presumably *S. aculeata* or *S. oculata* based on fishing depths) were commonly caught in the Balearic Islands, pointing to evidence of a special type of fishing net that was used for catching angelsharks in this area. These species were frequently caught in the coastal artisanal fisheries and also by the trawl and bottom longline fisheries until the 1970s, after which captures became more sporadic (Morey *et al.* 2007a). Morey *et al.* (2007a) also reference records from a lobster gillnet fishery operating in the Balearic Islands that showed it was common to catch angelsharks on a daily basis until the mid-1980s. The timing of the observed depletion in the *Squatina* populations coincides with the fast growth in bottom trawling fishing effort in the Balearic Islands, where growth (estimated in terms of vessel engine power (HP)) exponentially increased from around 5,000 HP in the mid-1960s to over 20,000 HP by the early 1980s (Coll *et al.* 2014). The depths at which these trawlers fished also got progressively deeper over this time period due to increases in ship technology and gear. From 1940–1959, around 85 percent were trawling in shallow grounds of 40–150 m depths, and 15 percent in 40–800 m depths (EVOMED 2011). Between 1960–1979, more fishermen were exploiting deeper waters, with 44 percent strictly fishing in the shallow grounds, 30 percent fishing in depths of 40–800 m, and 17 percent in 200–800 m depths (EVOMED 2011). Although *S. aculeata* and *S. oculata* could have potentially used deeper waters as a refuge from fishing mortality during the 1940s and 1950s (as their depth distribution extends from 20–30 m to over 500 m), by the 1960s and 1970s, these deeper waters were no longer safe from exploitation. *Squatina squatina* likely experienced the highest level of fishing mortality as this species is found in much shallower depths, from 5—150 m, and therefore was accessible to the trawl fishermen during this entire time period. Since the mid-1990s, these species have not been recorded in fishery records (Morey *et al.* 2007a; EVOMED 2011). In addition, the *Squatina* species are notably absent in recent data from multiple fishery-independent studies that aimed to characterize the demersal elasmobranch assemblage off the Balearic Islands. These studies analyzed bottom trawl survey data collected from the continental shelf and slope of the Balearic Islands in depths of 41 m down to 1713 m, and covering the years of 1996, 1998, and 2001 (Massutí and Moranta 2003; Massutí and Reñones 2005). No *Squatina* species were recorded from the trawl hauls despite the overlap of the surveyed area with the observed depth range of the species. Therefore, given the historical fishing effort in this area, the timing of the observed declines in the angelshark populations, and the recent absence of the *Squatina* species from both fishery records and fishery-independent survey data, it seems reasonable to conclude that historical overutilization of these angelshark species has led to the observed extirpation of these species from this area.

Larger surveys, covering vast regions of the Mediterranean, have also provided valuable insight regarding the impacts of historical utilization on the *Squatina* species. For example, from 1985 to 1998, scientific trawl surveys (as part of the Italian Gruppo Nazionale Risorse Demersali (GRUND) project) were conducted in all Italian seas using typical Italian commercial trawl gear. However, *S. aculeata* and *S. oculata* were notably absent from the survey data (9,281 hauls over 22 surveys; Morey *et al.* (2007a,b) citing Relini *et al.* 2001). More expansive surveys, covering waters from Alboran to the Aegean, were conducted as part of the Mediterranean International Trawl Survey (MEDITS) program. This program aimed to provide information on the status of demersal resources within the Mediterranean region (Bertrand *et al.* 1997). Numerous surveys were conducted along the Mediterranean coastline, in 10 m to 800 m depths, but also failed to find *S. oculata* and had very few observances of the other *Squatina* species (Baino *et al.* 2001). Out of the 6,336 tows conducted from 1995–1999, *S. aculeata* appeared in only one tow (from the Aegean Sea) and *S. squatina* appeared in two (from western Mediterranean: Defined as coasts of Morocco, Spain and France) (Baino *et al.* 2001). Similarly, the Mediterranean Large Elasmobranchs Monitoring (MEDLAM) program, which was designed to monitor the captures and sightings of large cartilaginous fishes occurring in the Mediterranean Sea, also has very few records of the *Squatina* species in its database. Since its inception in 1985, the program has collected around 1,866 records of more than 2,000 specimens from 20 participating countries. Out of the 2,048 elasmobranchs documented in the database through 2012, there are records identifying only 6 individuals of *S. oculata,* 4 of *S. squatina,* and 1 of *S. aculeata.* Given that fishing effort by the Mediterranean trawl fleet is estimated to have peaked in the mid-1980s (based on trends data from areas in the Catalan, Ligurian, Tyrrhenian, western Adriatic, Ionian, and Aegean Seas; EVOMED 2011), the rarity and absence of the *Squatina* species in survey data following this period suggests that the historical level of fishing effort likely resulted in substantial declines and significant overutilization of the species.

Many of these surveyed areas have also seen a shift in species composition and richness since the expansion of the trawl fisheries. Historically abundant larger elasmobranch species, including angelsharks, have seemingly been replaced by smaller, more opportunistic species, a strong indicator of overutilization of these larger elasmobranchs by commercial fisheries (Rogers and Ellis 2000; Damalas and Vassilopoulou 2011; McHugh *et al.* 2011). For instance, in the central Aegean Sea, a major fishing ground for the Greek bottom trawl fishery fleet, Damalas and Vassilopoulou (2011) noted a significant decrease in chondrichthyan species richness along with a decline in their abundance from 1995 to 2006. Specifically, the authors analyzed data collected from 335 commercial bottom trawl hauls conducted in depths between 50 m and 339 m from 1995 to 2006 (2001–2002 was excluded). A total of 217 species (141 bony fishes, 24 mollusks, 22 crustaceans, and 30 chondrichthyan species, including *S. aculeata* (n = 3) and *S. oculata* (n = 1)) were recorded from these hauls. However, in the last 4 years of the study (2003–2006), *S. aculeata* and *S. oculata* were absent from trawl catches, along with 9 other chondrichthyan species (over a third of the total). The authors estimated that species richness declined by an average of 0.66 species per year during the study period (with a more rapid decline exhibited from 1995–2000 compared to 2003–2006). They attributed the decline in part to the intense fishing pressure by the Greek bottom trawl fishery and the vulnerability of certain species, such as angelsharks, to exploitation (Damalas and Vassilopoulou 2011).

In the Adriatic Sea, a number of fishery-independent trawl surveys covering the entire basin have been conducted since 1948, allowing for an examination of the impact of historical exploitation on the Adriatic Sea demersal fish assemblage (Ungaro *et al.* 1998; Jukic-Peladic *et al.* 2001; Feretti *et al.* 2013). Comparing trawl catch from surveys conducted in 1948 and 1998, Jukic-Peladic *et al.* (2001) found a decrease in overall elasmobranch diversity and occurrence. Larger shark and ray species that were present in 1948, including *S. squatina,* were rare or, in the case of *S. squatina,* completely absent in 1998 (Jukic-Peladic *et al.* 2001). The authors attribute the extirpation of many species, including *S. squatina,* and the displacement of the larger elasmobranchs by smaller sized species to the overutilization of the Adriatic Sea demersal resources (Jukic-Peladic *et al.* 2001). A comparison of more recent bottom trawl survey data to the 1948–1949 survey data indicate that the abundance of sharks in the Adriatic Sea has declined by 95.6 percent over the past 57 years (Ferretti *et al.* 2013). *Squatina squatina* was still notably absent, with the last survey record of the species from these waters dated to 1958 (Ferretti *et al.* 2013).

In addition to these fishery-independent survey data, analyses of commercial landings data also indicate that historical overutilization throughout the northeast Atlantic and Mediterranean has led to a general decline in the abundance of demersal shark and ray species. For example, in an analysis of Italian landings data, Dell'Apa *et al.* (2001) noted that elasmobranch landings were fairly steady until the 1970s, at which point they began to increase, reaching peaks in 1985 and 1994 and then sharply declining, which the authors attribute to overharvesting. Between 1983 and 1994, mean annual elasmobranch landings were 10,583 ± 2,599 t compared to 2,014 ± 1681 t between 1996 and 2004, a time period that also showed a consistent annual decrease in catch per unit effort. Similarly, in the English Channel, landings of elasmobranchs have declined steadily since the 1950s, with an overall decrease in high trophic level species (such as gadoid fishes and elasmobranchs) and an increase in low trophic level species (such as invertebrates), indicative of unsustainable fisheries that are ''fishing down marine food webs'' (Molfese *et al.* 2014). For areas where landings of *Squatina* species have been recorded (down to species level), the data show a similar trend. For example, in the Celtic Sea, French landings of *S. squatina* appear to have declined after peaking in the 1970s (when annual landings >25 t), falling to less than 1 t per year by the late 1990s (ICES 2013). Similarly, aggregated landings data of the genus *Squatina* from Portuguese fisheries statistics also show a decreasing trend over the last 20 years (personal communication from R. Coelho to Morey *et al.* (2006)); however, no information is known regarding the corresponding effort or other factors such as changes in retention/discarding practices (R. Coehlo, personal communication, 2014).

Off the west coast of Ireland, recreational fishermen observed a decline in rod-caught *S. squatina* beginning in the late 1990s. In fact, since 2006, only two individuals have been caught in these waters. The decline in this *S. squatina* population, to the point where the species is now extremely rare, has been attributed to both the historical recreational angling of the species as well as the operations of commercial trammel net fishermen in this area (D. Quigley, pers. comm. 2015). In the1960s, *S. squatina* were regularly

caught in Tralee Bay by recreational anglers competing in fishing tournaments. Pictures from some of these competitions, found online in the Kennelly Archive (*http://www.kennellyarchive.com/*), depict the extensive catch of *S. squatina* during these tournaments and highlight the especially large individuals that were caught (with all fish brought ashore). For example, pictures from a June 1964 sea angling competition show a ''record catch,'' when 37 *S. squatina* were caught in less than 3 hours off the coast of Fenit Pier (Ireland). Another record catch was documented in June 1965 during a boat-angling competition in Tralee Bay, where four trophy *S. squatina* individuals, weighing 60, 59, 50, and 30 lbs (27.2, 26.8, 22.7, 13.6 kgs), respectively, were caught in addition to numerous smaller individuals. Given the life history characteristics of the species, this level of essentially unregulated utilization and removal of larger and, hence, probably mature individuals, likely contributed to the observed decline in the *S. squatina* population from this area.

Although catch-and-release became increasingly more common practice in Ireland over the years (Fahy and Carroll 2009), decreasing the threat of overutilization by recreational anglers, a new threat emerged in the 1970s in the form of trammel net usage by commercial fishermen. Trammel nets, which are a type of gill net consisting of three layers of netting tied together on a common floatline and leadline, were introduced off the coast of Kerry (Ireland) in the early 1970s (Quigley and MacGabhann 2014). They were primarily used to catch crawfish (*Palinurus elephas*), but given the non-specificity of the fishing gear, these nets also by-caught spider crab (*Maja brachydactyla*), another commercially important species in the area, as well as many other elasmobranchs and non-target species (Quigley and MacGabhann 2014). The prevalent use of these nets led to significant decreases in crawfish landings (from 300 t in 1971 to 34 t in 2006) as well as startling declines in the bycatch species, with Fahy and Carroll (2009) characterizing the angelsharks as having been fished ''almost to elimination'' by the use of these trammel nets.

Farther south, in waters off West Africa, *S. oculata* and *S. aculeata* were commonly observed in the 1970s and 1980s. However, it was also during this time period that shark fishing in the region really started to expand and intensify (Diop and Dossa 2011). In a review of shark fishing in the Sub Regional Fisheries Commission (SRFC) member countries: Cape-Verde, Gambia, Guinea, Guinea-Bissau, Mauritania, Senegal, and Sierra Leone, Diop and Dossa (2011) state that the shark fisheries and trade spread throughout this region in the 1980s and 1990s with the development of a market and increasing worldwide demand for shark fins. The number of boats and people entering the fishery, as well as improvements to fishing gear, steadily increased from 1994 to 2005, especially in the artisanal fishing sector where catches rose substantially. For example, before 1989, artisanal catch was less than 4,000 mt. However, from 1990 to 2005, fishing effort and catch increased dramatically, with catch estimates of over 26,000 mt by 2005 (Diop and Dossa 2011). Including bycatch estimates from the industrial fishing fleet increases this number to over 30,000 mt in 2005 (note that discards of shark carcasses at sea were not included in bycatch estimates, suggesting bycatch may be underestimated) (Diop and Dossa 2011). By 2008, shark landings had dropped by more than 50 percent to 12,000 mt (Diop and Dossa 2011). Although landings were not identified to the species level, it is likely that this intense and relatively unregulated fishing pressure on sharks significantly contributed to the observed decline of the *Squatina* species in this region, to the point where these sharks are now only rarely observed.

Overutilization of these angelshark species is still a threat, as the shark, trawl, and other demersal fisheries that historically contributed to the *Squatina* species' declines remain active throughout their respective ranges. In fact, in the Mediterranean Sea, trawling still provides one of the highest economic returns in the fishery sector operating in these waters (Sacchi 2008; STECF 2013). In 2008, Sacchi (2008) reported a Mediterranean fleet of approximately 84,000 fishing entities, with around 10 percent using trawl gear and contributing more than half of the catch. By 2012, the fleet size had decreased to around 76,023 vessels, but had a total fishing capacity of 1,578,015 gross tonnage and 5,807,827 kilowatt power (European Commission 2014). In April 2015, the General Fisheries Commission for the Mediterranean (GFCM) identified 9,171 large fishing vessels (*i.e.,* larger than 15 meters) as authorized to fish in the GFCM convention area (which includes Mediterranean waters and the Black Sea). Of these vessels, 46 percent identified as trawlers, although 28 percent did not report their class of fishing gear (GFCM 2015). These Mediterranean trawlers operate in depths of up to 800 m but normally conduct hauls in less than 300 m (Sacchi 2008), which overlaps with the depth range of the *Squatina* species. These trawlers also tend to participate in multi-species fisheries, meaning they are not just targeting one species but rather catching hundreds of different species during operations, posing a significant risk to non-targeted demersal species that are vulnerable to overexploitation, such as the *Squatina* species.

In addition to the demersal trawling, many of the artisanal fisheries, and even some commercial fisheries, throughout the range of these *Squatina* species employ the use of trammel and gillnets during fishing operations, which are also rather unselective types of gear. In a review of artisanal fisheries in the western-central Mediterranean (covering Morocco, Algeria, Tunisia, Libya, Italy, France, and Spain), Coppola (2001) found that the most important gear used in artisanal fisheries were gillnets and entangling nets (comprising 53 percent of the total gear utilized). In Turkey, the majority of fishermen work in the small-scale fishery (comprising around 83 percent of the total fleet; Turkish Statistical Institute 2014). The small-scale fishery operations consist of daily trips, generally in the Aegean and Black Seas, to target fish species using gillnets, trammel nets, entangling nets, and demersal and pelagic longlines (Tokac *et al.* 2012). Additionally, off the west coast of Ireland, there is evidence that commercial fishermen continue to use trammel nets in the inshore fisheries (Fahy and Carroll 2009). Despite the prohibition on these trammel nets in certain areas off the Kerry and Galway (Ireland) coasts (due to their associated level of elasmobranch bycatch, which historically contributed to the decline and present rarity of the *S. squatina* population in this area), these trammel nets are still widely used and deployed year-round (Fahy and Carroll 2009). And, as mentioned previously, artisanal fishing effort is also significant off the west coast of Africa, with fishermen employing a variety of nets to capture species, with some nets that are even specially designed for catching shark species (Diop and Dossa 2011).

Because of the low selectivity of the net and trawl gear and the intensity of fishing effort, a significant portion of the catch in these gears tends to be discarded at sea (Machias *et al.* 2001; Sacchi 2008; Damalas and Vassilopoulou 2010). Damalas and Vassilopoulou (2011) note that chondrichthyans, especially, tend to be

discarded due to their low commercial value. Based on their observations of 335 commercial bottom trawl hauls in the Aegean Sea between 1995 and 2006, they calculated that over 90 percent of chondrichthyans (by number) were discarded. However, data are limited on the discard rates of *Squatina* species. In the Damalas and Vassilopoulou (2011) study, only 4 *Squatina* sharks were observed caught (3 *S. aculeata* and 1 *S. oculata*), with two individuals discarded. Machias *et al.* (2001) observed that both *S. aculeata* and *S. oculata* were always discarded by the commercial trawlers operating in the Aegean and western Ionian Sea. Observer data from the French discard observer program from 2003–2013 recorded two discarded *S. squatina* individuals (both in 2012) (ICES 2014). In general, the available information suggests that *Squatina* species are generally bycaught (Edwards *et al.* 2001; Morey *et al.* 2007a, b; OSPAR Commission 2010; ICES 2014) and would more likely than not be discarded with the other chondrichthyan species. This is especially true for *S. squatina* which is currently prohibited from being retained in European Union (EU) waters (see *Inadequacy of Existing Regulatory Mechanisms* section). In fact, ICES (2014) reports that *S. squatina* is now only landed as a ''curio'' for fish stalls.

As such, the impact of the continued operation of these demersal trawl fleets as well as the net fisheries on the threat of overutilization really depends on the survival rate of these *Squatina* species upon capture and after discard. Unfortunately, at this time, the at-vessel mortality and discard survival rates of the *Squatina* species are unknown; however, based on mortality rates reported for two similar species, the African angelshark (*S. africana*) and the Australian angelshark (*S. australis*), discard survival may be low. For the African angelshark, Fennessy (1994) estimated an at-vessel mortality rate of 60 percent when caught by prawn trawlers and Shelmerdine and Cliff (2006) estimated a 67 percent mortality rate when the species was caught in protective shark gillnets. For the Australian angelshark, mortality rates of 25 and 34 percent have been estimated for capture in gillnets (Reid and Krogh 1992; Braccini *et al.* 2012), with a post-capture mortality rate (for those sharks discarded alive) of 40 percent (Braccini *et al.* 2012). Because these two angelsharks have similar life history traits to the *Squatina* species under review (see Miller (2015) for comparison of these species), we consider at-vessel mortality and discard survival rates for *S. aculeata, S. oculata,* and *S. squatina* to be comparable to those estimated for *S. africana* and *S. australis.*

Although current fishing mortality rates are unknown, even low levels of mortality would likely contribute to further population declines given the extremely depleted status of these species, to the point where all three species are rarely observed and extirpated in many areas. Yet, the discussion above provides evidence of high levels of fishing effort by commercial and artisanal fishermen using trawl and net gear throughout the range of these *Squatina* species. Therefore, given the inferred discard mortality estimates (with a 60 percent at-vessel mortality rate in trawls and 25–67 percent mortality rate in nets) and high likelihood of incidental capture, we find that the continued operation of the demersal trawl fleets and net fisheries is posing a threat of overutilization that is likely contributing to further population declines and significantly increasing the extinction risks of these species at this time.

In addition to the threat of overutilization from being bycaught, there is also evidence that these species are still being landed in certain parts of their ranges, contributing to the direct fishing mortality of the species. In Egypt, for example, which has the 2nd largest fishing fleet (of vessels >15 m) operating in the GFCM convention area, Moftah (2011) documented three *S. squatina* individuals for sale in a major fish market in western Alexandria. However, according to Bradai *et al.* (2012), the top elasmobranch fishing countries presently operating in the Mediterranean are Italy, Tunisia, and Turkey. From 1980 to 2008, these three countries were responsible for 76 percent of the total catch of elasmobranchs in the Mediterranean and Black Seas. Currently, Italy has the largest fishing fleet (of vessels >15 m) operating in the GFCM convention area, with 84 percent of its vessels (n = 1,421) identified as trawlers. Turkey has the third largest fishing fleet, with 54 percent identified as trawlers, and Tunisia has the fifth largest, with around 50 percent of its vessels considered to be trawlers. Although Italian vessels are currently prohibited from landing *S. squatina* in EU waters (see *Inadequacy of Existing Regulatory Mechanisms* section), Tunisia and Turkey do not have the same prohibitions for their respective waters. Additionally, there are no prohibitions from landing the other two species of angelsharks throughout their ranges.

In waters off Tunisia, the present level of fishing effort by trawlers as well as artisanal fishermen is a concern for any remaining populations of the three angelshark species. Tunisia is centrally located in the Mediterranean Sea. The Gulf of Gabès and Gulf of Tunis, which historically supported populations of the *Squatina* species (Capapé *et al.* 1990; Quignard and Ben Othman 1978), are two of the most important fishing grounds off the Tunisian coast (Echwikhi *et al.* 2013; Cherif *et al.* 2008). In 2011, the Tunisian fishing fleet consisted of 11,393 units, which included 10,500 coastal boats (artisanal fishermen), 430 trawlers, 400 sardine seiners, 38 tuna seiners, and 25 coral-fisher boats (Haddad 2011). Elasmobranchs, in particular, constitute an important catch component in Tunisian fisheries, especially artisanal fisheries (Echwikihi *et al.* 2013), and since 1970, annual catches of elasmobranchs have steadily increased with recent catches (2005–2012) of elasmobranchs averaging around 2,000 mt per year. Similarly, *S. squatina* catches in Tunisian waters also appear to show an increase in recent years, with a peak of 86 mt in 2010 and 60 mt in 2012. In 1990, Capapé *et al.* (1990) observed that *S. squatina* was fished throughout the year in Tunisian waters and sold in the Tunis fish market. Based on the recent catch data, it appears that *S. squatina* is still being exploited by Tunisian fisheries. It is unknown if this exploitation is sustainable; however, based on the species' life history traits as well as the observed decline of the species and potential extirpations in areas where reported catches and landings have been of lesser magnitude (*e.g.,* Bay of Biscay; Celtic Seas), this present level of exploitation is likely to cause declines in the *S. squatina* population from this area through the foreseeable future.

The absence of data for the other two *Squatina* species is also telling, especially since in 1978, *S. aculeata* was noted as abundant, and as recently as 2006, both species were ''regularly observed'' in the Gulf of Gabès (Quignard and Ben Othman 1978; Bradai *et al.* 2006). Additionally, in 1990, the Gulf of Tunis was posited as a nursery ground for *S. oculata* based on young-of-the-year individuals captured during trawling operations (Capapé *et al.* 1990). However, in a recent analysis of extensive trawl survey data collected off the southern coasts of Sicily from 1994 to 2009, Ragonese *et al.* (2013) found only one report of a captured *S. aculeata* individual. This shark was caught during a shelf haul in 86 m

depth close to the Gulf of Gabès in 2000. The fact that observations of these species are now rare, with the last record of the species in survey data from 15 years ago (Ragonese *et al.* 2013), and the most recent anecdotal characterizations of the species from almost a decade ago (Bradai *et al.* 2006), suggests that the remaining populations of *S. aculeata* and *S. oculata* are likely small and potentially isolated, placing them at risk from stochastic and demographic fluctuations. These risks will only increase in the future as more individuals are removed from the populations as a result of the continued fishing pressure by trawlers and artisanal fishermen within this region.

In Turkey, at least one angelshark species, *S. aculeata,* was a recent target of recreational fishermen. Based on field survey data collected between January and September 2007, boat-based recreational fishermen operating in Çanakkale Strait caught an estimated 23,820 kg of *S. aculeata* (Ünal *et al.* 2010). The number of surveyed fishermen represented only 2.7 percent of the estimated recreational fishery population. In addition, the results from the surveys indicated that the marine recreational fishery in Turkey is essentially unmonitored and hence potentially unsustainable (Ünal *et al.* 2010). In fact, almost half of the recreational activity can be considered commercial activity as many of the recreational fishermen are selling their catches (even though marine recreationally caught fish are not legally allowed to be traded; Ünal *et al.* 2010). Given the high level of marine recreational harvest (around 30 percent of the commercial fishing harvest; Ünal *et al.* 2010), evidence of *S. aculeata* as a potentially targeted and traded species, and lack of monitoring or controls regarding fishing practices, this marine recreational fishery is considered a threat contributing to the direct overutilization of the species in this area. In 2015, one of the co-authors of the above study noted that the species is presently rare in Turkish waters, but mentioned the recent capture of an *S. aculeata* shark from Gökova Bay by a fisherman using a trammel net (V. Ünal, personal communication 2015). This individual (a female *S. aculeata*) is the largest specimen ever recorded from Turkish waters (V. Ünal, pers. comm. 2015).

In addition to the marine recreational fisheries, the commercial fisheries of Turkey are also harvesting angelsharks; however, the information on catch is not species-specific. According to Turkey's ''Fisheries Statistics'' publication, catches of angelsharks have declined over the past 8 years after a peak of 51 tonnes was reported in 2006. In 2013, 17 tonnes of angelsharks were harvested, with 68 percent of the catch coming from the Aegean region, 26 percent from the Mediterranean region, and 6 percent from the Marmara region. Although there is no accompanying information on fishing effort, the bottom trawl fishery is highly active in Turkish waters. In 2015, the GFCM identified 554 Turkish trawl vessels (over 15 meters) as authorized to fish in the GFCM convention area, and according to Tokaç *et al.* (2012), the bottom trawl fishery is responsible for around 90 percent of the total demersal fish catch from the Aegean Sea. As such, the decline in angelshark catch may likely be a result of decreasing abundance of these sharks in the region as a result of the exploitation of the species by the demersal trawl fishery.

In the northeastern Atlantic, Spanish and French fleets have reported landings of *S. squatina* to ICES since the species' retention prohibition by the EU in 2009 (see *Inadequacy of Existing Regulatory Mechanisms* section). In 2010, Spanish-reported landings amounted to 9 tonnes (live weight), increased to 10 tonnes in 2011, and significantly increased to 63 tonnes in 2012. All of these landings occurred off the coasts of Portugal and Spain (ICES 2014). The ICES (2014) notes that there are also nominal records of *S. squatina* in French national landings for 2012 and 2013 but does not report the figures due to the unreliability of the data. There was no corresponding information on fishing effort and it is also unclear why this EU-prohibited species is still being landed by EU vessels.

Similarly, in the Canary Islands, where *S. squatina* retains its EU prohibited designation, there is evidence that individuals continue to be captured by local and sport fishermen. Although *S. squatina* is not a targeted species in the Canary Islands, nor is there large demand for the species, fishermen in the area do like to eat angelsharks and may illegally land the species (E. Meyers, pers. comm. 2014). This illegal fishing of the species by artisanal fishermen for personal consumption is a concern for the *S. squatina* population in these waters (E. Meyers, pers. comm. 2014). Artisanal Canarian fishermen tend to concentrate their fishing efforts on the narrow continental shelf around the islands (Popescu and Ortega-Gras 2013), which increases the likelihood of capture of *S. squatina* sharks. Although the artisanal fishery has experienced a significant reduction in the number of fishing vessels since 2004, there has also been an associated increase in engine power per small vessel (Popescu and Ortega-Gras 2013). In fact, between 1990 and 2003, these small vessels constituted only 12–18 percent of the total power of the Canarian fleet, but by 2013, this contribution had risen to 30.6 percent (Popescu and Ortega-Gras 2013). Additionally, despite the decrease in number of vessels, the artisanal sector remains the most important segment of the Canarian fishing fleet (both on a social and economic level), with small boats (less than 12 m) representing 86.7 percent of the total number of vessels in the Canarian fishing fleet (Popescu and Ortega-Gras 2013).

Recreational fishing in the Canary Islands is also identified as a potential threat to the species, as many Canarian sport fishing Web sites display photos of hooked angelsharks despite their prohibited status. There is evidence that angelsharks caught by sportfishermen are returned to the water after a photo has been taken; however, the post-release survival rates are unknown (J. Barker, pers. comm. 2015). This has become a concern in recent years due to the increasing number of sport fishermen in the area. According to Barker *et al.* (2014), from 2005 to 2010 there has been a nearly 3-fold increase in the number of recreational angler licenses (from 40,000 to 116,000), with over 830 registered charter fishing boats in operation. As the number of recreational anglers increases, so does the risk of hooking (and potentially killing) one of these prohibited sharks. Although *S. squatina* are regularly observed around the Canary Islands, very little is known about this population or the associated risks of this level of utilization (by artisanal and sport fishermen) on the local population.

In waters off West Africa, artisanal fishing pressure on sharks remains high and relatively unregulated. In 2010, the number of artisanal fishing vessels that landed elasmobranchs in the SRFC zone was estimated to be around 2,500 vessels, with 1,300 of those specializing in catching sharks (Diop and Dossa 2011). Morey *et al.* (2007a, b) note that although there are no directed fisheries for *Squatina* species, it is taken as bycatch in the international industrial demersal trawl fisheries and artisanal fisheries. In a personal communication to Morey *et al.* (2007b), M. Ducrocq states that *S. oculata* were common and frequently caught by artisanal Senegalese fishermen in line and gillnet gear around 30 years ago, and Capapé *et al.* (2005) noted that *S. aculeata* was relatively abundant off the coast of

Senegal and landed throughout the year. However, since 2005, fishermen have reported fewer observations of all squatinid species (C. Capapé, pers. comm. 2015), with no observed landings in recent years in the artisanal fishery (Mathieu Ducrocq, Programme Arc d'Emeraude, Agence Nationale des Parcs Nationaux, personal communication 2014). Although not as common anymore, this information suggests that *S. oculata* and *S. aculeata* were and potentially still are susceptible to being caught in artisanal fishing gear. Taking into account this susceptibility, as well as the fact that fishing for sharks occurs year-round in this region, and fishery management plans are still in the early implementation phase for this region (Diop and Dossa 2011), the continued operations of the artisanal fisheries may prevent any potential re-establishment of these *Squatina* species to this area (if already extirpated) or lead to further declines in existing local populations in the foreseeable future.

Illegal fishing in waters off West Africa is also a threat likely contributing to the observed declines of these species and contributing to their risk of extinction. Illegal fishing activities off West Africa are thought to account for around 37 percent of the region's catch, the highest regional estimate of illegal fishing worldwide (Agnew *et al.* 2009, EJF 2012). From January 2010 to July 2012, the UK-based non-governmental organization Environmental Justice Foundation (EJF) conducted a surveillance project in southern Sierra Leone to determine the extent of illegal fishing in waters off West Africa (EJF, 2012). The EJF staff received 252 reports of illegal fishing by industrial vessels in inshore areas, 90 percent of which were bottom trawlers (EJF 2012). The EJF (2012) surveillance also found these pirate industrial fishing vessels operating inside exclusion zones, using prohibited fishing gear, refusing to stop for patrols, attacking local fishers and destroying their gear, and fleeing to neighboring countries to avoid sanctions. Due to a lack of resources, many West African countries are unable to provide effective or, for that matter, any enforcement, with some countries even lacking basic monitoring systems. In waters off Senegal, which may have historically supported larger populations of *S. aculeata* and *S. oculata* (see Historical and Current Distribution and Population Abundance section), fishery resources have been severely depleted due to both foreign and illegal fishing activities. In 2006, after Senegal cancelled its licensing agreement with the subsidized EU fleet, dozens of large (10,000-tonne factory ships) foreign trawling vessels were granted new licenses by the government and were reportedly catching hundreds of tonnes of fish a day (and up to 300,000 tonnes a year; Vidal 2012b) in Senegalese waters (Vidal 2012a). Although these trawlers are prohibited from trawling within 12-miles of the coast, due to the lack of monitoring and policing capabilities, many move closer inshore at night to fish (Vidal 2012b). Quoting the manager of the largest fishing port in Senegal, Vidal (2012b) reports that fish catches have decreased 75 percent compared to 10 years ago. Based on the level of fishing activity, reported landings and trends, fishing gear, and area of operation, it is likely that these foreign and illegal trawling activities have significantly contributed to the observed decline of the *Squatina* species within these areas. Although many of the foreign vessel licenses were cancelled in 2012 (see *Inadequacy of Existing Regulatory Mechanisms* section), due to the lack of enforcement resources, illegal trawling is still considered to be a threat contributing to the overutilization of the demersal resources, including the *Squatina* species.

Overall, the available information on the past and present status of these species, including historical and present observations of the species from anecdotal, commercial, and fishery-independent survey data, in combination with trends in fishing effort and catch, suggests that the threat of overutilization alone is likely contributing significantly to the risk of extinction for all three *Squatina* species.

Inadequacy of Existing Regulatory Mechanisms

In the EU, there are some regulatory mechanisms in place to protect these three *Squatina* species. All three *Squatina* species are listed on Annex II of the Barcelona Convention, ''which requires Mediterranean countries to undertake maximum, cooperative efforts for their protection and recovery, including controlling or prohibiting their capture and sale, prohibiting damage to their habitat, and adopting measures for their conservation and recovery.'' In 2012, Spain published Order AAA/75/2012 which announced the inclusion of the Mediterranean populations of these three angelshark species (*S. squatina, S. oculata,* and *S. acuelata*) on Spain's List of Wild Species under Special Protection. Species on the list are protected from capture, injury, trade, import and export, and require periodic evaluations of their conservation status.

Elsewhere in the EU, however, specific regulations prohibiting the capture or trade of these angelshark species, or other efforts to protect and recover these species, are missing or only apply to *S. squatina* and not the other two species. For example, in 2008, *S. squatina* was listed under Schedule 5, Section 9(1) of the UK Wildlife and Countryside Act (1981), which protects the species from being killed, injured or taken on land and up to 6 nautical miles from English coastal baselines. In 2011, these protections were extended out to 12 nautical miles and the species was also added under section 9(2) and 9(5), protecting it from being possessed or traded. In 2010 and 2012, ICES advised that *S. squatina* remain on its list of Prohibited Species and that any incidental bycatch be returned to the sea (ICES 2014). In 2009, *S. squatina* received full protection in EU waters from the European Council (Council Regulation (EC) 43/2009). European Union vessels are currently prohibited from fishing for, retaining on board, transhipping, or landing *S. squatina* in all EU waters (including EU waters within the Mediterranean Sea) (EC 23/2010, 57/2011, 43/2012, 39/2013, 43/2014). These retention prohibitions may decrease, to some extent, fisheries-related mortality of the species, especially in those parts of its range where the species was previously landed. However, even prior to these prohibitions, it appears that the species was normally discarded due to its low commercial value. Given the assumed low survival rate of the species when bycaught and discarded by the trawl and demersal line fisheries (see *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes* section), these existing regulatory mechanisms may only have a minor impact on decreasing current fisheries-related mortality and, ultimately, *S. squatina's* risk of extinction.

In Ireland, in 2006, the Irish Specimen Fish Committee, which verifies and publicizes the capture of specimen (trophy) fish caught by anglers using rod and reel methods, removed *S. squatina* from its list of eligible ''specimen status'' species due to concern over its status. The committee reviewed the data on angler catches of angelsharks in 2009 and again in 2013, and after finding a decline in the number being caught and released, decided to keep the exclusion in place until the next review period in 2015. As long as this exclusion from the specimen status list is in place, it should provide some benefit to the local

populations, as it will decrease potential fisheries-related mortality of the larger (and likely mature individuals) that may occur during handling and processing of the fish to meet the claim requirements. However, these benefits may be offset by the fact that claims for a new record (which is different from a specimen fish) are still considered, with the requirement that the fish be weighed on shore, photographed and returned alive. Therefore, there is some risk that especially large angelsharks (as the current angling record is a 33 kg *S. squatina*) may still be brought ashore with the potential for mortality during the processing of angling records. Removal of these larger and mature individuals from an already declining population will greatly decrease its productivity, making it more susceptible to overexploitation that may lead to potential extirpations.

With respect to overutilization of the species by commercial fisheries in Ireland, a major threat identified for the angelsharks in Irish waters was the unsustainable level of bycatch of the species in trammel nets deployed by commercial fishermen. In 2002, a regulation (SI—Statutory Instrument) was implemented prohibiting the use of trammel nets to catch crawfish in specific areas off the coasts of Kerry and Galway (SI No. 179). This regulation was renewed in 2006 (SI No. 233); however the use of trammel nets to catch other species is still allowed (Fahy and Carroll 2009), decreasing the level of protection that this prohibition affords angelsharks. In addition, enforcement of inshore fishery regulations is lacking, and, as a consequence, Fahy and Carroll (2009) note that trammel nets are set year-round in Brandon and Tralee Bays (south-west Ireland—areas once known for large *S. squatina* populations) with the majority of landed crawfish caught by this method. Due to the deficiencies in the legislation (Bord Iascaigh Mhara (BIM) 2012) and enforcement of the SI, commercial trammel net fishing in the inshore areas off western Ireland still poses a significant risk to any remaining *S. squatina* individuals, and, as such, this regulatory measure is inadequate in decreasing the threat of overutilization by commercial fisheries in this area.

With respect to controlling general EU fishing effort in the Mediterranean, the Common Fisheries Policy (CFP; the fisheries policy of the EU) requires Member States to achieve a sustainable balance between fishing capacity and fishing opportunities. However, due to criticisms that the CFP has failed to control the problem of fleet overcapacity (European Commission 2009; 2010) and consequently prevent further declines in fish stocks (Khalilian et al. 2010), it was reformed in 2014. It is too soon to know if the new policies identified in the CFP, such as a complete ''discard ban'' and managing stocks according to maximum sustainable yield, will be adequate in controlling fishing effort by the European fishing fleet to the point where they no longer pose a threat to the remaining *Squatina* species populations.

In non-EU countries, regulations to protect any of these *Squatina* species from overutilization are lacking. There are no species-specific management measures and current regulations are likely inadequate to prevent further declines in the three *Squatina* species. In Turkey, for example, there are very few landing quotas for species due to a lack of stock assessments, even though evidence suggests that many of the species found in Turkish seas are presently overexploited (OECD 2003; Tokaç *et al.* 2012; Ulman *et al.* 2013). The number of registered fishing boats continues to increase, with previous attempts to control the fishing effort deemed unsuccessful. Based on an analysis of catch data, Ulman *et al.* (2013) note that the optimal fleet capacity has been exceeded by over 350 percent for all of Turkey's seas, suggesting that fishing effort and stocks will continue to decline through the foreseeable future. Although there are some seasonal prohibitions to protect spawning stocks in certain areas, minimum size regulations, and gear restrictions, including a bottom trawl ban in the Sea of Marmara, there is little enforcement of existing regulations, with current management measures and prohibitions likely insufficient to protect fish resources from further declines (OECD 2003; Ulman *et al.* 2013).

Off the coast of West Africa, fishing occurs year-round, including during shark breeding season (Diop and Dossa 2011). Many of the state-level management measures in this region lack standardization at the regional level (Diop and Dossa 2011), which weakens some of their effectiveness. For example, Sierra Leone and Guinea both require shark fishing licenses; however, these licenses are much cheaper in Sierra Leone, and, as a result, fishers from Guinea fish for sharks in Sierra Leone (Diop and Dossa 2011). Also, although many of these countries have recently adopted FAO recommended National Plans of Action—Sharks, their shark fishery management plans are still in the early implementation phase, and with few resources for monitoring and managing shark fisheries, the benefits to sharks, including *Squatina* species, from these regulatory mechanisms have yet to be realized (Diop and Dossa 2011). Additionally, many of these countries also lack the resources and capabilities to effectively enforce presently implemented fishing regulations, making this region a hotbed for illegal fishing activities (Agnew *et al.* 2009, EJF 2012). For example, although the Senegalese government took a significant step in controlling the exploitation of its fisheries when it cancelled the licenses of 29 foreign fishing trawlers in 2012, Senegal's director of Ministry of Fisheries and Maritime Affairs, Mr. Cheikh Sarr, recognizes that the country still lacks the enforcement resources and capabilities to combat illegal fishing activities. Mr. Sarr, quoted in Lazuta (2013), remarks: ''Revoking these licenses has been helpful in the general sense . . . But the reality is, whether or not a boat is authorized to enter our waters, if they decide to engage in IUU [illegal, unreported, and unregulated fishing], they will come . . . And often, we have very little power to stop them.'' These licenses were cancelled in response to the growing anger of artisanal fishermen at the level of overfishing by these trawlers and the alleged corruption of the previous government's licensing system (Vidal 2012a). It is unclear if these licenses will remain cancelled in the future under different government regimes. As such, the present regulatory mechanisms in this region, as well as means to enforce these mechanisms, appear inadequate to control the exploitation by illegal fishing vessels and thus pose a threat to the *Squatina* populations that may still be found in these waters.

Within the Canary Islands, the EU prohibited bottom trawling throughout the EEZ in 2005 ((EC) No 1568/2005) in an effort to protect deep-water coral reefs from fishing activities. As demersal trawling is identified as a significant threat to *S. squatina,* contributing to its past decline, this prohibition will provide needed protection to *S. squatina* in an area where the species is still commonly observed. In addition, there are also three designated marine reserves in the Canary Islands, which provide protection from fishing activities, but they are relatively small, covering only 0.15 percent of the Canarian EEZ. Given the uncertainty regarding the population distribution of *S. squatina* within the Canary Islands, it is unclear if these reserves are even effective in protecting *S. squatina* from fishery-related

mortality. In fact, based on the present threats to the species in the Canary Islands, which include sport fishing practices and illegal fishing by artisanal fishermen for personal consumption, it does not appear that the current regulatory mechanisms in place are adequate to address these threats. For example, in August 2014, due to the concern over the sport fishing of prohibited shark species, the Canarian Government required anyone obtaining a sport fishing license to prominently display a poster of prohibited shark species (including *S. squatina*) on board their boat. Although this new requirement may help deter sport fishermen from keeping the sharks, it does not address the stress of capture and lethal handling techniques used by these fishermen (*e.g.,* gaffing and long periods out of water; ZSL 2014). Additionally, those boats that had a sport fishing license prior to August 2014 are not required to have or display this poster (E. Meyers, pers. comm. 2015). Thus, the species may continue to suffer mortality in the sport fishery. Similarly, there is no information available to suggest that the current regulatory mechanisms will be adequate to curb the illegal fishing of the species by artisanal fishermen in the area. Although the species is protected in EU waters, the local Canarian government does not enforce this law, nor is there legal prosecution of violators (E. Meyers, pers. comm. 2015).

Overall, existing regulatory mechanisms appear inadequate in decreasing the main threat of overutilization of these species. This is especially true for *S. aculeata* and *S. oculata,* which are still allowed to be legally exploited, with this exploitation essentially unregulated, throughout their respective ranges. Although *S. squatina* is afforded a higher level of protection through the EU prohibition of landing of the species, its range extends to areas where this prohibition does not apply. In addition, given the level of fishing effort by the Mediterranean trawl and demersal line fisheries and Canarian artisanal and sport fishermen, and associated discard mortality of the species, the existing regulatory measures may only have a minor impact on decreasing current fisheries-related mortality of *S. squatina.* As such, we conclude that the threat of the inadequacy of existing regulatory mechanisms is likely contributing significantly to the risk of extinction for all three *Squatina* species.

Extinction Risk

Although accurate and precise data for many demographic characteristics of the *Squatina* shark species are lacking, the best available data provide multiple lines of evidence indicating that these species currently face a high risk of extinction. As defined by the status review (Miller 2015), a species is considered to be at a high risk of extinction when it is at or near a level of abundance, spatial structure and connectivity, and/or diversity that place its persistence in question. The demographics of the species may be strongly influenced by stochastic or depensatory processes. Similarly, a species may be at high risk of extinction if it faces clear and present threats (*e.g.,* confinement to a small geographic area; imminent destruction, modification, or curtailment of its habitat; or disease epidemic) that are likely to create such imminent demographic risks. Below, the analysis of extinction risk is given for each species.

Squatina aculeata

The sawback angelshark presently faces demographic risks that significantly increase its risk of extinction. Although there are no quantitative historical or current abundance estimates, the best available information (including anecdotal accounts as well as survey data) suggest the species has likely undergone substantial declines throughout its range, with no evidence to suggest a reversal of these trends. Recent and spatially expansive trawl data indicate the species is currently rare, including in areas where it once was common (*e.g.,* Tunisia, Balearic Islands), as well as notably absent throughout most of its historical Mediterranean range. The best available data indicate a decline in abundance that has subsequently led to possible extirpations of the species from the Adriatic Sea, central Aegean Sea, Ligurian and Tyrrhenian Seas, and off the Balearic Islands. In the northeast Atlantic, the species was characterized as common in waters off West Africa, from Mauritania to Sierra Leone, in the 1970s; however, it has since undergone declines to the point where individuals of the species are rarely observed or caught, with the last record of the species from survey records dating back to 1998. The rare occurrence and absence of the species in recent survey data, despite sampling effort in areas and depths where *S. aculeata* would potentially or previously be found, suggest current populations are likely small and fragmented, making them particularly susceptible to local extirpations from environmental and anthropogenic perturbations or catastrophic events. Additionally, the reproductive characteristics of the species: Late maturity, long gestation, and low fecundity (which may be further reduced as gravid *Squatina spp.* females easily abort embryos during capture and handling) suggest the species has relatively low productivity, similar to other elasmobranch species. These reproductive characteristics have likely hindered the species' ability to quickly rebound from threats that decrease its abundance (such as overutilization) and render it vulnerable to extinction. Although there is no genetic, morphological or behavioral information available that could provide insight into natural rates of dispersal and genetic exchange among populations, *S. aculeata* are ovoviviparous (lacking a dispersive larval phase) and the best available information suggests that they likely have a patchy distribution due to local extirpations, population declines, and limited migratory behavior. As such, connectivity of *S. aculeata* populations is likely low, and this limited inter-population exchange may increase the risk of local extirpations, possibly leading to complete extinction. The small, fragmented, and possibly isolated remaining populations suggest the species may be at an increased risk of random genetic drift and could experience the fixing of recessive detrimental alleles, reducing the overall fitness of the species.

In conclusion, although there is significant uncertainty regarding the current abundance of the species, the best available information indicates that the species has suffered substantial declines in portions of its range where it once was common, and is considered to be rare throughout its entire range. The species likely consists of small, fragmented, isolated, and declining populations that are likely to be strongly influenced by stochastic or depensatory processes and have little rebound potential or resilience. This vulnerability is further exacerbated by the present threats of overutilization and inadequacy of existing regulatory measures that continue to contribute to the decline of the existing populations, compromising the species' long-term viability. The demersal fisheries that historically contributed to the decline in *S. aculeata* are still active throughout the species' range and primarily operate in depths where *S. aculeata* would occur. The available information suggests heavy exploitation of demersal resources by these fisheries, including high levels of chondrichthyan discards and associated mortality due to the low gear selectivity and intensity of fishing effort throughout the Mediterranean and

eastern Atlantic. Given the depleted state of the *S. aculeata* populations and present demographic risks of the species, even low levels of mortality would pose a risk of extinction to the species. However, current regulatory measures appear inadequate to protect *S. aculeata* from further fishery-related mortality, especially in areas where recent fisheries data indicate the species may still be present. As such, the additional fishing mortality sustained by the species as a result of continued commercial, artisanal, recreational and illegal fishing activities is a threat that is significantly contributing to the species' risk of extinction throughout its range. In summary, based on the best available information and the above analysis, we conclude that *S. aculeata* is presently at a high risk of extinction throughout its range.

Squatina oculata

The smoothback angelshark presently faces demographic risks that significantly increase its risk of extinction. Although there are no quantitative historical or current abundance estimates, the best available information (including anecdotal accounts as well as survey data) suggest the species has likely undergone substantial declines throughout its range, with no evidence to suggest a reversal of these trends. Recent and spatially expansive trawl data indicate the species is currently rare, including in areas where it once was common (*e.g.,* Iberian coast, Tunisia, Balearic Islands), and notably absent throughout most of its historical Mediterranean range. The best available data indicate a decline in abundance that has subsequently led to possible extirpations of the species from the central Aegean Sea, Ligurian and Tyrrhenian Seas, and off the Balearic Islands. Although some qualitative descriptions of the abundance of the species from the literature suggest the species may be more common in portions of the central Mediterranean (*i.e.,* Libya) and the Levantine Sea (*i.e.,* Israel, Syria), these characterizations are almost a decade old. The absence of updated or recent data or information on the species within these areas is worrisome, and, based on the present threats to the species and its demographic risks, it is likely that these populations are also in decline. In the northeast Atlantic, the species was characterized as common in waters off West Africa, from Mauritania to Liberia, in the 1970s and 1980s; however, it has since decreased in abundance to the point where individuals of the species are rarely observed or caught, with the last record of the species from the survey records dating back to 2002. Based on the best available information, remaining populations of *S. oculata* are likely small and fragmented, making them particularly susceptible to local extirpations from environmental and anthropogenic perturbations or catastrophic events. Additionally, the reproductive characteristics of the species: Late maturity, long gestation, and low fecundity (which may be further reduced as gravid *Squatina spp.* females easily abort embryos during capture and handling) suggest the species has relatively low productivity, similar to other elasmobranch species. These reproductive characteristics have likely hindered the species' ability to quickly rebound from threats that decrease its abundance (such as overutilization) and render it vulnerable to extinction. Although there is no genetic, morphological or behavioral information available that could provide insight into natural rates of dispersal and genetic exchange among populations, *S. oculata* are ovoviviparous (lacking a dispersive larval phase) and the best available information suggests that they likely have a patchy distribution due to local extirpations, population declines, and limited migratory behavior. As such, connectivity of *S. oculata* populations is likely low, and this limited inter-population exchange may increase the risk of local extirpations, possibly leading to complete extinction. The small, fragmented, and possibly isolated remaining populations suggest the species may be at an increased risk of random genetic drift and could experience the fixing of recessive detrimental alleles, reducing the overall fitness of the species.

In conclusion, although there is significant uncertainty regarding the current abundance of the species, the best available information indicates that the species is presently rare throughout most of its range, likely consisting of small, fragmented, isolated, and declining populations that are likely to be strongly influenced by stochastic or depensatory processes and have little rebound potential or resilience. This vulnerability is further exacerbated by the present threats of overutilization and inadequacy of existing regulatory measures that continue to contribute to the decline of the existing populations, compromising the species' long-term viability. The demersal fisheries that historically contributed to the decline in *S. oculata* are still active throughout the species' range and primarily operate in depths where *S. oculata* would occur. The available information suggests heavy exploitation of demersal resources by these fisheries, including high levels of chondrichthyan discards and associated mortality due to the low gear selectivity and intensity of fishing effort throughout the Mediterranean and eastern Atlantic. Given the depleted state of the *S. oculata* populations and present demographic risks of the species, even low levels of mortality would pose a risk of extinction to the species. However, current regulatory measures appear inadequate to protect *S. oculata* from further fishery-related mortality. As such, the additional fishing mortality sustained by the species as a result of continued commercial, artisanal, and illegal fishing activities is a threat that is significantly contributing to the species' risk of extinction throughout its range. In summary, based on the best available information and the above analysis, we conclude that *S. oculata* is presently at a high risk of extinction throughout its range.

Squatina squatina

The common angelshark presently faces demographic risks that significantly increase its risk of extinction. Based on historical and current catches and survey data, *S. squatina* has undergone significant declines in abundance throughout most of its historical range, with no evidence to suggest a reversal of these trends. Once characterized as fairly common, the species is now considered to be extirpated from the western English Channel, North Sea, Baltic Sea, parts of the Celtic Seas, Adriatic Sea, Ligurian and Tyrrhenian Seas, and Black Sea, and rare throughout the rest of its range in the northeast Atlantic and Mediterranean, with one exception. The *S. squatina* population off the Canary Islands may be fairly stable (although there is no trend data to confirm this); however, this area only constitutes an extremely small portion of the species' range and its present abundance in this portion remains uncertain. Overall, the best available information suggests that *S. squatina* has undergone significant declines and is still in decline throughout most of its range. Current populations are likely small and fragmented, making them particularly susceptible to local extirpations from environmental and anthropogenic perturbations or catastrophic events. Additionally, the reproductive characteristics of the species: Late maturity, long gestation, and low fecundity (which may be further reduced as gravid *Squatina spp.* females easily abort embryos during capture and

handling) suggest the species has relatively low productivity, similar to other elasmobranch species. These reproductive characteristics have likely hindered the species' ability to quickly rebound from threats that decrease its abundance (such as overutilization) and render it vulnerable to extinction. Although there is no genetic, morphological or behavioral information available that could provide insight into natural rates of dispersal and genetic exchange among populations, *S. squatina* are ovoviviparous (lacking a dispersive larval phase) and the best available information suggests that they likely have a patchy distribution due to local extirpations, population declines, and limited migratory behavior with evidence of possible high site fidelity. As such, connectivity of *S. squatina* populations is likely low, and this limited inter-population exchange may increase the risk of local extirpations, possibly leading to complete extinction. The small, fragmented, and possibly isolated remaining populations suggest the species may be at an increased risk of random genetic drift and could experience the fixing of recessive detrimental alleles, reducing the overall fitness of the species.

In conclusion, although there is significant uncertainty regarding the current abundance of the species, the best available information indicates that the species has undergone a substantial decline in abundance. Once noted as common in historical records, the species is presently rare throughout most of its range (and considered extirpated in certain portions), with evidence suggesting it currently consists of small, fragmented, isolated, and declining populations that are likely to be strongly influenced by stochastic or depensatory processes. Based on tagging data, the Canary Island population, whose present abundance and population structure remains unknown, may be confined to this small geographic area. With limited inter-population exchange, its susceptibility to natural environmental and demographic fluctuations increases its risk of extirpation. The vulnerabilities of this species (small population sizes, declining trends, potential isolation) are further exacerbated by the present threats of curtailment of range, overutilization, and inadequacy of existing regulatory measures that will either contribute or continue to contribute to the decline of the existing populations, compromising the species' long-term viability. The demersal fisheries that historically contributed to the decline in *S. squatina* are still active throughout the species' range and primarily operate in depths where *S. squatina* would occur. Although the species is protected in EU waters, the available information suggests heavy exploitation of demersal resources by fisheries operating throughout the Mediterranean and eastern Atlantic, resulting in high levels of chondrichthyan discards and associated mortality. The species is still being landed, both legally and illegally, and, in some parts of its range, such as Tunisia, at levels that have historically led to population declines. In the Canary Islands, which are thought to be the last stronghold for the species, *S. squatina* is presently at risk of mortality at the hands of artisanal fishermen as well as a growing number of sport fishermen, despite the prohibition on capturing the species. Although trawling is banned within the Canary Islands, and a number of marine reserves have been established there, it is unclear to what extent these regulations will be effective in protecting important *S. squatina* habitat or decreasing fishing mortality rates. In summary, based on the best available information and the above analysis, we conclude that *S. squatina* is presently at a high risk of extinction throughout its range.

Protective Efforts

In response to the significant decline of *S. squatina* over the years, a number of conservation efforts are planned or in development with the goal of learning more about these sharks in order to understand how better to protect them. These efforts include projects to reduce sportfishing-related mortality and/or diver disturbance of the angelshark in the Canary Islands, data collection to inform conservation (including genetic and tagging research), and awareness-raising campaigns to promote the importance of the Canary Islands for angelshark conservation (ASP 2014; E. Meyers, pers. comm. 2015; J. Barker, pers. comm. 2015). While funding has been secured for some of these activities, including for a pilot angelshark tagging program, many of the other efforts described above are dependent on additional future funding (J. Barker, pers. comm. 2015). As such, the likelihood of implementation of these projects remains uncertain. There is also a collaborative effort sponsored by Deep Sea World (Scotland's National Aquarium) and Hastings Blue Reef Aquarium to breed angelsharks in captivity, and in 2011, they were successful. A female *S. squatina* successfully delivered 19 pups in captivity, marking the first time that an angelshark has successfully bred in captivity (Deep Sea World 2015), which may be an important first step in the conservation of the species.

Although these efforts will help increase the scientific knowledge about *S. squatina* and promote public awareness of declines in the species, there is no indication that these efforts are currently effective in reducing the threats to the species, particularly those related to overutilization and the inadequacy of existing regulatory mechanisms. Therefore, we cannot conclude that these existing conservation efforts have significantly altered the extinction risk for the common angelshark. We are not aware of any other planned or not-yet-implemented conservation measures that would protect this species or the other two *Squatina* species (*S. aculeata* and *S. oculata*). We seek additional information on other conservation efforts in our public comment process (see below).

Proposed Determination

Based on the best available scientific and commercial information, as summarized here and in Miller (2015), we find that all three *Squatina* species are in danger of extinction throughout their respective ranges. We assessed the ESA section 4(a)(1) factors and conclude that *S. aculeata, S. oculata,* and *S. squatina* all face ongoing threats of overutilization by fisheries and inadequate existing regulatory mechanisms throughout their ranges. *Squatina squatina* has also suffered a significant curtailment of its range. These species' natural biological vulnerability to overexploitation and present demographic risks (*e.g.,* low and declining abundance, small and isolated populations, patchy distribution, and low productivity) are currently exacerbating the negative effects of these threats and placing these species in danger of extinction. We therefore propose to list all three species as endangered.

Effects of Listing

Conservation measures provided for species listed as endangered or threatened under the ESA include recovery actions (16 U.S.C. 1533(f)); concurrent designation of critical habitat, if prudent and determinable (16 U.S.C. 1533(a)(3)(A)); Federal agency requirements to consult with NMFS under section 7 of the ESA to ensure their actions do not jeopardize the species or result in adverse modification or destruction of critical habitat should it be designated (16 U.S.C. 1536); and

prohibitions on taking (16 U.S.C. 1538). Recognition of the species' plight through listing promotes conservation actions by Federal and state agencies, foreign entities, private groups, and individuals. The main effects of the proposed endangered listings are prohibitions on take, including export and import.

Identifying Section 7 Conference and Consultation Requirements

Section 7(a)(2) (16 U.S.C. 1536(a)(2)) of the ESA and NMFS/USFWS regulations require Federal agencies to consult with us to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of listed species or destroy or adversely modify critical habitat. Section 7(a)(4) (16 U.S.C. 1536(a)(4)) of the ESA and NMFS/USFWS regulations also require Federal agencies to confer with us on actions likely to jeopardize the continued existence of species proposed for listing, or that result in the destruction or adverse modification of proposed critical habitat of those species. It is unlikely that the listing of these species under the ESA will increase the number of section 7 consultations, because these species occur outside of the United States and are unlikely to be affected by Federal actions.

Critical Habitat

Critical habitat is defined in section 3 of the ESA (16 U.S.C. 1532(5)) as: (1) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the ESA, on which are found those physical or biological features (a) essential to the conservation of the species and (b) that may require special management considerations or protection; and (2) specific areas outside the geographical area occupied by a species at the time it is listed upon a determination that such areas are essential for the conservation of the species. ''Conservation'' means the use of all methods and procedures needed to bring the species to the point at which listing under the ESA is no longer necessary. Section 4(a)(3)(A) of the ESA (16 U.S.C. 1533(a)(3)(A)) requires that, to the extent prudent and determinable, critical habitat be designated concurrently with the listing of a species. However, critical habitat shall not be designated in foreign countries or other areas outside U.S. jurisdiction (50 CFR 424.12(h)).

The best available scientific and commercial data as discussed above identify the geographical areas occupied by *Squatina aculeata, S. oculata,* and *S. squatina* as being entirely outside U.S. jurisdiction, so we cannot designate critical habitat for these species.

We can designate critical habitat in areas in the United States currently unoccupied by the species, if the area(s) are determined by the Secretary to be essential for the conservation of the species. Regulations at 50 CFR 424.12(e) specify that we shall designate as critical habitat areas outside the geographical range presently occupied by the species only when the designation limited to its present range would be inadequate to ensure the conservation of the species. The best available scientific and commercial information on these species does not indicate that U.S. waters provide any specific essential biological function for any of the *Squatina* species proposed for listing. Therefore, based on the available information, we do not intend to designate critical habitat for *S. aculeata, S. oculata,* or *S. squatina*.

Identification of Those Activities That Would Constitute a Violation of Section 9 of the ESA

On July 1, 1994, NMFS and FWS published a policy (59 FR 34272) that requires us to identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the ESA.

Because we are proposing to list all three *Squatina* species as endangered, all of the prohibitions of section 9(a)(1) of the ESA will apply to these species. These include prohibitions against the import, export, use in foreign commerce, or ''take'' of the species. These prohibitions apply to all persons subject to the jurisdiction of the United States, including in the United States, its territorial sea, or on the high seas. Take is defined as ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.'' The intent of this policy is to increase public awareness of the effects of this listing on proposed and ongoing activities within the species' range. Activities that we believe could result in a violation of section 9 prohibitions for these species include, but are not limited to, the following:

(1) Delivering, receiving, carrying, transporting, or shipping in interstate or foreign commerce any individual or part, in the course of a commercial activity;

(2) Selling or offering for sale in interstate commerce any part, except antique articles at least 100 years old; and

(3) Importing or exporting these angelshark species or any part of these species.

We emphasize that whether a violation results from a particular activity is entirely dependent upon the facts and circumstances of each incident. Further, an activity not listed may in fact result in a violation.

Public Comments Solicited

To ensure that any final action resulting from this proposed rule will be as accurate and effective as possible, we are soliciting comments and information from the public, other concerned governmental agencies, the scientific community, industry, and any other interested parties on information in the status review and proposed rule. Comments are encouraged on these proposals (See **DATES** and **ADDRESSES**). We must base our final determination on the best available scientific and commercial information when making listing determinations. We cannot, for example, consider the economic effects of a listing determination. Final promulgation of any regulation(s) on these species' listing proposals will take into consideration the comments and any additional information we receive, and such communications may lead to a final regulation that differs from this proposal or result in a withdrawal of this listing proposal. We particularly seek:

(1) Information concerning the threats to any of the *Squatina* species proposed for listing;

(2) Taxonomic information on any of these species;

(3) Biological information (life history, genetics, population connectivity, etc.) on any of these species;

(4) Efforts being made to protect any of these species throughout their current ranges;

(5) Information on the commercial trade of any of these species;

(6) Historical and current distribution and abundance and trends for any of these species; and

(7) Current or planned activities within the range of these species and their possible impact on these species.

We request that all information be accompanied by: 1) supporting documentation, such as maps, bibliographic references, or reprints of pertinent publications; and 2) the submitter's name, address, and any association, institution, or business that the person represents.

Role of Peer Review

In December 2004, the Office of Management and Budget (OMB) issued

a Final Information Quality Bulletin for Peer Review establishing a minimum peer review standard. Similarly, a joint NMFS/FWS policy (59 FR 34270; July 1, 1994) requires us to solicit independent expert review from qualified specialists, concurrent with the public comment period. The intent of the peer review policy is to ensure that listings are based on the best scientific and commercial data available. We solicited peer review comments on the status review report (Miller 2015) from four scientists familiar with the three angelshark species. We received and reviewed comments from these scientists, and their comments are incorporated into the draft status review report for the three *Squatina* species and this proposed rule. Their comments on the status review are summarized in the peer review report and available at *http://www.cio.noaa.gov/services_programs/prplans/PRsummaries.html*.

References

A complete list of the references used in this proposed rule is available upon request (see **ADDRESSES**).

Classification

National Environmental Policy Act

The 1982 amendments to the ESA, in section 4(b)(1)(A), restrict the information that may be considered when assessing species for listing. Based on this limitation of criteria for a listing decision and the opinion in *Pacific Legal Foundation* v. *Andrus,* 675 F. 2d 825 (6th Cir. 1981), we have concluded that ESA listing actions are not subject to the environmental assessment requirements of the National Environmental Policy Act (NEPA) (See NOAA Administrative Order 216–6).

Executive Order 12866, Regulatory Flexibility Act, and Paperwork Reduction Act

As noted in the Conference Report on the 1982 amendments to the ESA, economic impacts cannot be considered when assessing the status of a species. Therefore, the economic analysis requirements of the Regulatory Flexibility Act are not applicable to the listing process. In addition, this proposed rule is exempt from review under Executive Order 12866. This proposed rule does not contain a collection-of-information requirement for the purposes of the Paperwork Reduction Act.

Executive Order 13132, Federalism

In accordance with E.O. 13132, we determined that this proposed rule does not have significant Federalism effects and that a Federalism assessment is not required. In keeping with the intent of the Administration and Congress to provide continuing and meaningful dialogue on issues of mutual state and Federal interest, this proposed rule will be given to the relevant governmental agencies in the countries in which the species occurs, and they will be invited to comment. We will confer with the U.S. Department of State to ensure appropriate notice is given to foreign nations within the range of all three species. As the process continues, we intend to continue engaging in informal and formal contacts with the U.S. State Department, giving careful consideration to all written and oral comments received.

List of Subjects in 50 CFR Part 224

Endangered and threatened species, Exports, Imports, Transportation.

Dated: July 8, 2015.

Samuel D. Rauch, III.

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 224 is proposed to be amended as follows:

PART 224—ENDANGERED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 224 continues to read as follows:

Authority: 16 U.S.C. 1531–1543 and 16 U.S.C. 1361 *et seq.*

■ 2. In § 224.101, amend the table in paragraph (h) by adding new entries for three species in alphabetical order under the ''Fishes'' table subheading to read as follows:

§ 224.101 Enumeration of endangered marine and anadromous species.

* * * * *

(h) The endangered species under the jurisdiction of the Secretary of Commerce are:

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
*	*	*	*	*	*
		Fishes			
*	*	*	*	*	*
Shark, common angel-	*Squatina squatina*	Entire species	[*Insert **Federal Register** citation and date when published as a final rule*].	NA	NA.
Shark, sawback angel-	*Squatina aculeata*	Entire species	[*Insert **Federal Register** citation and date when published as a final rule*].	NA	NA.
Shark, smoothback angel-	*Squatina oculata*	Entire species	[*Insert **Federal Register** citation and date when published as a final rule*].	NA	NA.
*	*	*	*	*	*

[FR Doc. 2015–17016 Filed 7–13–15; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

RIN 0648–XD649

Fisheries of the Exclusive Economic Zone Off Alaska; Groundfish Fisheries in the Gulf of Alaska

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

ACTION: Notice; intent to prepare an environmental impact statement; request for written comments.

SUMMARY: NMFS, in consultation with the North Pacific Fishery Management Council (Council), announces its intent to prepare an Environmental Impact Statement (EIS) on a new management program for trawl groundfish fisheries in the Gulf of Alaska (GOA), in accordance with the National Environmental Policy Act of 1969 (NEPA). The proposed action would create a new management program that would allocate allowable harvest to individuals, cooperatives, and other entities that participate in GOA trawl groundfish fisheries. The proposed action is intended to improve stock conservation by imposing accountability measures for utilizing target, incidental, and prohibited species catch, creating incentives to eliminate wasteful fishing practices, providing mechanisms for participants to control and reduce bycatch in the trawl groundfish fisheries, and to improve safety of life at sea and operational efficiencies. The EIS will analyze the impacts to the human environment resulting from the proposed trawl bycatch management program. NMFS will accept written comments from the public to identify the issues of concern and assist the Council in determining the appropriate range of management alternatives for the EIS.

DATES: Written comments will be accepted through August 28, 2015.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2014–0150, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2014-0150*, click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Rachel Baker, (907) 586–7228 or email *rachel.baker@noaa.gov*.

SUPPLEMENTARY INFORMATION: Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the United States has exclusive fishery management authority over all living marine resources found within the exclusive economic zone (EEZ). The management of these marine resources, with the exception of marine mammals and birds, is vested in the Secretary of Commerce (Secretary). The Council has the responsibility to prepare fishery management plans for the fishery resources that require conservation and management in the EEZ off Alaska. Management of the Federal groundfish fisheries in the GOA is carried out under the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP). The FMP, its amendments, and implementing regulations (found at 50 CFR part 679) are developed in accordance with the requirements of the Magnuson-Stevens Act and other applicable Federal laws and executive orders, notably the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA).

The Council is considering the establishment of a new management program for the GOA trawl groundfish fisheries. The proposed action would allocate allowable harvest of selected target and bycatch species to individuals, cooperatives, and other entities. The purpose of the program is to improve management of all species caught in the GOA trawl groundfish fisheries by creating vessel-level and/or cooperative-level incentives to avoid and reduce bycatch, and to create accountability measures for participants when utilizing target and bycatch species. The Council also intends for the program to improve operational efficiencies, reduce incentives to fish during unsafe conditions, and support the continued participation of coastal communities that are dependent on the fisheries. NMFS and the Council have determined the preparation of an EIS may be required for this action because some important aspects of the bycatch management program on target and bycatch species and their users may be uncertain or unknown and may result in significant impacts on the human environment not previously analyzed. Thus, NMFS and the Council are initiating scoping for an EIS in the event an EIS is needed.

NMFS and the Council are seeking information from the public through the EIS scoping process on the range of alternatives to be analyzed, and on the environmental, social, and economic issues to be considered in the analysis. Written comments generated during this scoping process will be provided to the Council and incorporated into the EIS for the proposed action.

Management of the GOA Trawl Groundfish Fisheries

The Council and NMFS annually establish biological thresholds and annual total allowable catch limits for groundfish species to sustainably manage the groundfish fisheries in the GOA. To achieve these objectives, NMFS requires vessel operators participating in GOA groundfish fisheries to comply with various restrictions, such as fishery closures, to maintain catch within specified total allowable catch limits. The GOA groundfish fishery restrictions also include measures that are intended to minimize catch of certain species, called prohibited species, which may not be retained for sale by the vessel harvesting groundfish. For example, current GOA groundfish fishery regulations require Pacific halibut prohibited species catch (PSC) to be discarded immediately after it is recorded, and Chinook salmon must be retained by the harvest vessel only until sampled by an observer. The GOA groundfish fishery restrictions also include PSC limits for Pacific halibut and Chinook salmon to constrain the amount of bycatch of these species in the groundfish fisheries. When harvest of prohibited species in a groundfish fishery reaches the specified PSC limit for that fishery, NMFS closes directed fishing for the target groundfish species,

even if the total allowable catch limit for that species has not been harvested.

The GOA PSC limits are established on an annual basis by management area and are further apportioned by season, fishery category, gear, and operation type (*e.g.,* catcher vessel or catcher/processor). This apportionment process ensures that halibut and Chinook salmon PSC limit is available for use in groundfish fisheries earlier in the year, but limits that use so that PSC remains to support other groundfish fisheries that occur later in the year. The limits assigned to each season reflect halibut PSC likely to be taken during specific seasons by specific fisheries.

For many years, the Council and NMFS have controlled the amount of fishing in the North Pacific Ocean by establishing scientifically-based harvest limits which ensure that fisheries are conservatively managed and do not exceed established biological thresholds. In addition to measures that control the amount of harvest, the Council and NMFS also implemented the license limitation program (LLP), which limits access to the groundfish, crab, and scallop fisheries in the GOA and the Bering Sea and Aleutian Islands. The LLP limits entry into federally managed fisheries. The groundfish LLP requires each vessel in the GOA to have an LLP license on board the vessel at all times while directed fishing for license limitation groundfish, with limited exemptions. The preamble to the final rule implementing the groundfish LLP provides a more detailed explanation of the rationale for specific provisions in the LLP (October 1, 1998; 63 FR 52642).

While the LLP limits the total number of vessels that can participate in the fishery, it does not limit harvest by individual vessels or assign exclusive harvest privileges to specific vessels or entities. This has led to a competitive derby fishery in the GOA groundfish fisheries with fishermen racing each other to harvest as much fish as they can before the annual catch limit or the PSC limit is reached and the fishery is closed for the season. A derby fishery relies on a fairly rigid management structure that is not adaptable to changes in weather, markets, or other operating considerations. Therefore, a derby fishery often results in shorter fishing seasons and unsafe fishing practices. It can also create a substantial disincentive for participants to take actions to reduce bycatch use and waste, particularly if those actions could reduce groundfish catch rates. In a derby fishery, participants who choose not to take actions to reduce bycatch and waste stand to gain additional groundfish catch by continuing to harvest at a higher bycatch rate, at the expense of any vessels engaged in bycatch avoidance.

Allocation of allowable harvests in the form of exclusive harvest privileges is a management approach that replaces the rigid management structure of a derby fishery with a flexible program that provides accountability and removes disincentives to controlling and reducing bycatch and waste. Allocating exclusive harvest privileges to fishery participants can mitigate the potential negative impacts of a derby fishery on target and bycatch species, and on the operational and economic efficiency of the fisheries. In this type of management approach, a portion of the catch for a species is allocated to individual fishermen or groups. Each holder of a harvest privilege must stop fishing when his/her specific share of the quota is reached. This removes the incentives for each participant to maximize catch rates to capture a larger share of the available catch before the fishery is closed. As a result, participants can make operational choices to improve fishing practices. These choices could include fishing in a slower and more efficient fashion, using modified gear with a lower harvest rate but which reduces bycatch, coordinating with other vessel operators to avoid areas of high bycatch, and processing fish in ways that yield increased value but which are possible only by slowing the pace of the fishery. This management approach allows fishermen to plan their fishing effort around the weather, markets, or other business considerations and allows other fishery dependent businesses to plan more effectively.

The Council has recommended, and NMFS has implemented, management programs in the EEZ off Alaska that allocate exclusive harvest privileges to fishery participants. Based on experience with these programs, the Council and NMFS have determined that allocating exclusive harvest privileges of target and bycatch species creates a structure for fishery participants to efficiently manage harvesting and processing activities that can result in reduced bycatch and improved utilization of groundfish fisheries. Additional information on these management programs is provided in the final rules implementing the American Fisheries Act in the Bering Sea (67 FR 79692, December 30, 2002), the Amendment 80 Program in the Bering Sea and Aleutian Islands (72 FR 52668, September 14, 2007), and the Rockfish Program in the Central GOA (76 FR 81248, December 27, 2011).

Over the past few years, the Council has recommended amendments to the FMP to reduce PSC in the GOA groundfish fisheries. Under Amendments 93 and 97 to the FMP, the Council recommended and NMFS implemented Chinook salmon PSC limits in the GOA trawl fisheries (77 FR 42629, July 20, 2012 and 79 FR 71350, December 2, 2014). Under Amendment 95 to the FMP, the Council recommended and NMFS implemented reductions to halibut PSC limits for GOA trawl and hook-and-line fisheries (79 FR 9625, February 20, 2014). This series of actions reflects the Council's commitment to reduce PSC in the GOA groundfish fisheries. The Council also recognizes that although the current management system of establishing and apportioning PSC limits places a cap on the amount of PSC that may be used in GOA groundfish fisheries, the derby fishery under the LLP creates a substantial disincentive for participants to take actions to avoid and reduce PSC usage.

In October 2012, the Council unanimously adopted a purpose and need statement, and goals and objectives, to support the development of a new management program that would allocate allowable harvest to individual, cooperatives, or other entities. The Council determined that this kind of management program would mitigate the adverse effects of the current derby-style race for fish by removing disincentives to reduce bycatch and PSC, and providing a more flexible and efficient management system for participants to better manage and utilize groundfish species in the GOA trawl fisheries. This new management program is referred to as a bycatch management program in the following sections of this notice.

Proposed Action

The proposed action to be analyzed in the EIS is a bycatch management program for the GOA trawl groundfish fisheries that allocates allowable harvest to individuals, cooperatives, or other entities. The bycatch management program would replace the derby fishery with a program that provides tools to effectively manage bycatch and reduce PSC use, and that promotes increased utilization of groundfish harvested in the GOA. The proposed action would apply to participants in Federal groundfish fisheries prosecuted with trawl gear in the following areas: (1) The Western GOA Regulatory Area (Western GOA), (2) the Central GOA Regulatory Area (Central GOA), and (3) the West Yakutat District of the Eastern GOA Regulatory Area (West Yakutat

District). These areas are defined at § 679.2 and shown in Figure 3 to 50 CFR part 679.

Alternatives

NMFS, in coordination with the Council, will evaluate a range of alternative bycatch management programs for the trawl groundfish fisheries in the Western GOA, Central GOA, and West Yakutat District. NMFS and the Council recognize that implementation of a GOA trawl bycatch management program allocating exclusive harvest privileges would result in substantial changes to many of the current management measures for the groundfish fisheries. The EIS will analyze these changes as well as alternative ways to manage target and bycatch species in the GOA groundfish fisheries. The potential alternatives already identified for the EIS include:

Alternative 1

The existing management program (no action).

Alternative 2

A bycatch management program that would allocate exclusive harvest privileges to participants in the Western GOA, Central GOA, and West Yakutat District trawl groundfish fisheries who voluntarily join a cooperative. Participants who do not choose to join a cooperative would have the opportunity to participate in the current limited access management system under the groundfish LLP.

In Alternative 2, the Council is considering allocating exclusive harvest privileges to cooperatives. Alternative 2 contains several elements and options for determining eligible participants, groundfish and PSC species to be allocated, and methods for determining allocations to cooperatives and the limited access fishery. Alternative 2 also includes elements and options for cooperative formation and membership that are intended to provide incentives for participation by harvesters and processors to improve coordination and operational efficiencies. Alternative 2 also contains a number of elements that are intended to provide for fishery dependent community stability, such as harvest privilege consolidation limits and area- and port-specific delivery requirements.

Alternative 3

A bycatch management program that would allocate exclusive harvest privileges to fishery participants who voluntarily join a cooperative and either 1) a Community Fishing Association as defined in section 303A(c)(3) of the Magnuson-Stevens Act or 2) an Adaptive Management Program. Participants who do not choose to join a cooperative would have the opportunity to participate in the current limited access management system under the groundfish LLP.

In Alternative 3, the Council is considering allocating exclusive harvest privileges to cooperatives and either a Community Fishing Association or to persons who meet the criteria established for an Adaptive Management Program. The allocation to a Community Fishing Association or Adaptive Management Program would meet objectives that include providing for sustained participation of fishing communities, promoting conservation measures, and assisting vessel owner-operators, captains, and crew who want to enter and participate in the GOA trawl groundfish fisheries.

Public Involvement

Scoping is an early and open process for determining the scope of issues to be addressed in an EIS and for identifying the significant issues related to the proposed action. A principal objective of the scoping and public involvement process is to identify a range of reasonable management alternatives that, with adequate analysis, will delineate critical issues and provide a clear basis for distinguishing among those alternatives and selecting a preferred alternative. Through this notice, NMFS is notifying the public that an EIS and decision-making process for this proposed action have been initiated so that interested or affected people may participate and contribute to the final decision.

NMFS is seeking written public comments on the scope of issues, including potential impacts, and alternatives that should be considered for bycatch management programs for the trawl groundfish fisheries in the Western GOA, Central GOA, and West Yakutat District of the GOA. Written comments should be as specific as possible to be the most helpful. Written comments received during the scoping process, including the names and addresses of those submitting them, will be considered part of the public record of this proposal and will be available for public inspection. Written comments will be accepted at the address above (see **ADDRESSES**). Please visit the NMFS Alaska Region Web site at *http://www.alaskafisheries.noaa.gov* for more information on the GOA trawl bycatch management program EIS and for guidance on submitting effective written public comments.

The public is invited to participate and provide input at Council meetings where the latest scientific information regarding the GOA groundfish fisheries is reviewed and alternative bycatch management programs are developed and evaluated. Notice of future Council meetings will be published in the **Federal Register** and on the Internet at *http://www.npfmc.org/*. Please visit this Web site for information and guidance on participating in Council meetings. Additional information on the Council's development of the GOA trawl bycatch management program is available at *http://www.npfmc.org/goa-trawl-bycatch-management/*.

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

Dated: July 8, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–17191 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 80, No. 134

Tuesday, July 14, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Opportunity for Designation in Specified Geographical Areas in Texas

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice.

SUMMARY: The Grain Inspection, Packers and Stockyards Administration (GIPSA) is asking persons or governmental agencies interested in providing official services in Texas to submit an application for designation. Applicants must specify the geographical area(s) and include the county (or counties) for which you are applying.

DATES: Applications must be received by August 13, 2015.

ADDRESSES: Submit applications concerning this Notice using any of the following methods:

- *Applying for Designation on the Internet:* Use FGISonline *(https://fgis.gipsa.usda.gov/default_home_FGIS.aspx)* and then click on the Delegations/Designations and Export Registrations (DDR) link. You will need to obtain an FGISonline customer number and USDA eAuthentication username and password prior to applying.
- *Mail, Courier or Hand Delivery:* Eric J. Jabs, Deputy Director, USDA, GIPSA, FGIS, QACD, 10383 North Ambassador Drive, Kansas City, MO 64153.
- *Fax:* Eric J. Jabs, 816–872–1257.
- *Email: Eric.J.Jabs@usda.gov.*

Read Applications: All applications will be available for public inspection at the office above during regular business hours (7 CFR 1.27(c)).

FOR FURTHER INFORMATION CONTACT: Eric J. Jabs, 816–659–8408 or *Eric.J.Jabs@usda.gov.*

SUPPLEMENTARY INFORMATION: Section 79(f) of the United States Grain Standards Act (USGSA) authorizes the Secretary to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better able than any other applicant to provide such official services (7 U.S.C. 79(f)). Under section 79(g) of the USGSA (7 U.S.C. 79(g)), designations of official agencies are effective for three years unless terminated by the Secretary, but may be renewed according to the criteria and procedures prescribed in section 79(f) of the USGSA.

Areas Open for Designation

Pursuant to Section 79(f)(2) of the United States Grain Standards Act, the following areas are available for designation.

Texas

Bounded on the North by the northern El Paso, Hudspeth, Culberson, Reeves, Loving, Winkler, Ector, Midland, Glasscock, Sterling, Coke, Runnels, Coleman, Brown, Eastland, Stephens, Young, Jack, Montague, Cooke, Grayson, Fannin, Lamar, Red River, Morris, and Marion county lines.

Bounded on the East by the eastern Red River, Morris, Marion, Harrison, Panola, Shelby, Sabrine, Newton, Orange, Jefferson, Chambers, Harris, Galveston, Brazoria, Matagorda, Jackson, Calhoun, Refugio, Aransas, San Patricio, Nueces, Kleberg, Kennedy, Willacy, and Cameron County lines.

Bounded on the South by the Texas State Line.

Bounded on the West by the western Cameron, Hidalgo, Starr, Zapata, Webb, Maverick, Kinney, Val Verde, Terrell, Brewster, Presidio, Jeff Davis, Hudspeth, and El Paso county lines.

Excludes export port locations serviced by GIPSA's League City Field Office, Beaumont Sub-office, and Corpus Christi Duty Point.

Opportunity for Designation

Interested persons or governmental agencies may apply for designation to provide official services in any or all of the geographic area(s) specified above under the provisions of section 79(f) of the USGSA and 7 CFR 800.196. Applications must include the county (or counties) for which you are applying. Designation in the specified geographic area(s) is for a period of no more than three years. To apply for designation or for more information, contact Eric Jabs at the address listed above or visit GIPSA's Web site at *http://www.gipsa.usda.gov.*

Authority: 7 U.S.C. 71–87k.

Larry Mitchell,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2015–17210 Filed 7–13–15; 8:45 am]

BILLING CODE 3410–EN–P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Designation for the Montgomery, AL; Essex, IL; and Savage, MN Areas

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice.

SUMMARY: GIPSA is announcing the designation of Alabama Department of Agriculture and Industries (Alabama); Kankakee Grain Inspection, Inc. (Kankakee); and State Grain Inspection, Inc. (State Grain) to provide official services under the United States Grain Standards Act (USGSA), as amended.

DATES: *Effective Date:* January 1, 2015.

ADDRESSES: Eric J. Jabs, Deputy Director, USDA, GIPSA, FGIS, QACD, 10383 North Ambassador Drive, Kansas City, MO 64153.

FOR FURTHER INFORMATION CONTACT: Eric J. Jabs, 816–659–8408 or *Eric.J.Jabs@usda.gov.*

Read Applications: All applications and comments will be available for public inspection at the office above during regular business hours (7 CFR 1.27(c)).

SUPPLEMENTARY INFORMATION: In the August 26, 2014, **Federal Register** (79 FR 50886), GIPSA requested applications for designation to provide official services in the geographic areas presently serviced by Alabama, Gulf Country, Kankakee, and State Grain. Applications were due by September 25, 2014.

Alabama, Gulf Country, Kankakee, and State Grain were the sole applicants for designation to provide official services in these areas. As a result, GIPSA did not ask for additional comments.

GIPSA evaluated the designation criteria in section 79(f) of the USGSA (7 U.S.C. 79(f)) and determined that

Alabama, Kankakee, and State Grain are qualified to provide official services in the geographic area specified in the **Federal Register** on August 26, 2014. This designation action to provide official services for the specified areas for Alabama, Kankakee, and State Grain is effective January 1, 2015, to December 31, 2017.

GIPSA did not receive applications from any qualified applicants for the geographic area previously serviced by Gulf Country. GIPSA will be seeking additional applications under a separate notice in the **Federal Register**. In the interim, GIPSA will provide official services in the geographic area previously serviced by Gulf Country.

Interested persons may obtain official services by contacting these agencies at the following telephone numbers:

Official agency	Headquarters location and telephone	Designation start	Designation end
Alabama	Montgomery, AL (251) 438–2549	1/1/2015	12/31/2017
Kankakee	Essex, IL (815) 365–2268	1/1/2015	12/31/2017
State Grain	Savage, MN (952) 808–8566	1/1/2015	12/31/2017

Section 79(f) of the USGSA authorizes the Secretary to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better able than any other applicant to provide such official services (7 U.S.C. 79(f)).

Under section 79(g) of the USGSA (7 U.S.C. 79(g)), designations of official agencies are effective for no longer than three years unless terminated by the Secretary; however, designations may be renewed according to the criteria and procedures prescribed in section 79(f) of the USGSA.

Authority: 7 U.S.C. 71–87k.

Larry Mitchell,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2015–17211 Filed 7–13–15; 8:45 am]

BILLING CODE 3410–KD–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Oklahoma Advisory Committee for a Meeting To Hear Testimony on Civil Rights Concerns School-to-Prison Pipeline in Oklahoma

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Mississippi Advisory Committee (Committee) will hold a meeting on Friday, August 28, 2015, at 10:30 a.m. CDT for the purpose of hearing testimony on civil rights concerns relating to school-to-prison pipeline in Oklahoma on the basis of race or color. The testimony heard during this meeting will be used to prepare the Committee for its in person meeting on September 11, 2015, in Oklahoma City where it will hear from community members and other stakeholders on the same topic.

Members of the public can listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 888–337–8198, conference ID: 6979265. Any interested member of the public may call this number and listen to the meeting. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Member of the public are also invited and welcomed to make statements at the end of the conference call. In addition, members of the public may submit written comments; the comments must be received in the regional office by June 13, 2015. Written comments may be mailed to the Midwestern Regional Office, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Administrative Assistant, Carolyn Allen at *callen@usccr.gov.* Persons who desire additional information may contact the Midwestern Regional Office at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=269* and clicking on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Midwestern Regional Office at the above email or street address.

Agenda

Welcome and Introductions
10:30 a.m. to 10:35 a.m.
Vicki Limas, Chair
Panel Presentations on School-to-Prison Pipeline in Oklahoma
10:35 a.m. to 11:30 a.m.
Question and Answer Session with OK Advisory Committee
11:30 a.m. to 11:50 a.m.
Open Comment
11:50 a.m. to 12:00 p.m.
Adjournment
12:00 p.m.

DATES: The meeting will be held on Friday, August 28, 2015, at 10:30 a.m. CDT.

PUBLIC CALL INFORMATION: DIAL: 888–337–8198, Conference ID: 6979265.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at 312–353–8311 or *mwojnaroski@usccr.gov.*

Dated July 8, 2015.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2015–17077 Filed 7–13–15; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Indiana Advisory Committee for a Meeting To Discuss and Vote on Potential Project Topics

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules

and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Indiana Advisory Committee (Committee) will hold a meeting on Tuesday, July 30, 2015, at 12:00 p.m. EDT for the purpose of discussing the results of a straw poll taken at the Committees June 30th meeting. The Committee plans to vote on a future project of study at this meeting based upon the results of the poll.

Members of the public can listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 888–329–8877, conference ID: 6891670. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Member of the public are also entitled to submit written comments; the comments must be received in the regional office by August 30, 2015. Written comments may be mailed to the Midwestern Regional Office, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Administrative Assistant, Carolyn Allen at *callen@usccr.gov.* Persons who desire additional information may contact the Midwestern Regional Office at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Midwestern Regional Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Indiana Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Midwestern Regional Office at the above email or street address.

Agenda

Roll Call and Approval of Minutes
Discussion of Straw Poll Results and Project Topic
Discussion of Confirmed Project Plan and Next Steps
Open Comment
Adjournment

DATES: The meeting will be held on Thursday, July 30, 2015, at 12:00 p.m. EST.

PUBLIC CALL INFORMATION:
Dial: 888–329–8877
Conference ID: 6891670

FOR FURTHER INFORMATION CONTACT: Carolyn Allen at *callen@usccr.gov* or 312–353–8311.

Dated: July 8, 2015.

David Mussatt,
Chief, Regional Programs Unit.

[FR Doc. 2015–17078 Filed 7–13–15; 8:45 am]
BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; Redistricting Data Program

AGENCY: U.S. Census Bureau, 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, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: To ensure consideration, submit written comments, on or before September 14, 2015. The deadline for states to notify the Census Bureau that they wish to participate in Phase 1, the Block Boundary Suggestion Project (BBSP), is December 15, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information or copies of the information collection instrument(s) and instructions to James Whitehorne, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233 (or via the Internet at *rdo@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

The mission of the Geography Division (GEO) within the Census Bureau is to plan, coordinate, and administer all geographic and cartographic activities needed to facilitate Census Bureau statistical programs throughout the United States and its territories. GEO manages programs that continuously update features, boundaries, addresses, and geographic entities in the Master Address File/Topologically Integrated Geographic Encoding and Referencing (MAF/TIGER) System. GEO, also, conducts research into geographic concepts, methods, and standards needed to facilitate Census Bureau data collection and dissemination programs.

The Census Bureau is requesting a new collection to cover the five phases of the Redistricting Data Program (RDP) that was originally part of the Geographic Partnership Programs (GPPs) generic clearance. The Census Bureau requests a three-year clearance and a project specific Office of Management and Budget (OMB) Control Number for RDP. GEO, in coordination with OMB is creating a separate clearance for this critical program. A project specific clearance allows the Census Bureau to provide RDP specific materials, burden hours, and procedures. The need to only provide RDP materials ensures the program phases are uninterrupted by other program clearances unrelated to RDP. The RDP specific clearance provides flexibility in the timing, allowing the program to establish the schedule for RDP clearance needs and renewal.

Under the provisions of Title 13, Section 141(c) of the United States Code (U.S.C.), the Secretary of Commerce (Secretary) is required to provide the ''officers or public bodies having initial responsibility for the legislative apportionment or districting of each state . . .'' with the opportunity to specify geographic areas (*e.g.,* voting districts) for which they wish to receive Decennial Census population counts for the purpose of reapportionment or redistricting.

By April 1 of the year following the Decennial Census, the Secretary is required to furnish the state officials or their designees with population counts for American Indian areas (AIAs), counties, cities, census blocks, and

state-specified congressional, legislative, and voting districts.

The Census Bureau has issued an invitation to the officers or public bodies having initial responsibility for legislative reapportionment and redistricting, through the Census Redistricting Data Office (RDO), inviting states to identify a non-partisan liaison that will work directly with the Census Bureau on the 2020 Census RDP.

Since the 1990 Census, participation in both the Census RDP Block Boundary Suggestion Project (BBSP) and Voting District Project (VTDP), 2020 Census RDP Phases 1 and 2 under Title 13, U.S.C., is voluntary on the part of each state. However, if states choose not to participate in Phase 1 and Phase 2, the Census Bureau cannot ensure that the 2020 Decennial Census tabulation geography will support the redistricting needs of their state.

II. Method of Collection

The RDP invites respondent participation in the following phases of the program:

Phase 1: BBSP

The purpose of the BBSP is to afford states the opportunity to identify non-standard features often used as electoral boundaries (such as a power line or stream, rather than a street centerline, which might divide voters into two districts) as Census block boundaries. The BBSP option affords the state liaison the opportunity to provide suggestions for 2020 Census tabulation block boundaries resulting in more meaningful block data for the state. Liaisons are able to work with local officials including county election officers and others to ensure local geography is represented in the 2020 Census tabulation block inventory. In addition, the liaison, on behalf of the state, will make suggestions for features not desirable as census tabulation blocks. By identifying undesirable features, the liaison may assist the Census Bureau in reducing the overall number of census tabulation blocks from the 2010 inventory. Beginning in late fall of 2015, states that choose to participate in Phase 1 will begin receiving guidelines and training for providing their suggestions for the 2020 Census tabulation blocks as well as their suggestions for exclusion of line segments for consideration in the final 2020 Census tabulation block inventory. For the first time, states will have the opportunity to review legal limits, such as county and incorporated place boundaries, as reported through the Boundary and Annexation Survey (BAS). The Census Bureau conducts the BAS annually to update information about the legal boundaries and names of all governmental units. The alignment of the BAS with the BBSP will facilitate the cooperation between state and local government. A verification phase will occur in early 2017.

Phase 2: VTDP

The VTDP will provide the state liaison, on behalf of the state, to submit the voting districts (a generic term used to represent areas that administer elections such as precincts, election districts, wards, etc.) to the Census Bureau for representation in the 2020 Census Public Law 94–171 products (data and geographic products). Beginning in late 2017, states that choose to participate in VTDP will receive on a flow basis, geographic products that allow them the opportunity to update the Voting Districts (VTDs) for inclusion in the 2020 Census tabulation geography. State liaisons will continue to align their effort with updates from state and local government officials participating in the BAS. The VTD/BAS update and alignment will continue through spring of 2018. A verification phase will occur in early 2019 for states that participated in VTDP.

Phase 3: Delivery of the 2020 Decennial Census Redistricting Data

By April 1, 2021, the Director of the Census Bureau will, in accordance with Title 13, U.S.C., furnish the Governor and state legislative leaders, both the majority and minority, with 2020 Census population counts for standard census tabulation areas (*e.g.,* state, Congressional district, state legislative district, AIA, county, city, town, census tract, census block group, and census block) regardless of a state's participation in Phase 1 or 2. The Director of the Census Bureau will provide 2020 Census population counts for those states participating in Phase 2, for both the standard tabulation areas and for VTDs. For each state, this delivery will occur prior to general release and no later than April 1, 2021.

Phase 4: Collection of Post-Census Redistricting Data Plans

2010 Census:

As begun in 2011, the Census Bureau will solicit from each state the newly drawn legislative and Congressional district plans and prepares appropriate data sets based on the new districts. This effort will occur every two years in advance of the 2020 Census in order to update these boundaries with new or changed plans. A verification phase will occur with each update.

2020 Census:

Beginning in 2021, the Census Bureau will solicit from each state the newly drawn legislative and Congressional district plans and prepares appropriate data sets based on the new districts. This effort will occur every two years in advance of the 2030 Census in order to update these boundaries with new or changed plans. A verification phase will occur with each update.

Phase 5: Review of the 2020 Census RDP and Recommendations for the 2030 Census RDP

As the final phase of the 2020 Census RDP, the Census Bureau will work with the states to conduct a thorough review of the RDP. The intent of this review, and the final report that results, is to provide guidance to the Secretary and the Census Bureau Director in planning the 2030 Census RDP.

III. Data

OMB Control Number: 0607–XXXX.

Form Number: Not available at this time.

Type of Review: Regular submission.

Affected Public: All fifty states, the District of Columbia, and the Commonwealth of Puerto Rico.

Maximum Number of Respondents for all Phases: 52.

Estimated Time per Response Phase 1:

BBSP Annotation: 124 hours.

BBSP Verification: 62 hours.

Estimated Time per Response Phase 2:

VTDP Delineation: 248 hours.

VTDP Verification: 124 hours.

Estimated Time per Response Phase 4:

115th Congressional Districts (CDs) & State Legislative Districts (SLDs) Collection: 2 hours.

115th CDs & SLDs Verification: 2 hours.

116th CDs & SLDs Collection: 2 hours.

116th CDs & SLDs Verification: 2 hours.

Estimated Burden Hours Phase 1:

BBSP Annotation: 6,448 hours.

BBSP Verification: 3,224 hours.

Total Burden Hours: 9,672 hours.

Estimated Burden Hours Phase 2:

VTDP Delineation: 12,896 hours.

VTDP Verification: 6,448 hours.

Total Burden Hours: 19,344 hours.

Estimated Burden Hours Phase 4:

115th CDs & SLDs Collection: 104 hours.

115th CDs & SLDs Verification: 104 hours.

116th CDs & SLDs Collection: 104 hours.

116th CDs & SLDs Verification: 104 hours.

Total Burden Hours: 416 hours.

Estimated Total Burden Hours: 29,432 hours.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Voluntary.

Census Bureau Legal Authority: Title 13, U.S.C., Sections 16, 141, and 193.

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.

Summarization of comments submitted in response to this notice will be included in the request for OMB approval of this information collection. Comments will also become a matter of public record.

Sheleen Dumas,

Department PRA Lead, Office of the Chief Information Officer.

[FR Doc. 2015–17073 Filed 7–13–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Economic Development Administration.

Title: Application Forms for EDA Investment Assistance.

OMB Control Number: 0610–0094.

Form Number(s): ED–900, ED–900A, ED–900B, ED–900C, ED–900D, ED–900E, ED–900F, ED–900P.

Type of Request: Regular submission; Revision of a currently approved collection.

Number of Respondents: 1672.

Average Hours per Response: 13 hours, 28 minutes.

Burden Hours: 22,512.

Needs and Uses: The Application Forms for EDA Investment Assistance are required to apply for EDA investment assistance under its Public Works, Economic Adjustment, Technical Assistance, Research, and Planning Programs. This collection of information is required to ensure that the application meets the requirements for EDA assistance set out in EDA's regulations at 13 CFR Chapter III.

Affected Public: Not-for-profit institutions; Federal government; State, local, or tribal government.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Department PRA Lead, Office of the Chief Information Officer.

[FR Doc. 2015–17196 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–34–P

DEPARTMENT OF COMMERCE

[Docket No. 150619535–5535–01]

Privacy Act of 1974, New System of Records

AGENCY: U.S. Department of Commerce, National Institute of Standards and Technology.

ACTION: Notice of Proposed New Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, Title 5 United States Code (U.S.C.) 552(e)(4) and (11); and Office of Management and Budget (OMB) Circular A–130, Appendix 1, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' the Department of Commerce is issuing this notice of its intent to establish a new system of records entitled ''COMMERCE/NIST–8, Child Care Subsidy Program Records.'' This action is being taken to update the Privacy Act notice and Department of Commerce, Notice to Amend All Privacy Act System of Records. We invite the public to comment on the items noted in this publication. The purpose of this system of records is to verify NIST employees' eligibility for child care subsidies.

DATES: To be considered, written comments must be submitted on or before August 13, 2015.

Unless comments are received, the new system of records will become effective as proposed on the date of publication of a subsequent notice in the **Federal Register**.

ADDRESSES: You may submit written comments by any of the following methods:

Email: Essex.Brown@nist.gov. Include ''Privacy Act COMMERCE/NIST–8, Child Care Subsidy Program Records'' in the subtext of the message.

Fax: (301) 948–6107, marked to the attention of Essex W. Brown.

Mail: Essex W. Brown, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899, Building 101, Room A224, (301)–975–3801.

FOR FURTHER INFORMATION CONTACT: Kaitlyn Kemp, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899, Building 101, Room A123, (301) 975–3319.

SUPPLEMENTARY INFORMATION: This notice announces the Department of Commerce's (Department) proposal for a new system of records under the Privacy Act of 1974 for Child Care Subsidy Program Records. The Child Care Subsidy Program Records is a new system established to verify NIST employees' eligibility for child care subsidies.

COMMERCE/NIST–8

SECURITY CLASSIFICATION:

None

SYSTEM NAME:

COMMERCE/NIST–8, Child Care Subsidy Program Records.

SYSTEM LOCATION:

National Institute of Standards and Technology (NIST) Child Care Subsidy Program Manager, Office of Human Resources Management, 100 Bureau Drive, Room 1720, Gaithersburg, MD 20899.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees of NIST who voluntarily apply for child care subsidies.

CATEGORIES OF RECORDS IN THE SYSTEM:

Application forms for a child care subsidy may contain personal information, including employee's name, Social Security Number, grade, home phone number, home address, email address, total income, number of dependent children, and number of children on whose behalf the employee is applying for a subsidy, information on any tuition assistance received from

State/County/local child care subsidy, and information on child care providers used, including their name, address, provider license number, and State where license issues, tuition cost, provider tax identification number, bank routing number, bank account number, and copies of Internal Revenue Form 1040 for verification purposes.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

40 U.S.C. 490b–1; Sec. 630 of Pub. L. 107–67 November 12, 2001; and Executive Order 9397 as Amended by Executive Order 13478 (November 18, 2008).

PURPOSE:

To establish and verify NIST employees' eligibility for child care subsidies in order for NIST 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. In the event that a system of records maintained by the Department to carry out its functions indicates a violation or potential violation of law or contract, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute or contract, or rule, regulation, or order issued pursuant thereto, or the necessity to protect an interest of the Department and Federal partners, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, state, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or contract, or rule or order issued pursuant thereto, or protecting the interest of the DOC.

2. A record in this system of records may be disclosed to a Member of Congress submitting a request involving an individual when the individual has requested assistance from the Member with respect to the subject matter of the record.

3. A record in this system of records may be disclosed to the Department of Justice in connection with determining whether disclosure thereof is required by the Freedom of Information Act (5 U.S.C. 552).

4. A record in this system of records may be disclosed to a contractor of the Department having need for the information in the performance of the contract, but not operating a system of records within the meaning of 5 U.S.C. 552a(m).

5. A record from this system of records may be disclosed to the Administrator, General Services Administration (GSA), or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practice and programs, under the authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.* GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

6. A record from this system of records may be disclosed in the course of presenting evidence to a court, magistrate or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

7. A record in this system of records may be disclosed to appropriate agencies, entities and persons when (1) it is suspected or determined that the security or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or whether systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and to prevent, minimize, or remedy such harm.

8. A record from this system of records may be disclosed to a Federal, state, or local agency maintaining civil, criminal or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a Department decision concerning the assignment, hiring or retention of an individual, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

9. A record for this system of records may be disclosed to a Federal, state, local, or international agency, in response to the request, in connection with the assignment, hiring or retention of an individual, the issuance of a security clearance, the reporting of an investigation of an individual, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. Disclosure may be made to the Office of Personnel Management or the Government Accountability Office when the information is required for evaluation of the subsidy program.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Not applicable.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Hard copy files may be maintained in paper form and on diskettes; additional electronic files may be kept in electronic digital media in encrypted format within a controlled environment, and accessed only by authorized personnel.

RETRIEVABILITY:

The records are retrieved by name and may also be cross-referenced to Social Security Number.

SAFEGUARDS:

Paper records and disks as stored in file cabinets on secured premises with access limited to personnel whose official duties require access. For electronic media, the system is password protected and is FIPS 199 (Federal Information Processing Standard Publication 199, ''Standards for Security Categorization of Federal Information and Information Systems'') compliant. The electronic system adheres to a Moderate security rating.

RETENTION AND DISPOSAL:

Records are disposed of in accord with the appropriate records disposition schedule approved by the Archivist of the United States.

SYSTEM MANAGER(S) AND ADDRESSE(S):

National Institute of Standards and Technology (NIST) Child Care Subsidy Program Manager, Office of Human Resources Management, 100 Bureau Drive, Room 1720, Gaithersburg, MD 20899.

NOTIFICATION PROCEDURE:

An individual requesting notification of existence of records on himself or herself should send a signed, written inquiry to the location listed below. The request letter should be clearly marked, ''PRIVACY ACT REQUEST.'' The written inquiry must be signed and notarized or submitted with certification of identity under penalty of perjury. Requesters should reasonably specify the record contents being sought.

National Institute of Standards and Technology, Freedom of Information and Privacy Act Officer, Room 1710, 100 Bureau Drive, Gaithersburg, MD 20899.

RECORD ACCESS PROCEDURE:

An individual requesting access to records on himself or herself should send a signed, written inquiry to the same address as stated in the Notification Procedure section above. The request letter should be clearly marked, ''PRIVACY ACT REQUEST.'' The written inquiry must be signed and notarized or submitted with certification of identity under penalty of perjury. Requesters should reasonably specify the record contents being sought.

CONTESTING RECORD PROCEDURE:

An individual requesting corrections or contesting information contained in his or her records must send a signed, written request inquiry to the same address as stated in the Notification Procedure section above. Requesters should reasonably identify the records, specify the information they are contesting and state the corrective action sought and the reasons for the correction with supporting justification showing how the record is incomplete, untimely, inaccurate, or irrelevant.

The Department's rules for access, for contesting contents, and for appealing initial determination by the individual concerned appear in 15 CFR part 4.

RECORD SOURCE CATEGORIES:

Information is provided by NIST employees who apply for child care subsidies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: July 8, 2015.

Michael J. Toland,

Acting Freedom of Information and Privacy Act Officer, Department of Commerce.

[FR Doc. 2015–17246 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

[Docket No. 150619534–5534–01]

Privacy Act of 1974; Abolished System of Records

AGENCY: National Institute of Standards and Technology, U.S. Department of Commerce.

ACTION: Notice to delete a Privacy Act System of Records: COMMERCE/NBS–2, ''Inventors of Energy-Related Processes and Devices.''

SUMMARY: In accordance with the Privacy Act of (5 U.S.C. 552a(e)(4) and (11)); the Department of Commerce is issuing notice of its intent to delete the system of records entitled ''Inventors of Energy-Related Processes and Devices.'' The system of records is no longer collected or maintained by the National Institute of Standards and Technology (NIST). There are no records remaining in the system.

DATES: To be considered, written comments must be submitted on or before August 13, 2015. Unless comments are received, the deletion of the system of records will become effective as proposed on the date of publication of a subsequent notice in the **Federal Register**.

ADDRESSES: You may submit written comments by any of the following methods:

Email: Catherine.Fletcher@nist.gov. Include ''Privacy Act COMMERCE/NBS–2, Inventors of Energy-Related Processes and Devices'' in the subtext of the message.

Fax: (301) 973–5301, marked to the attention of Catherine S. Fletcher, Director, Management and Organization Office, National Institute of Standards and Technology, Gaithersburg, Maryland 20899.

Mail: Catherine Fletcher, National Institute of Standards and Technology Freedom of Information Act Office, 100 Bureau Drive, Mail Stop 1710, Gaithersburg, MD 20899–1710.

FOR FURTHER INFORMATION CONTACT: Director, Management and Organization Office, 100 Bureau Drive, Mail Stop 1710, Gaithersburg, MD 20899–1710, 301–975–4074.

SUPPLEMENTARY INFORMATION: This Privacy Act System of Records is being deleted because the records are no longer collected or maintained by the National Institute of Standards and Technology. There are no records remaining in the system.

Dated: July 8, 2015.

Michael J. Toland,

Department of Commerce, Acting Freedom of Information and Privacy Act Officer.

[FR Doc. 2015–17245 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Information Systems Technical Advisory Committee; Notice of Partially Closed Meeting

The Information Systems Technical Advisory Committee (ISTAC) will meet on July 29 and 30, 2015, 9 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Constitution and Pennsylvania Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to information systems equipment and technology.

Wednesday, July 29

Open Session

1. Welcome and Introductions
2. Working Group Reports
3. Old Business
4. Industry Presentation: Proposal on coherent optical communications technology
5. Industry Presentation: Penetration Testing and Implemention of Wassenaar 2013 Cyber-Related Provisions
6. New Business

Thursday, July 30

Closed Session

7. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than July 22, 2015.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that public presentation materials or comments be forwarded before the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on March 23, 2015, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 sec. (l0)(d))), that the portion of the meeting concerning trade secrets and commercial or financial information deemed privileged or confidential as described in 5 U.S.C. 552b(c)(4) and the portion of the meeting concerning matters the disclosure of which would be likely to frustrate significantly implementation of an agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt

from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and l0(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Dated: July 9, 2015.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2015–17235 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2012–2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On January 8, 2015, the Department of Commerce (the ''Department'') published its *Preliminary Results* in the 2012–2013 administrative review of the antidumping duty order on crystalline silicon photovoltaic cells, whether or not assembled into modules (''solar cells'') from the People's Republic of China (''PRC'').[1] The period of review (''POR'') is May 25, 2012, through November 30, 2013. This administrative review covers two mandatory respondents, Yingli Energy (China) Company Limited and Wuxi Suntech Power Co., Ltd. (''Wuxi Suntech''), which was found to be ineligible for a separate rate in the *Preliminary Results*. Based on our analysis of the comments received, we made certain changes to our margin calculations for Yingli Energy (China) Company Limited. Additionally, we now find that Wuxi Suntech is eligible for a separate rate, and have calculated a dumping margin for Wuxi Suntech. The final dumping margins for this review are listed in the ''Final Results'' section below.

DATES: *Effective date:* July 14, 2015.

FOR FURTHER INFORMATION CONTACT: Brandon Farlander or Drew Jackson AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0182 or (202) 482–4406, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 8, 2015, the Department published its *Preliminary Results* in this review. On January 22, 2015, Petitioner[2] submitted comments regarding the preliminary margin calculation of the companies that are considered as the Yingli Single Entity in this final determination including Yingli Energy (China) Company Limited.[3]

On January 9, 2015, Wuxi Suntech submitted a hearing request.[4] On February 9, 2015 Shanghai JA Solar Technology Co., Ltd., JA Solar Technology Yangzhou Co., Ltd. and JingAo Solar Co., Ltd. submitted a request to participate in any hearing held by the Department in this review.[5] Petitioner submitted an untimely hearing request on February 9, 2015, which was rejected by the Department in accordance with 19 CFR 351.302(d).[6] On February 25, 2015, Petitioner submitted an untimely request for additional time to submit a hearing request.[7] The Department did not grant Petitioner's request.[8] On May 18, 2015, Wuxi Suntech withdrew its request for a hearing.[9] On June 1, 2015, the Department notified interested parties that it would not hold a hearing in this administrative review.[10]

Between January 2015 and March 2015, the Department issued supplemental questionnaires regarding separate rates to, and received timely responses from, the Wuxi Suntech Single Entity.[11] In March 2015, the Department conducted verification of the Wuxi Suntech Single Entity's separate rates information.

On March 23, 2015, the following interested parties submitted case briefs: (1) Petitioner; (2) Yingli Energy (China) Company Limited;[12] (3) Goal Zero, LLC;

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2012–2013,* 80 FR 1021 (January 8, 2015) (''*Preliminary Results''*), and Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Gary Taverman, Associate Deputy Assistant Secretary for Antidumping and Countervailing Operations, ''Decision Memorandum for the Preliminary Results of the 2012–2013 Antidumping Duty Administrative Review of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China'' (''Preliminary Decision Memorandum''), dated December 31, 2014.

[2] Petitioner in this proceeding is SolarWorld America, Inc.

[3] *See* Letter to the Department from Petitioner, ''Certain Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Comments on Ministerial Errors in the Preliminary Results,'' dated January 22, 2015. The Department determined, pursuant to 19 CFR 351.401(f), that the following affiliated companies should be treated as a single entity: Yingli Energy (China) Company Limited ; Baoding Tianwei Yingli New Energy Resources Co., Ltd. (''Tianwei Yingli''); Tianjin Yingli New Energy Resources Co., Ltd. (''Tianjin Yingli''); Hengshui Yingli New Energy Resources Co., Ltd. (''Hengshui Yingli''); Lixian Yingli New Energy Resources Co., Ltd. (''Lixian Yingli''); Baoding Jiasheng Photovoltaic Technology Co., Ltd. (''Jiasheng''); Beijing Tianneng Yingli New Energy Resources Co., Ltd. (''Beijing Tianneng''); Hainan Yingli New Energy Resources Co., Ltd. (''Hainan Yingli'') (collectively, the ''Yingli Single Entity''). *See* Memorandum to Abdelali Elouaradia, Director, AD/CVD Operations, Office IV, through Howard Smith, AD/CVD Operations, Office IV, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Affiliation and Single Entity Status,'' dated December 31, 2014.

[4] *See* Letter to the Department from Wuxi Suntech, ''Crystalline Silicon Photovoltaic Cells from the People's Republic of China: Request for Hearing- Wuxi Suntech Power Co., Ltd.,'' dated January 9, 2015.

[5] *See* Letter to the Department from Shanghai JA Solar Technology Co., Ltd., JA Solar Technology Yangzhou Co., Ltd. and JingAo Solar Co., Ltd., ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Hearing,'' dated January 9, 2015.

[6] *See* Letter to the File through Howard Smith, Program Manager, AD/CVD Operations, Office IV ''Rejection and Removal from the Record of Untimely Filed Hearing Request,'' dated March 3, 2015.

[7] *See* Letter to the Department from Petitioner, ''Crystalline Silicon Photovoltaic Cells, Whether Or Not Assembled Into Modules, from the People's Republic of China: Request for Opportunity to Submit Hearing Requests,'' dated February 9, 2015.

[8] *See* Letter to the Petitioner from the Department, ''Antidumping Duty Administrative Review of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Rejection and Removal from the Record of Untimely Filed Hearing Request,'' dated March 3, 2015.

[9] *See* Letter to the Department from Wuxi Suntech, ''Crystalline Silicon Photovoltaic Cells, Whether Or Not Assembled into Modules, from the People's Republic of China: Withdraw of Request for Hearing—Wuxi Suntech Power Co., Ltd.,'' dated May 18, 2015.

[10] *See* Memorandum to All Interested Parties, through Howard Smith, AD/CVD Operations, Office IV, Administrative Review of the Antidumping Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China; Withdrawal of Hearing Request, dated June 1, 2015.

[11] In the *Preliminary Results,* the Department preliminarily found that the Wuxi Suntech Single Entity included the following companies: Wuxi Suntech; Luoyang Suntech Power Co., Ltd. (''Luoyang Suntech''); Suntech Power Co., Ltd. (''Shanghai Suntech''); and Wuxi Sunshine Power Co. Ltd (''Wuxi Sunshine''). *See* Memorandum to Abdelali Elouaradia, Director, AD/CVD Operations, Office IV, through Howard Smith, Program Manager, AD/CVD Operations. Office IV, ''Affiliation and Single Entity Status of Wuxi Suntech Power Co., Ltd.; Luoyang Suntech Power Co., Ltd.; Suntech Power Co., Ltd.; and Wuxi Sunshine Power Co., Ltd.,'' dated December 31, 2014.

[12] Yingli Energy (China) Company Limited's case and rebuttal briefs were submitted on behalf of Yingli Green Energy Holding Company Limited and Yingli Green Energy Americas, Inc., and their affiliates, including Yingli Energy (China) Co., Ltd.

(4) LDK Solar Hi-Tech (Nanchang) Co. Ltd.; (5) Jiangsu Sunlink PV Technology Co., Ltd.; (6) Years Solar Co. Ltd.; (7) CSG PVTech Co., Ltd.; and (8) Shanghai JA Solar Technology Co. Ltd, JA Solar Technology Yangzhou Co., Ltd. and JingAo Solar Co., Ltd. On March 25, 2015, Yingli Energy (China) Company Limited alleged that Petitioner's March 23, 2015 case brief contained untimely filed new factual information,[13] and on March 27, 2015, Petitioner rebutted these allegations.[14] After considering Yingli Energy (China) Company Limited's allegation, the Department did not require Petitioner to redact its case brief. On March 30, 2015, the Department notified Yingli Energy (China) Company Limited that its March 23, 2015 case brief contained untimely filed new factual information. The Department subsequently rejected the case brief in accordance with 19 CFR 351.302(d)(1)(i) and 19 CFR 351.104(a)(2)(ii)(A) because it contained untimely filed new factual information but provided Yingli Energy (China) Company Limited the opportunity to resubmit its case brief with the new factual information redacted.[15] On March 31, 2015, Yingli Energy (China) Company Limited submitted comments on the new factual information allegation, and resubmitted its rejected case brief.[16] On March 30, 2015, the following interested parties submitted rebuttal briefs: (1) Petitioner; (2) Yingli Energy (China) Company Limited; and, (3) Wuxi Suntech. These case briefs and rebuttal briefs did not include comments regarding the separate-rate status of the Wuxi Suntech Single Entity, which was preliminarily found to include the following companies: (1) Wuxi Suntech, (2) Luoyang Suntech; (3) Shanghai Suntech; and (4) Wuxi Sunshine.[17] Subsequently, on May 8, 2015, and May 11, 2015, Wuxi Suntech and Petitioner, respectively, submitted case briefs regarding the separate-rate status of the Wuxi Suntech Single Entity. On May 13, 2015, the following parties submitted rebuttal comments related to the separate-rate status of the Wuxi Suntech Single Entity: (1) Petitioner; (2) Wuxi Suntech; (3) Shanghai BYD Co., Ltd. and Shangluo BYD Industrial Co., Ltd.; and (4) Changzhou Trina Solar Energy Co., Ltd.

On April 28, 2015, the Department extended the deadline for issuing these final results of review by 60 days, until July 7, 2015.[18]

Scope of the Order

The merchandise covered by the order is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.[19] Merchandise covered by this review is classifiable under subheading 8501.61.0000, 8507.20.80, 8541.40.6020, 8541.40.6030, and 8501.31.8000 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in this review are addressed in the Issues and Decision Memorandum,[20] which is hereby adopted by this notice. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, follows as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/*. The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Changes Specific to Wuxi Suntech

- Found that Wuxi Suntech and Luoyang Suntech should be treated as a single entity (the ''Wuxi Luoyang Single Entity.''
- Found that the Wuxi Luoyang Single Entity has established its eligibility for a separate rate.
- Calculated a dumping margin for the Wuxi Luoyang Single Entity.

Changes Specific to Yingli Energy (China) Company Limited

- Revised surrogate value calculations for certain direct materials, labor, financial ratios, and movement expenses.
- Revised certain material offsets.
- Revised the indirect selling expense ratio.
- Corrected ministerial errors.
- Revised the partial AFA calculation.

Other Changes

- Corrections to list of separate rate companies and no shipment companies.

Final Determination of No Shipments

In the *Preliminary Results,* we found that 23 companies subject to this administrative review did not have reviewable transactions during the POR.[21] We did not receive any comments concerning our finding of no shipments by these 23 companies. For these final results, the Department

and Baoding Tianwei Yingli New Energy Resources Co., Ltd.

[13] *See* Letter to the Department from Yingli Energy (China) Company Limited, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the People's Republic of China: Request that the Department Reject SolarWorld's Case Brief,'' dated May, 2015.

[14] *See* Letter to the Department from Petitioner, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Response to Yingli's Request to Reject SolarWorld's Case Brief,'' dated May 27, 2015.

[15] *See* Memorandum to The File through Howard Smith, Program Manager, AD/CVD Operations, Office IV, ''Rejection from the Record of Untimely Filed New Factual Information,'' dated April 2, 2015.

[16] *See* Letter from Yingli Energy (China) Company Limited to the Department, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules from the People's Republic of China: Resubmission of Yingli's Case Brief,'' dated March 31, 2015.

[17] *See* Memorandum to The File through Jeffrey Pedersen, Acting Program Manager, AD/CVD Operations, Office IV, ''Administrative Review of the Antidumping Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China; Briefing Schedule,'' dated February 27, 2015 (establishing a deadline for case briefs and rebuttal briefs concerning all issues except the separate-rate status of the Wuxi Suntech Single Entity).

[18] *See* Memorandum to Edward Yang, Senior Director, AD/CVD Operations, Office VII, through Howard Smith, Acting Director, AD/CVD Operations, Office IV, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated April 28, 2015.

[19] For a complete description of the scope of the order, *see* Memorandum from Edward Yang, Senior Director, AD/CVD Operations, Office VII, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Decision Memorandum for the Final Results of the 2012–2013 Antidumping Duty Administrative Review of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China,'' (''Issues and Decision Memorandum''), dated concurrently with this notice.

[20] *See* Issues and Decision Memorandum.

[21] *See Preliminary Results* and accompanying Preliminary Decision Memorandum at 5–6. We also preliminarily treated two companies which reported making no shipments during the POR, Luoyang Suntech and Shanghai Suntech, as part of the Wuxi Suntech Single Entity.

continues to find that 23 companies that claimed no shipments during the POR did not have any reviewable transactions of subject merchandise during the POR.[22]

In the *Preliminary Results,* we found that two companies, CSG PVTech Co., Ltd. and Jiangsu Sunlink PV Technology Co., Ltd., that claimed no exports, sales or entries of subject merchandise during the POR did, in fact, sell subject merchandise to the United States during the POR.[23] Interested parties commented on the Department's preliminary finding with respect to these two companies.[24] After considering these comments, the Department continues to find that these companies sold or made entries of subject merchandise to the United States during the POR. Neither of these companies filed a separate rate application or certification and thus they have not established their entitlement to a separate rate in this review.

Affiliation and Single Entity Determination

For these final results of review, the Department finds, pursuant to 19 CFR 351.401(f), that Wuxi Suntech and Luoyang Suntech comprise a single entity (*i.e.,* the Wuxi Luoyang Single Entity), which does not include Shanghai Suntech or Wuxi Sunshine.[25]

Additionally, the Department continues to find, pursuant to 19 CFR 351.401(f), that the following affiliated companies should be treated as a single entity: (1) Yingli Energy (China) Company Limited; (2) Baoding Tianwei Yingli; (3) Tianjin Yingli; (4) Hengshui Yingli; (5) Lixian Yingli; (6) Jiasheng; (7) Beijing Tianneng; and (8) Hainan Yingli.[26]

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the ''Act''), the Department verified separate rate information provided by the Wuxi Suntech Single Entity.[27] The Department conducted the verification using standard verification procedures including the examination of relevant records and the selection and review of original documentation containing relevant information. The results of the verification are outlined in the public version of the verification reports. The verification reports are on file electronically *via* ACCESS.

Use of Partial Facts Available and Adverse Facts Available

Section 776(a) of the Act provides that the Department shall apply facts available (''FA'') if (1) necessary information is not on the record, or (2) an interested party or any other person (A) withholds information that has been requested, (B) fails to provide information within the deadlines established, or in the form and manner requested by the Department, subject to subsections (c)(1) and (e) of section 782 of the Act, (C) significantly impedes a proceeding, or (D) provides information that cannot be verified as provided by section 782(i) of the Act.

Section 776(b) of the Act further provides that the Department may use adverse facts available (''AFA'') when a party has failed to cooperate by not acting to the best of its ability to comply with a request for information.

Pursuant to sections 776(a) and (b) of the Act, in the *Preliminary Determination,* the Department applied partial adverse facts available (''AFA'') to a portion of Yingli Energy (China) Company Limited's sales. After considering comments submitted by interested parties, the Department continues to find that the application of partial AFA is warranted, however, the Department has revised the methodology used to apply partial AFA to a portion of Yingli Energy (China) Company Limited's sales for these final results of review.[28] Further, the Department continues to find that the application of FA to account for Yingli (China) Company Limited's unreported factors of production (''FOP'') data is warranted.[29]

Wuxi Suntech did not report certain FOP data from certain suppliers or tollers. Based on the specific facts on the record of this review and in accordance with section 776(a)(1) of the Act, the Department is applying FA with respect to these unreported FOP data.[30] Due to the proprietary nature of the factual information concerning these FOP data, we explain the decision to use FA with respect to these FOP data in a separate business proprietary memorandum.[31] As FA, we used FOP data that Wuxi Suntech was able to obtain from certain tollers or its own FOP information.

Separate Rates

In the *Preliminary Results,* the Department listed 20 companies not selected as mandatory respondents as having demonstrated their eligibility for separate rates.[32] Since the *Preliminary Results,* the Department has not received any comments that would warrant a review of our preliminary results regarding 19 of these companies. Therefore we continue to find that these companies are eligible for a separate rate.[33] Regarding LDK Solar Hi-tech

[22] Those 23 companies with no shipments during the POR are: (1) DelSolar Co., Ltd.; (2) Dongfang Electric (Yixing) MAGI Solar Power Technology Co., Ltd.; (3) ET Solar Energy Limited; (4) Hengdian Group DMEGC Magnetics Co., Ltd.; (5) Himin Clean Energy Holdings Co., Ltd.; (6) Jiangsu Green Power PV Co., Ltd.; (7) Jiangsu Jiasheng Photovoltaic Technology Co., Ltd.; (8) JinkoSolar International Limited; (9) Konca Solar Cell Co., Ltd.; (10) Kuttler Automation Systems (Suzhou) Co., Ltd.; (11) Motech (Suzhou) Renewable Energy Co., Ltd.; (12) Ningbo Ulica Solar Science & Technology Co., Ltd.; (13) Perlight Solar Co., Ltd.; (14) Shenzhen Suntech Power Co., Ltd.; (15) ShunFeng PV; (16) Sumec Hardware & Tools Co., Ltd.; (17) Tianwei New Energy (Chengdu) PV Module Co., Ltd.; (18) Upsolar Group Co., Ltd.; (19) Wanxiang Import & Export Co., Ltd.; (20) Yangzhou Rietech Renewal Energy Co., Ltd.; (21) Yangzhou Suntech Power Co., Ltd.; (22) Zhejiang Jiutai New Energy Co., Ltd.; (23) Zhenjiang Rietech New Energy Science & Technology Co., Ltd. As noted above, the Department has treated Luoyang Suntech, which reported making no shipments during the POR, as part of the Wuxi Luoyang Single Entity.

[23] *See Preliminary Results* and accompanying Preliminary Decision Memorandum at 5–6.

[24] *See* Issues and Decision Memorandum at comment entitled, ''Treatment of Jiangsu Sunlink PV Technology Co., Ltd.'' and comment entitled, ''Treatment of CSG PVTech Co., Ltd.''

[25] *See* Issues and Decision Memorandum at the comment entitled, ''The Department's Separate Rates Practice,'' and the comment entitled, ''Separate Rate Status of the Wuxi Suntech Collapsed Entity.'' *See also* Memorandum to Robert Bolling, Acting Director, AD/CVD Operations, Office IV, through Howard Smith, Program Manager, AD/CVD Operations, IV, ''Affiliation and Single Entity Status of Wuxi Suntech Power Co., Ltd. and Luoyang Suntech Power Co., Ltd., Final Results of Review,'' dated concurrently with this notice.

[26] *See* Memorandum to Abdelali Elouaradia, Director, AD/CVD Operations, Office IV, through Howard Smith, Program Manager, AD/CVD Operations, Office IV, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Affiliation and Single Entity Status,'' dated December 31, 2014.

[27] See Memorandum to the File through Howard Smith, Program Manager, AD/CVD Operations, Office IV, Verification of the Separate Rates Questionnaire Responses of Wuxi Suntech Power Co., Ltd., dated April 28, 2015; Memorandum to the File through Howard Smith, Program Manager, AD/CVD Operations, Office IV, Verification of the Separate Rates Questionnaire Responses of Suntech Power Co., Ltd., dated April 28, 2015; and Memorandum to the File through Howard Smith, Program Manager, AD/CVD Operations, Office IV, Verification of the Separate Rates Questionnaire Responses of Wuxi Sunshine Power Co., Ltd., dated April 28, 2015.

[28] See Issues and Decision Memorandum at Comment 9.

[29] *See Preliminary Determination.*

[30] *See* Issues and Decision Memorandum at Comment 9.

[31] *See* Memorandum through Howard Smith, Program Manager, AD/CVD Operations, Office IV, to Robert Bolling, Acting Director, AD/CVD Operations, Office IV, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Unreported Factors of Production,'' dated concurrently with this notice.

[32] *See* Preliminary Decision Memorandum at 13.

[33] The Department finds that the following 19 non-selected companies demonstrated their

(Nanchang) Co., Ltd., in the *Preliminary Results,* the Department inadvertently listed this company as a company that was granted a separate rate. Because the review of LDK Solar Hi-tech (Nanchang) Co., Ltd. was rescinded in July 2014, that company is not subject to this review and thus no determination was made in this review with respect to its separate rate status.[34]

PRC-Wide Entity

In the *Preliminary Results,* the Department preliminarily determined to treat 21 companies subject to this review as part of the PRC-wide entity because they did not establish their eligibility to receive a separate rate.[35] Interested parties commented on the Department's preliminary decision to treat the Wuxi Suntech Single Entity, ERA Solar Co., Ltd., Jiangsu Sunlink PV Technology Co., Ltd., CSG PVTech Co., Ltd., and Leye Photovoltaic Co., Ltd. as part of the PRC-wide entity.[36] In the *Preliminary Results,* the Department collapsed Wuxi Suntech, Luoyang Suntech, Shanghai Suntech, and Wuxi Sunshine into a single entity, the Wuxi Suntech Single Entity, and did not grant this single entity a separate rate. In these final results we are only collapsing Wuxi Suntech and Luoyang Suntech. Based on record information, we find the collapsed entity comprising Wuxi Suntech and Luoyang Suntech has established its entitlement to a separate rate because it is wholly foreign owned.[37] With respect to the other two companies that we preliminarily collapsed, but are no longer collapsing, with Wuxi Suntech, Shanghai Suntech reported that it made no shipments during the POR,[38] and the Department, based on its examination of record evidence, finds that this company did not have any reviewable transactions of subject merchandise during the POR.[39] Because Shanghai Suntech did not have any reviewable transactions during the POR, it does not qualify to be granted separate rates status.[40] Additionally, all parties withdrew their requests to review Wuxi Sunshine and thus it is not subject to this administrative review.[41] The Department continues to find that the remaining companies preliminarily found not to have established their eligibility for a separate rate to be part of the PRC-wide entity.[42] In addition, the Department finds that LDK Hi-Tech (Nanchang Co., Ltd., which did not provide the Department with information regarding its eligibility for separate rate status, is also a part of the PRC-wide entity.[43] Further, the Department finds that Leye Photovoltaic Co., Ltd. is not subject to this administrative review, and, therefore, retains its combination rate, *i.e.,* separate rate for merchandise produced and exported by Leye Photovoltaic Co., Ltd., which it received in the underlying investigation.[44]

Rate for Separate-Rate Companies Not Selected as Mandatory Respondents

The statute and the Department's regulations do not address the establishment of a rate to be applied to individual respondents not selected for examination when the Department limits its examination in an administrative review pursuant to section 777A(c)(2)(B) of the Act. Generally, the Department looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents which we did not individually examine in an administrative review. Section 735(c)(5)(A) of the Act instructs the Department to avoid calculating an all-others rate using rates which are zero, *de minimis* or based entirely on facts available. Accordingly, the Department's usual practice has been to average the weighted-average dumping margins for the selected companies, excluding rates that are zero, *de minimis,* or based entirely on facts available.[45] Accordingly, the Department assigned to the companies that it did not individually examine, but which demonstrated their eligibility for a separate rate, the weighted-average dumping margins calculated for the two mandatory respondents.[46]

Final Results

We determine that the following weighted-average dumping margins exist for the POR:

Exporter	Weighted-average dumping margin (percent)
Yingli Single Entity: Yingli Energy (China) Company Limited/Baoding Tianwei Yingli New Energy Resources Co., Ltd./Tianjin Yingli New Energy Resources Co., Ltd./Hengshui Yingli New Energy Resources Co., Ltd./Lixian Yingli New Energy Resources Co., Ltd./Baoding Jiasheng Photovoltaic Technology Co., Ltd./Beijing Tianneng Yingli New Energy Resources Co., Ltd./Hainan Yingli New Energy Resources Co., Ltd.[47]	0.79
Wuxi Suntech Power Co., Ltd./Luoyang Suntech Power Co., Ltd	33.08

eligibility for separate rates: (1) Canadian Solar International Limited; (2) Canadian Solar Manufacturing (Changshu) Inc.; (3) Canadian Solar Manufacturing (Luoyang) Inc.; (4) Changzhou Trina Solar Energy Co., Ltd./Trina Solar (Changzhou) Science and Technology Co., Ltd.; (5) Chint Solar (Zhejiang) Co., Ltd.; (6) De-Tech Trading Limited HK; (7) Eoplly New Energy Technology Co., Ltd.; (8) Hangzhou Zhejiang University Sunny Energy Science and Technology Co., Ltd.; (9) Jinko Solar Import and Export Co., Ltd.; (10) Ningbo Qixin Solar Electrical Appliance Co., Ltd.; (11) Renesola Jiangsu Ltd.; (12) Shanghai BYD Co., Ltd.; (13) Shenzhen Topray Solar Co. Ltd.; (14) Sopray Energy Co., Ltd.; (15) Star Power International Limited; (16) Sun Earth Solar Power Co., Ltd.; (17) Yingli Green Energy Holding Company Limited; (18) Yingli Green Energy International Trading Company Limited; and (19) Zhejiang Sunflower Light Energy Science & Technology Limited Liability Company.

[34] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules From the People's Republic of China: Amended Partial Rescission of Antidumping Duty Administrative Review,* 79 FR 43713, 43714 (July 28, 2014). For additional discussion, *see* Issues and Decision Memorandum at Comment 8.

[35] *See* Preliminary Decision Memorandum at 15.

[36] *See* Issues and Decision Memorandum.

[37] *Id.*

[38] *See* Shanghai Suntech's February 26, 2014 submission to the Department.

[39] *See* Shanghai Suntech's October 21, 2014 submission to the Department.

[40] Shanghai Suntech received its separate rate as a company that belonged to the Wuxi Suntech Single Entity. Because we find that Shanghai Suntech is no longer part of the Wuxi Suntech Single Entity and is subject to review, we have considered whether it qualifies to be granted a separate-rate in this review.

[41] In the investigation, Wuxi Sunshine received its separate rate as a company that belonged to the Wuxi Suntech Single Entity. Because we find that Wuxi Sunshine is no longer part of the Wuxi Suntech Single Entity, Wuxi Sunshine is not entitled to the separate-rate rate status previously granted to that Single Entity. Accordingly, it is part of the PRC-Wide Entity for cash deposit purposes.

[42] *See infra* n. 49 for a list of companies that the Department has determined should be treated as part of the PRC-wide entity.

[43] *See* Issues and Decision Memorandum at Comment 8.

[44] *Id.* at Comment 7.

[45] *See Ball Bearings and Parts Thereof From France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Reviews in Part,* 73 FR 52823, 52824 (September 11, 2008), and accompanying Issues and Decision Memorandum at Comment 16.

[46] *See* Memorandum to the File, through Howard Smith, Program Manager, AD/CVD Operations, Office IV, ''Calculation of the Final Margin for Separate Rate Recipients,'' dated concurrently with this notice.

Exporter	Weighted-average dumping margin (percent)
Canadian Solar International Limited	9.67
Canadian Solar Manufacturing (Changshu) Inc	9.67
Canadian Solar Manufacturing (Luoyang) Inc	9.67
Changzhou Trina Solar Energy Co., Ltd./Trina Solar (Changzhou) Science and Technology Co., Ltd.[48]	9.67
Chint Solar (Zhejiang) Co., Ltd	9.67
De-Tech Trading Limited HK	9.67
Eoplly New Energy Technology Co., Ltd	9.67
Hangzhou Zhejiang University Sunny Energy Science and Technology Co., Ltd	9.67
Jinko Solar Import and Export Co., Ltd	9.67
Ningbo Qixin Solar Electrical Appliance Co., Ltd	9.67
Renesola Jiangsu Ltd	9.67
Shanghai BYD Co., Ltd	9.67
Shenzhen Topray Solar Co. Ltd	9.67
Sopray Energy Co., Ltd	9.67
Star Power International Limited	9.67
Sun Earth Solar Power Co., Ltd	9.67
Yingli Green Energy Holding Company Limited	9.67
Yingli Green Energy International Trading Company Limited	9.67
Zhejiang Sunflower Light Energy Science & Technology Limited Liability Company	9.67
PRC-Wide Entity[49]	[50] 238.95

Assessment Rates

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 these 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. For any individually examined respondent whose weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent), the Department will calculate importer- (or customer)-specific assessment rates for merchandise subject to this review. Where the respondent reported reliable entered values, the Department calculated importer- (or customer)-specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to the importer- (or customer) and dividing this amount by the total entered value of the sales to the importer- (or customer).[51] Where the Department calculated an importer- (or customer)-specific weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to the importer- (or customer) by the total sales quantity associated with those transactions, the Department will direct CBP to assess importer- (or customer)-specific assessment rates based on the resulting per-unit rates.[52] Where an importer- (or customer)-specific ad valorem or per-unit rate is greater than *de minimis,* the Department will instruct CBP to collect the appropriate duties at the time of liquidation. Where either the respondent's weighted average dumping margin is zero or *de minimis,* or an importer (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis,* the Department will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[53]

On October 24, 2011, the Department announced a refinement to its assessment practice in NME antidumping duty cases.[54] Pursuant to this refinement in practice, for merchandise that was not reported in the U.S. sales databases submitted by an exporter individually examined during this review, but that entered under the case number of that exporter (*i.e.,* at the individually-examined exporter's cash deposit rate), the Department will instruct CBP to liquidate such entries at the PRC-wide rate, as adjusted for export subsidies and estimated domestic subsidy pass-through. Additionally, pursuant to this refinement, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number will be liquidated at the PRC-wide rate, as adjusted for export subsidies and estimated domestic subsidy pass-through.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from the PRC

[47] As noted above these companies comprise the Yingli Single Entity.

[48] In the investigation in this proceeding, the Department treated Changzhou Trina Solar Energy Co., Ltd. and Trina Solar (Changzhou) Science & Technology Co., Ltd. as a single entity. *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, and Affirmative Final Determination of Critical Circumstances, in Part,* 77 FR 63791 (October 17, 2012). Because no party has provided information on the record of the review contradicting this determination, the Department has continued to treat these companies as a single entity for purposes of this review.

[49] The PRC-wide entity includes the following companies: (1) Shanghai Suntech; (2) Wuxi Sunshine; (3) Changzhou NESL Solartech Co., Ltd.; (4) CSG PVTech Co., Ltd.; (5) Era Solar Co., Ltd.; (6) Innovosolar; (7) Jiangsu Sunlink PV Technology Co., Ltd.; (8) Jiawei Solarchina Co., Ltd.; (9) Jinko Solar Co., Ltd.; (10) LDK Solar Hi-tech (Suzhou) Co., Ltd.; (11) Leye Photovoltaic Science Tech.; (12) Magi Solar Technology; (13) Ningbo ETDZ Holdings, Ltd.; (14) ReneSola; (15) Shanghai Machinery Complete Equipment (Group) Corp., Ltd.; (16) Shenglong PV-Tech; (17) Solarbest Energy-Tech (Zhejiang) Co., Ltd.; (18) Suzhou Shenglong PV–TECH Co., Ltd.; (19) Zhejiang Shuqimeng Photovoltaic Technology Co., Ltd.; (20) Zhejiang Xinshun Guangfu Science and Technology Co., Ltd.; (21) Zhejiang ZG-Cells Co., Ltd.; (22) Zhiheng Solar Inc.; and (23) LDK Hi-Tech (Nanchang Co., Ltd. In addition, the PRC-wide entity includes the companies listed in Appendix II of the notice *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules From the People's Republic of China: Amended Partial Rescission of Antidumping Duty Administrative Review,* 79 FR 43713 (July 28, 2014).

[50] This PRC-wide entity rate equals the PRC-wide entity rate of 249.96% adjusted for export subsidies and estimated domestic subsidy pass-through.

[51] *See* 19 CFR 351.212(b)(1).

[52] *Id.*

[53] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[54] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), for a full discussion of this practice.

entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register,** as provided by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate listed for each exporter in the table in the ''Final Results'' section of this notice; (2) for previously investigated PRC and non-PRC exporters that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (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 rate previously established for the PRC-wide entity; 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 that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Notification to Importers Regarding the Reimbursement of Duties

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 entries during this POR. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order (''APO'')

This notice also serves as a reminder to parties subject to APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. 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 violation which is subject to sanction.

We are issuing these results of administrative review and publishing notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: July 7, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—Issues and Decision Memorandum

Summary
Background
Scope of the Order
Treatment of Wuxi Suntech, Luoyang Suntech, Shanghai Suntech, and Wuxi Sunshine
Adjustment Under Section 777A(f) of the Act for Wuxi Suntech
Discussion of the Issues
Comment 1. Rescission of the Reviews of JingAo Solar Co., Ltd. and Shanghai JA Solar PV Technology Co., Ltd.
Comment 2. Treatment of ERA Solar Co., Ltd.
Comment 3. PRC-Wide Entity Rate
Comment 4. Assessment of Entries Made Prior to the International Trade Commission's Final Determination
Comment 5. Treatment of Jiangsu Sunlink PV Technology Co., Ltd.
Comment 6. Treatment of CSG PVTech Co., Ltd.
Comment 7. Treatment of Leye Photovoltaic Science & Technology Co. Ltd.
Comment 8. Rescission of Review of LDK Solar Hi-Tech (Nanchang) Co., Ltd.
Comment 9. Whether to Apply Adverse Facts Available (''AFA'') to Two Unreported Yingli Sales
Comment 10. Unreported FOPs by Suppliers and Tollers
Comment 11. Surrogate Value for Cutting Wire
Comment 12. Surrogate Value for Aluminum-Silver Paste
Comment 13. Surrogate Value for Silver Paste
Comment 14. Surrogate Value for Unclassified Stores
Comment 15. Ocean Freight
Comment 16. Brokerage and Handling
Comment 17. Labor Calculation
Comment 18. Surrogate Value for Natural Gas
Comment 19. Surrogate Value for Nitric Acid
Comment 20. Surrogate Value for Hydrofluoric Acid
Comment 21. Application of Surrogate Marine Insurance Rate
Comment 22. Conversion Factor for Natural Gas
Comment 23. Movement Expenses for Yingli's EP Sale
Comment 24. Surrogate Value for Backsheet
Comment 25. Calculation of Surrogate Financial Profit Ratio
Comment 26. Gross Unit Price Adjustments
Comment 27. Surrogate Value for Wafers
Comment 28. Export Subsidy Adjustment
Comment 29. By-Product Offset for Broken Wafers
Comment 30. Surrogate Value for Quartz Crucibles
Comment 31. Surrogate Value for Junction Boxes
Comment 32. Differential Pricing
Comment 33. Surrogate Value for the Polysilicon Feedstock and Solar Cell Offsets
Comment 34. Surrogate Value for Semi-finished Polysilicon Ingots and Blocks
Comment 35. Surrogate Value for Aluminum Angle Keys
Comment 36. Surrogate Value for Aluminum Frames
Comment 37. Indirect Selling Expenses
Comment 38. Application of a By-Product Recovery Cap on Recycled Paste
Comment 39. Whether the Department Improperly Calculated the Partial AFA Rate Applied to Yingli
Comment 40. Whether to Exclude Certain Reported CEP Sales
Comment 41. Wuxi Suntech Separate Rate Status
Comment 42. The Department's Separate Rates Practice in AD Proceedings Involving the PRC

[FR Doc. 2015–17238 Filed 7–13–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–980]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2012

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) has completed its administrative review of the countervailing duty (CVD) order on crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from the People's Republic of China (the PRC) for the period of review (POR) covering March 26, 2012, through December 31, 2012. On January 8, 2015, we published the preliminary results of this review and the post-preliminary results were completed on April 21, 2015.[1]

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review; 2012; and Partial Rescission of Countervailing Duty Administrative Review,* 80 FR 1019 (January 8, 2015) (*Preliminary Results*); *see also* Department Memorandum, ''Post-Preliminary Analysis in the Countervailing Duty Administrative Review: Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's

Continued

We provided interested parties with an opportunity to comment on the *Preliminary Results* and Post-Preliminary Results. Our analysis of the comments submitted resulted in a change to the net subsidy rates for Lightway Green New Energy Co., Ltd. (Lightway), and for Shanghai BYD Co., Ltd. (Shanghai BYD), Shangluo BYD Industrial Co., and BYD Company Ltd. (collectively, the BYD Group). The final net subsidy rates are listed below in the section entitled, ''Final Results of the Review.''

Withdrawals of certain requests for review were timely filed by SolarWorld Industries America Inc. (Petitioner) and the BYD Group. As a result, we rescinded this administrative review with respect to certain companies, pursuant to 19 CFR 351.213(d)(1), and proceeded with the review of Lightway and Shanghai BYD, and other companies not selected for individual review.[2]

DATES: Effective Date: July 14, 2015.

FOR FURTHER INFORMATION CONTACT: Gene Calvert, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–3586.

SUPPLEMENTARY INFORMATION:

Background

Following the *Preliminary Results* and Post-Preliminary Results, from March 11 through March 18, 2015, the Department conducted verification of the questionnaire responses submitted by the Government of the PRC (the GOC), Lightway, and the BYD Group. The verification reports were released between April 2 and April 6, 2015.[3] We received case briefs from interested parties on April 30, 2015.[4] On May 7, 2015, interested parties submitted their rebuttal briefs.[5] No hearing was held in this case as the only timely hearing request was withdrawn.[6]

Scope of the Order

The merchandise covered by this order is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials. The product is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) item numbers 8501.61.0000, 8507.20.80, 8541.40.6020, 8541.40.6030, and 8501.31.8000. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of this order is dispositive.

A full description of the scope of the order is contained in the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review: Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China,'' (Final Decision Memorandum), dated concurrently with this notice, and hereby adopted by this notice.

Analysis of Comments Received

All issues in the case briefs are addressed in the Final Decision Memorandum. A list of the issues raised is attached to this notice as Appendix I. The Final Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Final Decision Memorandum can be accessed directly on the internet at *http://www.trade.gov/enforcement/*. The signed Final Decision Memorandum and the electronic version of the Final Decision Memorandum are identical in content.

Methodology

The Department conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we determine that there is a subsidy, *i.e.,* a financial contribution from an ''authority'' that confers a benefit to the recipient, and that the subsidy is specific.[7] For a full description of the methodology underlying our conclusions, *see* the Final Decision Memorandum.

In making these findings, we relied, in part, on facts available and, because the GOC and Lightway did not act to the best of their ability in responding to the Department's requests for information, we drew an adverse inference in selecting from among the facts otherwise available.[8] For further information, *see* the section, ''Use of Facts Otherwise Available and Adverse Inferences,'' in the Final Decision Memorandum.

Final Results of the Review

In accordance with 19 CFR 351.221(b)(5), we determine a net countervailable subsidy rate of 23.28 percent *ad valorem* for Lightway, and a net countervailable subsidy rate of 15.43 percent *ad valorem* for the BYD Group.

Republic of China,'' (April 21, 2015) (Post-Preliminary Results).

[2] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Notice of Correction to Preliminary Results of Countervailing Duty Administrative Review; 2012 and Partial Rescission of Countervailing Duty Administrative Review,* 80 FR 8597 (February 18, 2015) at Appendix II.

[3] *See* Department Memoranda, ''Verification of the Questionnaire Responses Submitted by Lightway Green New Energy Co., Ltd.,'' (April 2, 2015); ''Verification of the Questionnaire Responses Submitted by Shanghai BYD Co., Ltd.,'' (April 3, 2015); ''Verification of the Questionnaire Responses Submitted by the Government of the People's Republic of China,'' (April 6, 2015).

[4] *See* Letter to the Secretary from SolarWorld Americas, Inc. (Petitioner), ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Case Brief,'' (April 30, 2015); Letter from the GOC, ''GOC Administrative Case Brief: First Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or not Assembled Into Modules from the People's Republic of China (C–570–980),'' (April 30, 2015); Letter from the BYD Group, ''Crystalline Silicon Photovoltaic Cells, Whether Or Not Assembled Into Modules, from the People's Republic of China—2012 Review: Case Brief,'' (April 30, 2015); Letter from Lightway, ''Crystalline Silicon Photovoltaic Cells from P.R. China: Case Brief,'' (April 30, 2015).

[5] *See* Letter to the Secretary from Petitioner, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Rebuttal Brief,'' (May 7, 2015); Letter from the GOC, ''GOC Rebuttal Brief: First Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or not Assembled into Modules from the People's Republic of China (C–570–980),'' (May 7, 2015); Letter from Shanghai BYD, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China—2012 Review: Rebuttal Brief,'' (May 7, 2015); Letter from Lightway, ''Crystalline Silicon Photovoltaic Cells from P.R. China: Rebuttal Case Brief,'' (May 7, 2015); Letter from Goal Zero, LLC (a U.S. importer of subject merchandise), ''Crystalline Silicon Photovoltaic Cells, Whether Or Not Assembled Into Modules from the People's Republic of China; Rebuttal Brief of Goal Zero, LLC,'' (May 7, 2015).

[6] *See* Letter to the Secretary from Shanghai BYD, ''Crystalline Silicon Photovoltaic Cells, Whether Or Not Assembled Into Modules, From the People's Republic of China: Shanghai BYD Co., Ltd. Request for Hearing,'' (February 9, 2015); *see also* Letter to the Secretary from Shanghai BYD, ''Crystalline Silicon Photovoltaic Cells, Whether Or Not Assembled Into Modules, from the People's Republic of China—2012 Review: Withdrawal of Hearing Request,'' (May 11, 2015).

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5)(A) of the Act regarding specificity.

[8] *See* sections 776(a) and (b) of the Act.

For non-reviewed companies that are subject to this administrative review (see Appendix II), because the rates calculated for Lightway and the BYD Group were above de minimis and not based entirely on facts available, we applied a subsidy rate based on a weighted-average of the subsidy rates calculated for Lightway and Shanghai BYD using publicly-ranged sales data submitted by the company respondents so as to avoid disclosure of proprietary information. The subsidy rate for these non-reviewed companies is 20.94 percent.

Assessment Rates

The Department intends to issue appropriate assessment instructions directly to U.S. Customs and Border Protection (CBP) 15 days after the date of publication of these final results, to liquidate shipments of subject merchandise by Lightway and the BYD Group entered, or withdrawn from warehouse, for consumption on or after March 26, 2012, through December 31, 2012.

Cash Deposit Instructions

The Department also intends to instruct CBP to collect cash deposits of estimated CVDs in the amount shown above for shipment of subject merchandise by Lightway and the BYD Group entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed companies that are subject to this administrative review, we will instruct CBP to collect cash deposits based on the weighted-average of Lightway's and the BYD Group's calculated subsidy rates using publicly ranged sales data submitted by the company respondents, pursuant to section 777A(e)(2)(A) of the Act. A list of the non-reviewed companies that are subject to this administrative review is attached as Appendix II to this notice.

For non-reviewed firms that are not subject to this administrative review, we will instruct CBP to collect cash deposits of estimated CVDs at the most recent company-specific or all-others rate applicable to the company. Accordingly, the cash deposit requirements that will be applied to companies covered by this order, but not subject to this review, are those established in the investigation for each company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice serves as a reminder to parties subject to 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 written notification of 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 in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 7, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Final Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Partial Rescission of the 2012 Administrative Review
V. Companies Not Selected for Individual Review
VI. Subsidies Valuation Information
VII. Use of Facts Otherwise Available and Adverse Inferences
VIII. Analysis of Programs
IX. Analysis of Comments
- Comment 1: Whether the Ex-Im Bank Buyer's Credit Program is Countervailable
- Comment 2: Whether the Department Should Continue to Apply AFA in Determining Whether to Use an Internal or External Benchmark
- Comment 3: Whether the Provision of Aluminum Extrusions at LTAR is Specific
- Comment 4: Whether the Department Should Adjust the Polysilicon Benchmark for the Final Results
- Comment 5: Whether the Department Should Remove Certain Polysilicon Purchases Regarding the Polysilicon for LTAR Benefit Calculation with Respect to Lightway
- Comment 6: Whether the Department Should Find the BYD Group to be Uncreditworthy During 2008, 2011, and 2012
- Comment 7: Whether the Department Should Revise the Benefit Calculation Regarding the BYD Group's Loans
- Comment 8: Whether the Department Should Find the Subsidies Discovered at Lightway's Verification to be Countervailable
- Comment 9: Whether the Department Should Revise Lightway's Benefit Calculation to Remove Certain Transactions Regarding the Preferential Policy Lending Program
- Comment 10: Whether the Department Should Revise the Principal Amounts with Respect to Certain Lightway Loans
- Comment 11: Whether the Department Should Revise the Rate for the Non-Selected Companies for these Final Results

X. Recommendation

Appendix II

Companies Not Selected for Individual Review

1. Baoding Jiansheng Photovoltaic Technology Co., Ltd.
2. Boading Tianwei Yingli New Energy Resources Co., Ltd.
3. Beijing Tianneng Yingli New Energy Resources Co. Ltd.
4. Canadian Solar International Limited
5. Canadian Solar Manufacturing (Changshu) Inc.
6. Canadian Solar Manufacturing (Luoyang) Inc.
7. Changzhou NESL Solartech Co., Ltd.
8. Changzhou Trina Solar Energy Co., Ltd.
9. Chint Solar (Zhejiang) Co., Ltd.
10. CSG PVTech Co., Ltd.
11. DelSolar Co., Ltd.
12. De-Tech Trading Limited HK
13. Dongfang Electric (Yixing) MAGI Solar Power Technology Co., Ltd.
14. Eoplly New Energy Technology Co., Ltd.
15. Era Solar Co., Ltd.
16. ET Solar Energy Limited.
17. Hainan Yingli New Energy Resources Co., Ltd.
18. Hangzhou Zhejiang University Sunny Energy Science and Technology Co. Ltd.
19. Hendigan Group Dmegc Magnetics
20. Hengshui Yingli New Energy Resources Co., Ltd.
21. Himin Clean Energy Holdings Co., Ltd.
22. Innovosolar
23. Jiangsu Green Power PV Co., Ltd.
24. Jiangxi Sunlink PV Technology Ltd.
25. Jiangsu Jiasheng Photovoltaic Technology Co., Ltd.
26. Jiangsu Sunlink PV Technology Co., Ltd.
27. Jiawei Solarchina Co. Ltd.
28. Jinko Solar Co., Ltd.
29. Jinko Solar Import and Export Co., Ltd.
30. Jinko Solar International Limited
31. Konca Solar Cell Co., Ltd.
32. Kuttler Automation Systems (Suzhou) Co. Ltd.
33. LDK Solar Hi-tech (Suzhou) Co., Ltd.
34. LDK Solar Hi-tech (Nanchang)
35. Leye Photovoltaic Science & Technology Co., Ltd.
36. Lixian Yingli New Energy Resources Co., Ltd.
37. Luoyang Suntech Power Co., Ltd.
38. Magi Solar Technology
39. Motech (Suzhou) Renewable Energy Co., Ltd.
40. MS Solar Investments LLC
41. Ningbo Ulica Solar Science & Technology Co., Ltd.
42. Ningbo Qixin Solar Electrical Appliance Co. Ltd.
43. Ningbo ETDZ Holdings Ltd.
44. Perlight Solar Co., Ltd.
45. ReneSola
46. Renesola Jiangsu Ltd.
47. Shenzen Topray Solar Co., Ltd.
48. Shanghai Machinery Complete Equipment (Group) Corp., Ltd.
49. Shenglong PV Tech.
50. Shenzhen Suntech Power Co., Ltd.
51. ShunFeng PV

52. Solarbest Energy—Tech (Zhejiang) Co., Ltd.
53. Sopray Energy
54. Sumec Hardware & Tools Co., Ltd.
55. Sun Earth Solar Power Co., Ltd.
56. Suntech Power Co., Ltd.
57. Suzhou Shenglong PV-Tech Co., Ltd.
58. Tianwei New Energy (Chengdu) PV Module Co., Ltd.
59. Tianjin Yingli New Energy Resources Co, Ltd.
60. Trina Solar (Changzhou) Science & Technology Co, Ltd.
61. Topray
62. Upsolar Group, Co. Ltd.
63. Wanxiang Import & Export Co., Ltd.
64. Wuxi Sunshine Power
65. Wuxi Suntech Power Co., Ltd.
66. Yangzhou Rietech Renewal Energy Co., Ltd.
67. Yangzhou Suntech Power Co., Ltd.
68. Yingli Energy (China) Company Limited.
69. Yingli Green Energy International Trading Company Limited.
70. Zhejiang Jiutai New Energy Co. Ltd.
71. Zhejiang Shuqimeng Photovoltaic Technology Co., Ltd.
72. Zhejiang Xinshun Guangfu Science and Technology Co., Ltd.
73. Zhejiang ZG-Cells Co, Ltd.
74. Zhenjiang Rietech New Energy Science & Technology Co., Ltd.
75. Zhiheng Solar Inc.
76. Zhejiang Sunflower Light Energy Sciences & Technology Limited Liability Company

[FR Doc. 2015–17241 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–552–819]

Certain Steel Nails From the Socialist Republic of Vietnam: Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Department) and the International Trade Commission (ITC), the Department is issuing a countervailing duty order on certain steel nails (nails) from the Socialist Republic of Vietnam (Vietnam).

DATES: Effective July 14, 2015.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer or Sergio Balbontin, AD/CVD Operations, Office 1, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0410 and (202) 482–6478, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 20, 2015, the Department published its final determination in the countervailing duty investigation of nails from the Vietnam.[1] On July 6, 2015, the ITC notified the Department of its final determination pursuant to section 705(b)(1)(A)(i) of the Tariff Act of 1930, as amended (Act), that an industry in the United States is materially injured by reason of subsidized imports of subject merchandise from Vietnam.[2]

Scope of the Order

The merchandise covered by this order is certain steel nails having a nominal shaft length not exceeding 12 inches.[3] Certain steel nails include, but are not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this order are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of i) medical, surgical, dental or veterinary furniture; and ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (*e.g.,* furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this order are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this order are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this order are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth

[1] *See Certain Steel Nails From the Socialist Republic of Vietnam: Final Affirmative Countervailing Duty Determination,* 80 FR 28962 (May 20, 2015).

[2] *See* Certain Steel Nails from Korea, Malaysia, Oman, Taiwan, and Vietnam, USITC Investigation Nos. 701–TA–521 and 731–TA–1252–1255 (Final), USITC Publication 4541 (July 2015). Because the final CVD determinations with respect to Korea, Malaysia, Oman, and Taiwan were negative, the CVD investigations with respect to those countries were terminated.

[3] The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this order are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this order are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this order are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this order also may be classified under HTSUS subheadings 7907.00.60.00, 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Countervailing Duty Order

In accordance with sections 705(b)(1)(A)(i) and 705(d) of the Act, the ITC has notified the Department of its final determination that the industry in the United States producing nails is materially injured by reason of subsidized imports of nails from Vietnam. Therefore, in accordance with section 705(c)(2) of the Act, we are publishing this countervailing duty order.

As a result of the ITC's final determination, in accordance with section 706(a) of the Act, the Department will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by the Department, countervailing duties on unliquidated entries of nails from Vietnam entered, or withdrawn from warehouse, for consumption on or after November 3, 2014, the date on which the Department published its preliminary countervailing duty determination in the **Federal Register**,[4] and before March 3, 2015, the date on which the Department instructed CBP to discontinue the suspension of liquidation in accordance with section 703(d) of the Act. Section 703(d) of the Act states that the suspension of liquidation pursuant to a preliminary determination may not remain in effect for more than four months. Therefore, entries of nails made on or after March 3, 2015, and prior to the date of publication of the ITC's final determination in the **Federal Register** are not liable for the assessment of countervailing duties due to the Department's discontinuation, effective March 3, 2015, of the suspension of liquidation.

Suspension of Liquidation

In accordance with section 706 of the Act, the Department will direct CBP to reinstitute the suspension of liquidation of nails from Vietnam, effective the date of publication of the ITC's notice of final determination in the **Federal Register,** and to assess, upon further instruction by the Department pursuant to section 706(a)(1) of the Act, countervailing duties for each entry of the subject merchandise in an amount based on the net countervailable subsidy rates for the subject merchandise. On or after the date of publication of the ITC's final injury determination in the **Federal Register**, CBP must require, at the same time as importers would normally deposit estimated duties on this merchandise, a cash deposit equal to the rates noted below:

Company	Subsidy rate (percent)
Region Industries Co., Ltd	288.56
United Nail Products Co. Ltd ...	313.97
All Others	301.27

This notice constitutes the countervailing duty order with respect to nails from Vietnam pursuant to section 706(a) of the Act. Interested parties may contact the Department's Central Records Unit, Room B8024 of the main Commerce Building, for copies of an updated list of countervailing duty orders currently in effect.

This order is issued and published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: July 8, 2015.

Lynn M. Fischer Fox

Deputy Assistant Secretary for Policy & Negotiation.

[FR Doc. 2015–17363 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–DS–P

[4] *See Certain Steel Nails From the Socialist Republic of Vietnam: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination,* 79 FR 65184 (November 3, 2014).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–971]

Multilayered Wood Flooring From the People's Republic of China: Final Results and Partial Rescission of Countervailing Duty Administrative Review; 2012

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Department) has conducted an administrative review of the countervailing duty (CVD) order on multilayered wood flooring (wood flooring) from the People's Republic of China (PRC).[1] On January 7, 2015, we published the *Preliminary Results* for this administrative review.[2] The period of review (POR) is January 1, 2012, through December 31, 2012. We find that Fine Furniture (Shanghai) Limited (Fine Furniture) and The Lizhong Wood Industry Limited Company of Shanghai (Lizhong) (also known as Shanghai Lizhong Wood Products Co., Ltd.), the individually examined companies in this administrative review, received countervailable subsidies during the POR. The Department is also rescinding the review of Changzhou Hawd Flooring Co., Ltd. (Changzhou) because it had no shipments of subject merchandise to the United States during the POR.

DATES: Effective date July 14, 2015.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg or Dana Mermelstein, AD/CVD Operations, Office I, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1785 or (202) 482–1391, respectively.

SUPPLEMENTARY INFORMATION:

Background

In the *Preliminary Results,* we deferred our analysis of certain programs to a post-preliminary analysis. On March 11, 2015, we issued a post-preliminary analysis memorandum.[3] We

[1] *See Multilayered Wood Flooring from the People's Republic of China: Countervailing Duty Order,* 76 FR 76693 (December 8, 2011) (*Order*); *see also Multilayered Wood Flooring from the People's Republic of China: Amended Antidumping and Countervailing Duty Orders,* 77 FR 5484 (February 3, 2012) (*Amended Order*).

[2] *See Multilayered Wood Flooring From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review and Intent To Rescind the Review in Part; 2012,* 80 FR 859 (January 7, 2015) (*Preliminary Results*).

[3] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and

Continued

invited interested parties to file case and rebuttal briefs following the release of the post-preliminary analysis memorandum. Only the Government of the PRC (the GOC) filed a case brief.[4] No party filed a rebuttal brief. We also received letters from Fine Furniture [5], Suzhou Dongda Wood Co., Ltd.[6], and Yixing Lion-King Timber Industry Co., Ltd.[7]

On May 5, 2015, the Department extended the time period for issuing the final results of this administrative review to July 6, 2015, as permitted by section 751(a)(3)(A) of the Tariff Act of 1930 (the Act) and 19 CFR 351.213(h)(2).[8] On the same date, we issued a supplemental questionnaire to the GOC,[9] and we received the GOC's response on May 22, 2015.[10] On May 29, 2015, the Department provided parties with an opportunity to comment on the GOC's supplemental response.[11] No comments were received.

Scope of the Order

Multilayered wood flooring is composed of an assembly of two or more layers or plies of wood veneer(s) [12] in combination with a core. Imports of the subject merchandise are provided for under the following subheadings of the Harmonized Tariff Schedule of the United States (HTSUS): 4412.31.0520; 4412.31.0540; 4412.31.0560; 4412.31.2510; 4412.31.2520; 4412.31.4040; 4412.31.4050; 4412.31.4060; 4412.31.4070; 4412.31.5125; 4412.31.5135; 4412.31.5155; 4412.31.5165; 4412.31.6000; 4412.31.9100; 4412.32.0520; 4412.32.0540; 4412.32.0560; 4412.32.2510; 4412.32.2520; 4412.32.3125; 4412.32.3135; 4412.32.3155; 4412.32.3165; 4412.32.3175; 4412.32.3185; 4412.32.5600; 4412.39.1000; 4412.39.3000; 4412.39.4011; 4412.39.4012; 4412.39.4019; 4412.39.4031; 4412.39.4032; 4412.39.4039; 4412.39.4051; 4412.39.4052; 4412.39.4059; 4412.39.4061; 4412.39.4062; 4412.39.4069; 4412.39.5010; 4412.39.5030; 4412.39.5050; 4412.94.1030; 4412.94.1050; 4412.94.3105; 4412.94.3111; 4412.94.3121; 4412.94.3131; 4412.94.3141; 4412.94.3160; 4412.94.3171; 4412.94.4100; 4412.94.5100; 4412.94.6000; 4412.94.7000; 4412.94.8000; 4412.94.9000; 4412.94.9500; 4412.99.0600; 4412.99.1020; 4412.99.1030; 4412.99.1040; 4412.99.3110; 4412.99.3120; 4412.99.3130; 4412.99.3140; 4412.99.3150; 4412.99.3160; 4412.99.3170; 4412.99.4100; 4412.99.5100; 4412.99.5710; 4412.99.6000; 4412.99.7000; 4412.99.8000; 4412.99.9000; 4412.99.9500; 4418.71.2000; 4418.71.9000; 4418.72.2000; and 4418.72.9500.

While HTSUS subheadings are provided for convenience and customs purposes, the written product description remains dispositive. A full description of the scope of the order is contained in the Issues and Decision Memorandum.[13]

The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html*. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Partial Rescission of Administrative Review

On April 4, 2014, we received a timely filed no-shipment certification from Changzhou. Because there is no evidence on the record to indicate that this company had sales of subject merchandise during the POR, and no party objected to our intent to rescind as stated in the *Preliminary Results,* pursuant to 19 CFR 351.213(d)(3), we are rescinding the review with respect to Changzhou.

Methodology

We have conducted this review in accordance with section 751(a)(1)(A) of the Act. A full description of the methodology underlying our conclusions is presented in the Issues and Decision Memorandum.

Use of Facts Otherwise Available, Including Adverse Inferences

For purposes of the Support for Developing a National Technology Standard program, the Department has concluded that, despite two requests, the GOC did not provide the Department with necessary information with respect to the length of time that the subsidy program has been in operation. Accordingly, the Department has determined that the GOC did not act to the best of its ability in responding to the Department's request for information and that the application of facts available with an adverse inference is warranted.[14] Based upon the available facts and the GOC's failure to cooperate to the best of its ability in providing this information as requested, the Department has concluded that the Support for Developing a National Technology Standard program was in existence prior to the POR. For further information, see the section ''Use of Facts Otherwise Available and Adverse Inferences,'' in the Issues and Decision Memorandum.

Final Results of the Review

In accordance with 19 CFR 351.221(b)(5), we calculated individual subsidy rates for the mandatory respondents, Fine Furniture and Lizhong.

Countervailing Duty Operations, ''Post-Preliminary Analysis of Countervailing Duty Administrative Review: Multilayered Wood Flooring from the People's Republic of China'' (March 11, 2015).

[4] *See* Letter from the GOC to the Department, ''Case Brief of the Government of the People's Republic of China: Multilayered Wood Flooring from The People's Republic of China'' (March 19, 2015).

[5] *See* Letter from Fine Furniture to the Department, ''Administrative Review of the Countervailing Duty Order on Multilayered Wood Flooring from the People's Republic of China: Letter in Lieu of Case Brief'' (March 19, 2015).

[6] *See* Letter from Suzhou Dongda Wood Co., Ltd. and Yixing Lion-King Timber Industry Co., Ltd. to the Department, ''*Multilayered Wood Flooring from the People's Republic of China: Correction of Typographical Errors''* (January 8, 2015).

[7] *Id.*

[8] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Multilayered Wood Flooring from the People's Republic of China: Extension of Deadline for Final Results of Countervailing Duty Administrative Review; 2012'' (May 5, 2015).

[9] *See* Letter to the GOC, ''Multilayered Wood Flooring from the People's Republic of China: *2012 Countervailing Duty Administrative Review''* (May 5, 2015).

[10] *See* Letter from the GOC to the Department, ''Response of the Government of the People's Republic of China to the Department's Fourth Supplemental Questionnaire'' (May 22, 2015).

[11] *See* Memorandum to the File from Josh Morris, International Trade Compliance Analyst, Office I, ''Multilayered Wood Flooring from the People's Republic of China: Countervailing Duty Administrative Review; 2012-Additional Comment Period'' (May 29, 2015).

[12] A ''veneer'' is a thin slice of wood, rotary cut, sliced or sawed from a log, bolt or flitch. Veneer is referred to as a ply when assembled.

[13] *See* memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Issues and Decision Memorandum for Final Results of Countervailing Duty Administrative Review: Multilayered Wood Flooring from the People's Republic of China'' (Issues and Decision Memorandum), dated concurrently with this notice.

[14] *See* sections 776(a) and (b) of the Act.

For the non-selected respondents, we have followed the Department's practice, which is to base the subsidy rates on an average of the subsidy rates calculated for those companies selected for individual review, excluding *de minimis* rates or rates based entirely on adverse facts available.[15] We have assigned to the non-selected respondents the simple average of the rates calculated for Fine Furniture and Lizhong. We have used a simple average rather than a weighted average due to inconsistent units of measure in the publicly ranged quantity and value data.

We find the net countervailable subsidy rate for the producers and/or exporters under review to be as follows:[16]

Producer/exporter	Net subsidy rate
Shanghai Lizhong Wood Products Co., Ltd. (also known as The Lizhong Wood Industry Limited Company of Shanghai)	0.99
Fine Furniture (Shanghai) Limited	0.99
A&W (Shanghai) Woods Co., Ltd	0.99
Suzhou Dongda Wood Co., Ltd	0.99
Armstrong Wood Products (Kunshan) Co., Ltd	0.99
Baishan Huafeng Wood Product Co., Ltd	0.99
Baiying Furniture Manufacturer Co., Ltd	0.99
Baroque Timber Industries (Zhongshan) Co., Ltd	0.99
Cheng Hang Wood Co., Ltd[17]	0.99
Changbai Mountain Development and Protection Zone Hongtu Wood Industrial Co., Ltd	0.99
Chinafloors Timber (China) Co., Ltd	0.99
Dalian Dajen Wood Co., Ltd	0.99
Dalian Huade Wood Product Co., Ltd	0.99
Dalian Huilong Wooden Products Co., Ltd	0.99
Dalian Jiuyuan Wood Industry Co., Ltd	0.99
Dalian Kemian Wood Industry Co., Ltd	0.99
Dalian Penghong Floor Products Co., Ltd	0.99
Dalian T-Boom Wood Products Co., Ltd	0.99
Dongtai Fuan Universal Dynamics, LLC	0.99
Dun Hua City Jisen Wood Industry Co., Ltd	0.99
Dunhua City Dexin Wood Industry Co., Ltd	0.99
Dunhua City Hongyuan Wood Industry Co., Ltd	0.99
Dunhua City Wanrong Wood Industry Co., Ltd	0.99
Dunhua Sentai Wood Co., Ltd	0.99
Dunhua Shengda Wood Industry Co., Ltd	0.99
Fu Lik Timber (HK) Co., Ltd	0.99
Fusong Jinlong Wooden Group Co., Ltd	0.99
Fusong Qianqiu Wooden Product Co., Ltd	0.99
GTP International Ltd	0.99
Guangdong Yihua Timber Industry Co., Ltd	0.99
Guangzhou Homebon Timber Manufacturing Co., Ltd	0.99
Guangzhou Panyu Kangda Board Co., Ltd	0.99
Guangzhou Panyu Southern Star Co., Ltd	0.99
HaiLin XinCheng Wooden Products, Ltd	0.99
Hangzhou Dazhuang Floor Co., Ltd (dba Dasso Industrial Group Co., Ltd.)	0.99
Hangzhou Hanje Tec Co., Ltd	0.99
Hangzhou Zhengtian Industrial Co., Ltd	0.99
Hunchun Forest Wolf Wooden Industry Co., Ltd	0.99
Hunchun Xingjia Wooden Flooring Inc	0.99
Huzhou Chenghang Wood Co., Ltd	0.99
Huzhou Fulinmen Imp. & Exp. Co., Ltd	0.99
Huzhou Fuma Wood Co., Ltd	0.99
Huzhou Jesonwood Co., Ltd	0.99
Huzhou Ruifeng Imp. & Exp. Co., Ltd	0.99
Huzhou Sunergy World Trade Co., Ltd	0.99
Jiafeng Wood (Suzhou) Co., Ltd	0.99
Jiangsu Senmao Bamboo and Wood Industry Co., Ltd	0.99
Jiangsu Simba Flooring Co., Ltd	0.99
Jiashan Hui Jia Le Decoration Material Co., Ltd	0.99
Jilin Forest Industry Jinqiao Flooring Group Co., Ltd	0.99
Jilin Xinyuan Wooden Industry Co., Ltd	0.99
Karly Wood Product Limited	0.99
Kemian Wood Industry (Kunshan) Co., Ltd	0.99
Linyi Anying Wood Co., Ltd	0.99
Linyi Bonn Flooring Manufacturing Co., Ltd	0.99
Mudanjiang Bosen Wood Industry Co., Ltd	0.99
Nakahiro Jyou Sei Furniture (Dalian) Co., Ltd	0.99
Nanjing Minglin Wooden Industry Co., Ltd	0.99
Power Dekor Group Co., Ltd	0.99
Riverside Plywood Corporation	0.99
Samling Elegant Living Trading (Labuan) Limited	0.99

[15] *See, e.g., Certain Pasta From Italy: Preliminary Results of the 13th (2008) Countervailing Duty Administrative Review,* 75 FR 18806, 18811 (April 13, 2010), unchanged in *Certain Pasta from Italy: Final Results of the 13th (2008) Countervailing Duty Administrative Review,* 75 FR 37386 (June 29, 2010).

[16] *See* Memorandum to The File from Mary Kolberg, International Trade Analyst, ''*Multilayered Wood Flooring from the People's Republic of China; 2012*'' dated concurrently with this notice.

Producer/exporter	Net subsidy rate
Samling Riverside Co., Ltd	0.99
Shanghai Anxin (Weiguang) Timber Co., Ltd	0.99
Shanghai Eswell Timber Co., Ltd	0.99
Shanghai Lairunde Wood Co., Ltd	0.99
Shanghai New Sihe Wood Co., Ltd	0.99
Shanghai Shenlin Corporation	0.99
Shenyang Haobainian Wooden Co., Ltd	0.99
Shenzhenshi Huanwei Woods Co., Ltd	0.99
Vicwood Industry (Suzhou) Co. Ltd	0.99
Xiamen Yung De Ornament Co., Ltd	0.99
Xuzhou Shenghe Wood Co., Ltd	0.99
Yekalon Industry, Inc	0.99
Yingyi-Nature (Kunshan) Wood Industry Co., Ltd	0.99
Yixing Lion-King Timber Industry Co. Ltd	0.99
Zhejiang Anji Xinfeng Bamboo and Wood Co., Ltd	0.99
Zhejiang Biyork Wood Co., Ltd	0.99
Zhejiang Dadongwu Green Home Wood Co., Ltd	0.99
Zhejiang Desheng Wood Industry Co., Ltd	0.99
Zhejiang Fudeli Timber Industry Co., Ltd	0.99
Zhejiang Fuerjia Wooden Co., Ltd	0.99
Zhejiang Fuma Warm Technology Co., Ltd	0.99
Zhejiang Haoyun Wooden Co., Ltd	0.99
Zhejiang Longsen Lumbering Co., Ltd	0.99
Zhejiang Shiyou Timber Co., Ltd	0.99
Zhejiang Tianzhen Bamboo & Wood Development Co., Ltd	0.99

Assessment Rates

Consistent with 19 CFR 351.212(b)(2), we intend to issue assessment instructions to the U.S. Customs and Border Protection (CBP) fifteen days after the date of publication of these final results. We will instruct CBP to assess countervailing duties on POR entries in the amounts shown above.

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, we intend to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed companies (except Zhejiang Layo Wood Industry Co., Ltd., its affiliate Jiaxing Brilliant Import & Export Co., Ltd., and Zhejiang Yuhua Timber Co., Ltd., which are excluded from the *Order*),[18] we will instruct CBP to continue to collect cash deposits at the most recent company-specific or all-others rate applicable to the company. Accordingly, the cash deposit rates that will be applied to companies covered by the *Amended Order,* but not examined in this review, are those established in the most recently completed segment of the proceeding for each company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice serves as a final reminder to parties subject to 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 written notification of return or 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 in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: July 6, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Partial Rescission of Administrative Review
5. Use of Facts Otherwise Available and Adverse Inferences
6. Subsidy Valuation Information
7. Analysis of Programs
8. Analysis of Comments
   Comment 1: Specificity of the Support for Developing a National Technology Standard Program
   Comment 2: Names of Companies in U.S. Customs and Border Protection Instructions
9. Recommendation

[FR Doc. 2015–17079 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–DS–P

[17] *See* Memorandum To The File from Mary Kolberg, International Trade Analyst, ''Addition of Cheng Hang Wood Co., Ltd. to Final Results'' (June 29, 2015).

[18] *See Order,* 76 FR at 76694.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Alaska Region Amendment 80 Permits and Reports

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before September 14, 2015.

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 NMFS Alaska Region, Patsy A. Bearden, at *patsy.bearden@noaa.gov* or call (907) 586–7008.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection.

Amendment 80 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area allocates several Bering Sea and Aleutian Islands Management Area non-pollock trawl groundfish fisheries among fishing sectors, established a limited access privilege program, and facilitated the formation of harvesting cooperatives in the non-American Fisheries Act (non-AFA) trawl catcher/processor sector. The Amendment 80 Fishery Management Plan applies retention standards on an aggregate basis to all activities of a cooperative, allowing participants within the cooperative to coordinate fishing and retention practices across the cooperative to meet the retention requirements.

II. Method of Collection

Information may be submitted online at *http://www.alaskafisheries.noaa.gov* or submitted as an attachment to email to *RAM.Alaska@noaa.gov.* Applications are ''fillable'' on the computer screen at *http://alaskafisheries.noaa.gov/sustainablefisheries/amds/80/default.htm#apps,* then downloaded, printed, faxed or mailed to NMFS.

III. Data

OMB Control Number: 0648–0565.

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: 37.

Estimated Time per Response: 2 hours each for Application for Amend 80 QS; Application for Amend 80 Cooperative and CQ Permit; Application for Amend 80 limited access fishery; Application to transfer Amend 80 QS; Application for Amendment 80 Vessel Replacement and Application for inter-cooperative transfer Amend 80 CQ; 25 hours for Amend 80 cooperative report; 4 hours for Amend 80 appeals letter; 30 minutes for Flatfish Exchange Application.

Estimated Total Annual Burden Hours: 204.

Estimated Total Annual Cost to Public: $544 in recordkeeping/reporting costs.

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: July 9, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–17194 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE039

Notice of Intent To Conduct Public Scoping and Prepare an Environmental Impact Statement for Five Early Winter Steelhead Hatchery Programs in Puget Sound

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

ACTION: Notice of intent to prepare an environmental impact statement; request for comments; notice of public workshops.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA), this notice announces that NMFS intends to obtain information necessary to prepare an Environmental Impact Statement (EIS) for five Hatchery and Genetic Management Plans (HGMPs) for early winter steelhead hatchery programs jointly submitted by the Washington Department of Fish and Wildlife (WDFW), with the Jamestown S'Klallam Tribe, the Lummi Nation, the Nooksack Tribe, the Stillaguamish Tribes, and the Tulalip Tribes (referred to as the co-managers) for NMFS's evaluation and determination under Limit 6 of the Endangered Species Act (ESA) 4(d) Rule for threatened salmon and steelhead. The HGMPs specify the propagation of early-returning (''early'') winter steelhead in the Dungeness, Nooksack, Stillaguamish, Skykomish, and Snoqualmie River watersheds in Washington State.

NMFS provides this notice to advise other agencies and the public of its plans to analyze effects related to the action, and obtain suggestions and information that may be useful to the scope of issues and alternatives to include in the EIS. Two public workshops will be held in July 2015 for this action.

DATES: Written or electronic scoping comments must be received at the appropriate address or email mailbox (see **ADDRESSES**) no later than 5 p.m. Pacific Time August 13, 2015. The public workshops will be held between July 20, 2015 and July 22, 2015 (see PUBLIC WORKSHOPS).

ADDRESSES: Written comments may be sent by any of the following methods:

- Email to the following address: *EWShatcheriesEIS.wcr@noaa.gov* with the following identifier in the subject line: Early Winter Steelhead Hatcheries EIS.
- Mail or hand-deliver to NMFS Sustainable Fisheries Division, 510 Desmond Drive SE., Suite 103, Lacey, WA 98503.
- Fax to (360) 753–9517.

Comments received will be available for public inspection, by appointment, during normal business hours at the above address. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Steve Leider, NMFS, by phone at (360) 753–4650, or email to *steve.leider@noaa.gov.*

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Steelhead (*Oncorhynchus mykiss*): threatened, naturally and artificially produced in Puget Sound.

Chinook salmon (*O. tshawytscha*): threatened, naturally and artificially produced in Puget Sound.

Chum salmon (*O. keta*): threatened, naturally and artificially produced Hood Canal summer-run.

Bull trout (*Salvelinus confluentus*): threatened Puget Sound/Washington Coast.

Background

On March 26, 2015 (80 FR 15985), NMFS announced the availability of a draft Environmental Assessment (EA) pursuant to NEPA (42 U.S.C. *et seq.*), for three HGMPs for early-returning (early winter) steelhead hatchery programs in the Dungeness, Nooksack, and Stillaguamish River basins, submitted to NMFS by the co-managers. A 30-day public comment period was extended to May 4, 2015 for a total comment period of 37 days (80 FR 22973, April 24, 2015). NMFS received and considered comments on the EA and, has subsequently decided to prepare an EIS to evaluate effects on the human environment of the three early winter steelhead hatchery programs in the Dungeness, Nooksack, and Stillaguamish River watersheds in Washington State. In the EIS, NMFS will also evaluate three additional early winter steelhead HGMPs for hatchery programs in the Skykomish and Snoqualmie Rivers in the Snohomish River watershed in Puget Sound. All of the programs would release early winter steelhead that are not included as part of the ESA-listed Puget Sound Steelhead Distinct Population Segment, and that are not native to the watersheds in which they would be released.

NEPA requires Federal agencies to conduct environmental analyses of proposed actions to determine if the actions may affect the human environment. NMFS's action of evaluating the co-managers' HGMPs, pursuant to the limitation on take prohibitions for actions conducted under Limit 6 of the 4(d) Rule for salmon and steelhead promulgated under the ESA, is a major Federal action subject to environmental review under NEPA. Therefore, NMFS is seeking public input on the scope of the required NEPA analysis, including the range of reasonable alternatives, recommendations for relevant analysis methods, and information associated with impacts of the alternatives to the resources listed below or other relevant resources.

NMFS will perform an environmental review of the HGMPs and prepare an EIS that will identify potentially significant direct, indirect, and cumulative impacts on the following resources identified to have a potential for effect from the proposed action:

- Listed and Non-listed Species and their habitats
- Water Quantity
- Socioeconomics
- Environmental Justice
- Cumulative Impacts

NMFS will rigorously explore and objectively evaluate a full range of reasonable alternatives in the EIS, including the proposed action (implementation of the co-managers' HGMPs) and a no-action alternative. Additional alternatives could include the following: (1) A decrease in artificial production of 50 percent, and (2) a change in program type from isolated (*i.e.,* producing hatchery-origin fish that are intended to be reproductively segregated and different from the natural-origin population) to integrated (*i.e.,* producing hatchery-origin fish that are intended to be similar to and part of the natural-origin population) programs that would use native steelhead for broodstock.

For all potentially significant impacts, the EIS will identify measures to avoid, minimize, and mitigate the impacts, where feasible, to a level below significance.

Request for Comments

NMFS provides this notice to: (1) Advise other agencies and the public of its plans to analyze effects related to the action, and (2) obtain suggestions and information that may be useful to the scope of issues and the full range of alternatives to include in the EIS. In addition to considering comments received in response to this notice in developing an EIS, relevant comments received on the 2015 draft EA for three early winter steelhead hatchery programs (80 FR 15985, March 26, 2015), and on the 2014 draft EIS for Puget Sound salmon and steelhead hatcheries (80 FR 15986, March 26, 2015) will also be considered in developing the EIS.

NMFS invites comment from all interested parties to ensure that the full range of issues related to the early winter steelhead HGMPs is identified. Comments should be as specific as possible.

Written comments concerning the proposed action and the environmental review should be directed to NMFS as described above (see **ADDRESSES**). All comments and materials received, including names and addresses, will become part of the administrative record and may be released to the public.

Public Workshops

Two public workshops will be offered to assist in gathering information on development of the EIS. Those workshops will be held as follows; further information regarding the workshops may be found at *http://www.westcoast.fisheries.noaa.gov/hatcheries/salmon_and_steelhead_hatcheries.html.*

Monday, July 20, 2015

6 to 8 p.m., Skagit Public Utilities District, Aqua Room, 1415 Freeway Drive, Mt Vernon, Washington

Tuesday, July 21, 2015

6 to 8 p.m., Lynnwood Convention Center, 3711 196th St SW., Lynnwood, Washington

Authority

The environmental review of the early winter steelhead HGMPS will be conducted in accordance with requirements of the NEPA of 1969 as amended (42 U.S.C. 4321 *et seq.*), NEPA Regulations (40 CFR parts 1500–1508), other appropriate Federal laws and regulations, and policies and procedures of NMFS for compliance with those regulations. This notice is being furnished in accordance with 40 CFR 1501.7 to obtain suggestions and information from other agencies and the public on the scope of issues and alternatives to be addressed in the EIS.

Dated: July 8, 2015.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–17156 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RIN 0648–XE046]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) Atlantic Bluefish Advisory Panel will hold a public meeting.

DATES: The meeting will be held on July 28, 2015, from 10 a.m. until noon.

ADDRESSES: The meeting will be held via webinar with a telephone-only connection option. Details on webinar registration and telephone-only connection details are available at: *http://www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 North State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fisheries Management Council's (MAFMC) Atlantic Bluefish Advisory Panel (AP) will meet jointly with the Atlantic States Marine Fisheries Commission's (ASMFC) Atlantic Bluefish AP. The purpose of this meeting is to review and comment on the reports of the MAFMC's Scientific and Statistical Committee (SSC) and the Bluefish Monitoring Committee meetings held in July 2015. The MAFMC and the ASMFC will consider the input from the Bluefish AP in August when setting fishery specifications (*i.e.* catch and landings limits and management measures) for 2016–2018.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: July 9, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–17216 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Release of the Draft 2015 Edition of the U.S. Arctic Nautical Charting Plan

AGENCY: Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Request for comments.

SUMMARY: The NOAA Office of Coast Survey has released a draft of the 2015 edition of the U.S. Arctic Nautical Charting Plan. The plan provides information about three topics: NOAA electronic navigational chart (NOAA ENC®) coverage in U.S. Arctic waters, progress on publishing new Arctic charts, and specifications for eleven proposed new charts. The primary purpose of the plan is to propose new chart coverage in the U.S. Arctic and to encourage feedback from stakeholders on the extent, scale, and other aspects of the proposed new coverage. Coast Survey invites written comments about this latest edition which is available from *http://nauticalcharts.noaa.gov/arcticplan.*

DATES: Comments are due by midnight, October 1, 2015.

ADDRESSES: Mail written comments to National Ocean Service, NOAA (N/CS2), Attention: U.S. Arctic Nautical Charting Plan, 1315 East-West Highway Silver Spring, MD 20910–3282. See **SUPPLEMENTARY INFORMATION** section for how to comment electronically.

FOR FURTHER INFORMATION CONTACT: Colby Harmon, telephone 301–713–2737, ext.187; email: *colby.harmon@noaa.gov.*

SUPPLEMENTARY INFORMATION: You are invited to comment on the U.S. Arctic Nautical Charting Plan through NOAA's Nautical Discrepancy Report System at *http://ocsdata.ncd.noaa.gov/idrs/discrepancy.aspx.* In the ''OTHER PRODUCTS'' box, enter ''U.S. Arctic Nautical Charting Plan.'' Enter your comments, suggestions, or questions in the ''DESCRIPTION OF DISCREPANCY'' box.

For the first time, the U.S. Arctic Nautical Charting Plan provides information about existing, recently added, and proposed new electronic navigational chart (ENC) coverage in U.S. Arctic waters. A series of graphics depicts the existing extent of different usage (or scale) bands of ENC coverage. Recently added and proposed new ENC coverage is based on existing or proposed raster (traditional paper) chart footprints, although the final extent and display scale of the ENCs may vary slightly from their corresponding raster chart counterparts. NOAA will soon close a significant gap in small-scale ENC coverage and is adding new large-scale Arctic ENC cells.

Coast Survey released the first edition of the U.S. Arctic Nautical Charting Plan in 2011. Three of the raster charts identified in the original plan have now been published. Two of these have large-scale insets. The ''Progress Report'' section of the plan details these charts and provides links to an online viewer for these charts.

Coast Survey's plan recommends making 11 new charts in the Arctic to complement existing chart coverage. Seven of the charts will fill gaps in medium-scale chart coverage from the Alaska Peninsula to Cape Lisburne at the edge of the North Slope. Other larger scale charts will provide for safer passage though the Etolin and Bering Straits and for entry into harbors such as Barrow, the northernmost town in the United States. The ''Proposed New Raster Charts'' section of the plan provides detailed specifications for each of the proposed new charts. The specifications include scale, geographic extent, an image of the chart footprint, and other information.

Authority: 33 U.S.C. Chapter 17, Coast and Geodetic Survey Act of 1947.

Dated: June 22, 2015.

Rear Admiral Gerd Glang,

Director, Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2015–17243 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Multistakeholder Process To Develop Best Practices for Privacy, Transparency, and Accountability Regarding Commercial and Private Use of Unmanned Aircraft Systems

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of open meetings.

SUMMARY: The National Telecommunications and Information Administration (NTIA) will convene meetings of a multistakeholder process concerning privacy, transparency, and accountability issues regarding commercial and private use of unmanned aircraft systems. This Notice announces the meetings to be held in August, September, October, and November 2015. The first meeting is scheduled for August 3, 2015.

DATES: The meetings will be held on August 3, 2015; September 24, 2015; October 21, 2015; and November 20, 2015 from 1 p.m. to 5:00 p.m., Eastern Time. See **SUPPLEMENTARY INFORMATION** for details.

ADDRESSES: The meetings will be held in the Boardroom at the American Institute of Architects, 1735 New York Avenue NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: John Verdi, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4725, Washington, DC 20230; telephone (202) 482–8238; email *jverdi@ntia.doc.gov.*

Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002; email *press@ntia.doc.gov*.

SUPPLEMENTARY INFORMATION:

Background: Congress recognized the potential wide-ranging benefits of Unmanned Aircraft Systems (UAS) operations within the United States in the Federal Aviation Administration (FAA) Modernization and Reform Act of 2012 (Pub. L. 112–95), which requires a plan to safely integrate civil UAS into the National Airspace System (NAS) by 2015. Compared to manned aircraft, UAS may provide lower-cost operation and augment existing capabilities while reducing risks to human life. Estimates suggest the positive economic impact to U.S. industry of the integration of UAS into the NAS could be substantial and likely will grow for the foreseeable future.[1] UAS may be able to provide a variety of commercial services less expensively than manned aircraft, including aerial photography and farm management, while reducing or eliminating safety risks to aircraft operators. In addition, UAS may be able to provide some commercial services that would be impossible for manned aircraft. For example, improvements in technology may allow small UAS to deliver packages to homes and businesses where manned aircraft cannot land, and high-altitude UAS could provide Internet service to remote areas by remaining aloft for months at a time—far longer than manned aircraft.

On February 15, 2015, President Obama issued the Presidential Memorandum ''Promoting Economic Competitiveness While Safeguarding Privacy, Civil Rights, and Civil Liberties in Domestic Use of Unmanned Aircraft Systems.'' The Presidential Memorandum states: ''As UAS are integrated into the NAS, the Federal Government will take steps to ensure that the integration takes into account not only our economic competitiveness and public safety, but also the privacy, civil rights, and civil liberties concerns these systems may raise.'' [2] The Presidential Memorandum establishes a ''multi-stakeholder engagement process to develop and communicate best practices for privacy, accountability, and transparency issues regarding commercial and private UAS use in the NAS.'' [3] The process will include stakeholders from industry, civil society, and academia, and will be initiated by the Department of Commerce, through NTIA, and in consultation with other interested agencies.

On March 5, 2015, NTIA sought public comment on three broad questions: (1) What privacy, transparency, and accountability issues concerning UAS are the highest priorities for stakeholders to address; (2) how might best practices address those issues; and (3) how should stakeholders' work be structured as the group works openly and transparently toward consensus.[4] More than fifty commenters filed responses.[5] Individuals and entities in the commercial, academic, civil society, and government sectors filed comments. The comments highlight a range of issues that might be addressed through the multistakeholder process and suggest various ways in which the group's work might be structured.

NTIA will convene stakeholders in an open and transparent forum to develop consensus best practices for utilization by commercial and private UAS operators. For this process, commercial and private use includes the use of UAS for commercial purposes as civil aircraft, even if the use would qualify a UAS as a public aircraft under 49 U.S.C. 40102(a)(41) and 40125. The process will not focus on law enforcement or other noncommercial governmental use of UAS.

NTIA is convening this process to address privacy concerns raised by commercial and private UAS. UAS can enable aerial data collection that is more sustained, pervasive, and invasive than manned flight; at the same time, UAS flights can reduce costs, provide novel services, and promote economic growth. These attributes create opportunities for innovation, but also pose privacy challenges regarding collection, use, retention, and dissemination of data collected by UAS. NTIA encourages stakeholders to work together within the NTIA process to identify safeguards that mitigate the privacy challenges posed by commercial and private UAS use, and to include appropriate safeguards in a stakeholder-drafted best practices document.

The NTIA-convened process is intended to promote transparent UAS operation by companies and individuals. Transparent operation can include identifying the entities that operate particular UAS, the purposes of UAS flights, and the data practices associated with UAS operations. Transparent UAS operation can enhance privacy and bolster other values. Transparency can help property owners identify UAS if an aircraft erroneously operates or lands on private property. Transparency can also facilitate reports of UAS operations that cause nuisances or appear unsafe. NTIA encourages stakeholders to work together within the NTIA process to identify transparency mechanisms, such as standardized physical markings (in addition to the markings required by the FAA for purposes of registration) or electronic identifiers, which could promote transparent UAS operation, and to include appropriate mechanisms in a stakeholder-drafted best practices document.

The NTIA-convened process is intended to promote accountable UAS operation by companies and individuals. UAS operators can employ accountability mechanisms to help ensure that privacy protections and transparency policies are enforced within an organization. Accountability mechanisms can include rules regarding oversight and privacy training for UAS pilots, as well as policies for how companies and individuals operate UAS and handle data collected by UAS. Accountability programs can also employ audits, assessments, and internal or external reports to verify UAS operators' compliance with their privacy and transparency commitments. Accountability mechanisms can be implemented by companies, model aircraft clubs, UAS training programs, or others. NTIA encourages stakeholders to work together within the NTIA process to identify mechanisms that can promote accountable UAS operation, and to include appropriate accountability mechanisms in a stakeholder-drafted best practices document.

NTIA's role in the multistakeholder process is to provide a forum for discussion and consensus-building among stakeholders. When stakeholders disagree, NTIA's role is to help the parties reach clarity on what their positions are and whether there are options for compromise toward consensus, rather than substituting NTIA's own judgment.

[1] Presidential Memorandum, *Promoting Economic Competitiveness While Safeguarding Privacy, Civil Rights, and Civil Liberties in Domestic Use of Unmanned Aircraft Systems,* (Feb. 15, 2015), *available at: http://www.whitehouse.gov/the-press-office/2015/02/15/presidential-memorandum-promoting-economic-competitiveness-while-safegua.*

[2] Presidential Memorandum at 1.

[3] Presidential Memorandum at 4.

[4] NTIA, Request for Public Comment, *Privacy, Transparency, and Accountability Regarding Commercial and Private Use of Unmanned Aircraft Systems,* 80 FR 11978 (March 5, 2015), *available at: http://www.ntia.doc.gov/federal-register-notice/2015/request-comments-privacy-transparency-and-accountability-regarding-comm.*

[5] NTIA has posted the public comments received at *http://www.ntia.doc.gov/federal-register-notice/2015/comments-privacy-transparency-and-accountability-regarding-commercial-a.*

Matters To Be Considered: The August 3, 2015 meeting will be the first in a series of NTIA-convened multistakeholder discussions concerning privacy, transparency, and accountability issues regarding commercial and private use of UAS. Subsequent meetings will follow on September 24, 2015; October 21, 2015; and November 20, 2015. Additional meetings will be scheduled as needed. Stakeholders will engage in an open, transparent, consensus-driven process to develop best practices for privacy, accountability, and transparency issues regarding commercial and private UAS use in the NAS.

The objectives of the August 3, 2015, meeting are to: (1) Briefly review the current regulatory environment for commercial UAS operation; (2) briefly discuss the range of commercial uses of UAS; (3) engage stakeholders in a discussion of high-priority substantive issues stakeholders believe should be addressed by best practices for privacy, transparency, and accountability for UAS operation; and (4) engage stakeholders in a discussion of logistical issues, including the potential establishment of working groups and identification of concrete goals and stakeholder work between the August and September meetings. This first meeting is intended to provide stakeholders with factual background regarding how UAS technology is currently used by businesses and individuals, how the technology might be employed in the near future, and what privacy, transparency, and accountability issues might be raised by the technology. NTIA will publish an agenda in advance of the August 3, 2015 meeting.

The main objective of the September 24, 2015; October 21, 2015; and November 20, 2015 meetings is to encourage and facilitate continued discussion among stakeholders concerning a best practices document that sets forth privacy, transparency, and accountability practices for commercial and individual UAS operation. This discussion may include circulation of stakeholder-developed straw-man drafts and discussion of the appropriate scope of best practices. Stakeholders may also agree on procedural work plans for the group, including additional meetings or modified logistics for future meetings.

NTIA suggests that stakeholders consider ''freezing'' the draft code of conduct after the November 20, 2015 meeting in order to facilitate external review of the draft. Stakeholders would then likely reconvene the group in December 2015 or January 2016 to take account of external feedback. More information about stakeholders' work will be available at: *http://www.ntia.doc.gov/other-publication/2015/multistakeholder-process-unmanned-aircraft-systems*.

Time and Date: NTIA will convene meetings of the multistakeholder process regarding unmanned aircraft systems on August 3, 2015; September 24, 2015; October 21, 2015; and November 20, 2015, from 1:00 p.m. to 5:00 p.m., Eastern Time. The meeting dates and times are subject to change. The meetings are subject to cancelation if stakeholders complete their work developing a code of conduct. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2015/multistakeholder-process-unmanned-aircraft-systems*, for the most current information.

Place: The meeting will be held in the Boardroom at the American Institute of Architects, 1735 New York Avenue NW., Washington, DC 20006. The location of the meetings is subject to change. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2015/multistakeholder-process-unmanned-aircraft-systems*, for the most current information.

Other Information: The meetings are open to the public and the press. The meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to John Verdi at (202) 482–8238 or *jverdi@ntia.doc.gov* at least seven (7) business days prior to each meeting. The meetings will also be webcast. Requests for real-time captioning of the webcast or other auxiliary aids should be directed to John Verdi at (202) 482–8238 or *jverdi@ntia.doc.gov* at least seven (7) business days prior to each meeting. There will be an opportunity for stakeholders viewing the webcast to participate remotely in the meetings through a moderated conference bridge, including polling functionality. Access details for the meetings are subject to change. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2015/multistakeholder-process-unmanned-aircraft-systems*, for the most current information.

Dated: July 9, 2015.

Milton Brown,

Acting Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2015–17206 Filed 7–13–15; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 15–25]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, DoD.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Sarah A. Ragan or Heather N. Harwell, DSCA/LMO, (703) 604–1546/(703) 607–5339. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 15–25 with attached Policy Justification.

Dated: July 9, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–C

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

JUL 07 2015

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding a revised Transmittal No. 15-25 concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Egypt for defense articles and services estimated to cost $100 million. The original Transmittal was delivered on June 04, 2015, and it erroneously identified principal contractors in the Policy Justification. In fact, the principal contractor has not been determined and will be determined during contract negotiations. This submission corrects this discrepancy and makes no other changes. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified Document Provided Under Separate Cover)

BILLING CODE 5001–06–P

Transmittal No. 15–25

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Egypt

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 0 million
Other	$100 million
TOTAL	$100 million

(iii) *Description and Quantity of Articles or Services under Consideration for Purchase:* procurement and construction of one (1) commercial off-the-shelf border security mobile surveillance sensor security system that will include the following sub-systems: mobile surveillance sensor towers, mobile command and control (C2) systems, a regional C2 system, voice/data communications equipment, spare parts, support equipment, personnel training, training equipment, publications and technical documentation, U.S. Government and contractor technical and logistics support services, and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (DAB)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None.

(viii) *Date Report Delivered to Congress:* 07 JULY 2015

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Egypt—Border Security Mobile Surveillance Sensor Security System

The Government of Egypt has requested a possible sale for procurement and construction of one (1) commercial off-the-shelf border security mobile surveillance sensor security system that will include the following sub-systems: mobile surveillance sensor towers, mobile command and control (C2) systems, a regional C2 system, voice/data communications equipment, spare parts, support equipment, personnel training, training equipment, publications and technical documentation, U.S. Government and contractor technical and logistics support services, and other related elements of logistics and program support. The estimated cost is $100 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country that has been and continues to be an important force for political stability and economic progress in the Middle East.

This mobile surveillance sensor security system will provide Egypt with advanced capabilities intended to bolster its border surveillance capabilities along its border with Libya and elsewhere. This procurement is intended for Egyptian Border Guard Forces, which currently lack any remote detection capability along unpatrolled areas of Egypt's borders. This system would provide an early warning capability to allow for faster response times to mitigate threats to the border guards and the civilian population. Egypt should have no difficulty absorbing these systems into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor is undetermined at this time and will be determined during negotiations. There are no known offset arrangements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Egypt. However, the proposed sale will require periodic travel to Egypt by multiple U.S. Government and contractor representatives' for program and technical review meetings, testing, and training for a period of up to 5 years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2015–17204 Filed 7–13–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0056]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; An Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior (MTSS–B)

AGENCY: Institute of Education Sciences/National Center for Education Evaluation (IES/NCEE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before August 13, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0056 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Lauren Angelo, 202–219–2180.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. 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: An Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior (MTSS–B).

OMB Control Number: 1850—NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 12,343.

Total Estimated Number of Annual Burden Hours: 5,909.

Abstract: This submission requests approval of data collection activities that will be used to support An Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior (MTSS–B). The evaluation will estimate the impact on school staff practices, school climate, and student outcomes of providing training and support in the MTSS–B framework plus universal (Tier I) positive behavior supports and targeted (Tier II) interventions.

Dated: July 9, 2015.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–17218 Filed 7–13–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0091]

Agency Information Collection Activities; Comment Request; Early Childhood Longitudinal Study, Kindergarten Class of 2010–11 (ECLS–K:2011) Spring Fifth-Grade National Data Collection

AGENCY: Institute of Education Sciences/ National Center For Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 14, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0091 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E105, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, 202–502–7411.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. 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: Early Childhood Longitudinal Study, Kindergarten Class of 2010–11 (ECLS–K:2011) Spring Fifth-Grade National Data Collection.

OMB Control Number: 1850–0750.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals.

Total Estimated Number of Annual Responses: 99,576.

Total Estimated Number of Annual Burden Hours: 36,108.

Abstract: The Early Childhood Longitudinal Study, Kindergarten Class of 2010–11 (ECLS–K:2011), conducted by the National Center for Education Statistics (NCES) within the Institute of Education Sciences (IES) of the U.S. Department of Education (ED), is a survey that focuses on children's early school experiences beginning with kindergarten and continuing through the fifth grade. It includes the collection of data from parents, teachers, school administrators, and nonparental care providers, as well as direct child assessments. Like its sister study, the Early Childhood Longitudinal Study, Kindergarten Class of 1998–99 (ECLS–K), the ECLS–K:2011 is exceptionally broad in its scope and coverage of child development, early learning, and school progress, drawing together information from multiple sources to provide rich data about the population of children who were kindergartners in the 2010–11 school year. This submission requests OMB's clearance for the spring 2016 fifth-grade data collection, which will be the last data collection for the study.

Dated: July 9, 2015.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–17217 Filed 7–13–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0051]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; U.S. Department of Education Pre-Authorized Debit Account Brochure and Application

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 13, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0051 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E105, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an

opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. 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: U.S. Department of Education Pre-Authorized Debit Account Brochure and Application.

OMB Control Number: 1845–0025.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 1,600.

Total Estimated Number of Annual Burden Hours: 133.

Abstract: The Preauthorized Debit Account Brochure and Application (PDA Application) serves as the means by which an individual with a defaulted federal education debt (student loan or grant overpayment) that is held by the U.S. Department of Education (ED) requests and authorizes the automatic debiting of payments toward satisfaction of the debt from the borrower's checking or savings account. The PDA Application explains the automatic debiting process and collects the individual's authorization for the automatic debiting and the bank account information needed by ED to debit the individual's account.

Dated: July 8, 2015.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–17157 Filed 7–13–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Record of Decision; Electrical Interconnection of the Whistling Ridge Energy Project

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Record of Decision (ROD).

SUMMARY: The Bonneville Power Administration (BPA) has decided to implement its part of the Proposed Action identified in the Whistling Ridge Energy Project Final Environmental Impact Statement (EIS) (DOE/EIS–0419, August 2011). Under the Proposed Action, BPA will offer Whistling Ridge Energy LLC (WRE) contract terms for interconnection of WRE's planned Whistling Ridge Energy Project (Wind Project) with the FCRTS. WRE's Wind Project will be an up to 75-megawatt (MW) wind energy facility located in Skamania County, Washington. WRE has received approval to construct and operate the Wind Project from the Governor of the State of Washington, based on the recommendation of the Washington Energy Facility Site Evaluation Council (EFSEC), which is the siting authority for the Wind Project.

To allow the interconnection of WRE's Wind Project to the FCRTS, BPA will construct and operate a new 230-kilovolt (kV) substation and associated facilities that will connect the Wind Project to BPA's existing North Bonneville-Midway 230-kV transmission line, which passes through the southern portion of the Wind Project site.[1] These interconnection facilities will be located entirely within the boundaries of the Wind Project site. BPA also will execute a Large Generation Interconnection Agreement (LGIA) with WRE to provide interconnection services for the Wind Project.

ADDRESSES: This Record of Decision will be available to all interested parties and affected persons and agencies and is being sent to all stakeholders who requested a copy. Copies of the Whistling Ridge Energy Project Draft and Final EISs, the Supplement Analysis that has been prepared, and additional copies of this document can be obtained from BPA's Public Information Center, P.O. Box 3621, Portland, Oregon, 97208–3621. Copies of these documents may also be obtained by calling BPA's nationwide toll-free request line at 1–800–622–4520, or by accessing BPA's Project Web site at *www.bpa.gov/go/whistling.*

FOR FURTHER INFORMATION CONTACT: Amy Gardner, Transmission Project Manager, Bonneville Power Administration—TEP–TPP–1, P.O. Box 61409, Vancouver, WA 98666–1409; toll-free telephone number 1–800–622–4519; or email *amgardner@bpa.gov* or Katey Grange, Environmental Protection Specialist, Bonneville Power Administration—KEC–4, P.O. Box 3621, Portland, Oregon, 97208–3621; toll-free telephone number 1–800–622–4519; or email *kcgrange@bpa.gov.*

SUPPLEMENTARY INFORMATION:

Background

BPA and FCRTS Interconnection Requests

BPA is a federal agency that owns and operates the majority of the high-voltage electric transmission system in the Pacific Northwest. This system is known as the FCRTS. BPA has adopted an Open Access Transmission Tariff (tariff) for transmission and interconnection services on the FCRTS, generally consistent with the Federal Energy Regulatory Commission's (FERC) *pro forma* open access tariff.[2]

BPA's tariff establishes processes for accepting requests to interconnect to the FCRTS, conducting interconnection studies and environmental reviews for these requests, and offering LGIAs on a first-come, first served basis in response to the requests. For all requests for interconnection of generating facilities that exceed 20 MW, BPA has adopted processes that are generally consistent with FERC's Order No. 2003, Standardization of Large Generator Interconnection Agreement and Procedures, and Order No. 661, Interconnection for Wind Energy. Orders No. 2003 and 661 provide a uniform process and agreement for studying and offering interconnection to wind generating facilities exceeding 20 MW. In its Order No. 2003 compliance filing, BPA included provisions in its Large Generator Interconnection Procedures (LGIP) that reflect BPA's obligation to complete environmental

[1] This Record of Decision generally uses the term ''Wind Project'' to refer to all aspects of WRE's proposal except for the BPA interconnection facilities, and uses the term ''Project'' in referring to both the Wind Project and the BPA interconnection facilities. In this Record of Decision, ''Interconnection facilities'' may include any network upgrades or transmission provider interconnection facilities that are necessary to support the interconnection of the Wind Project.

[2] Although BPA is not subject to FERC's jurisdiction, BPA follows the open access tariff as a matter of national policy. This course of action ensures that BPA will receive reciprocal and non-discriminatory access to the transmission systems of utilities that are subject to FERC's jurisdiction.

review under the National Environmental Policy Act (NEPA) of a proposed large generation interconnection before deciding whether to offer a LGIA to the party requesting interconnection.

Although BPA accepts requests for interconnection of proposed and existing generating facilities to the FCRTS, BPA does not have siting authority or regulatory jurisdiction over these facilities. That is the purview of appropriate state and local entities, and BPA acknowledges and respects the authority and jurisdiction of these entities on generation facility siting matters.

WRE's Application and EIS Process

In 2009, WRE [3] submitted an Application for Site Certification to Washington EFSEC to construct and operate the Whistling Ridge Energy Project in Skamania County, Washington. EFSEC is a Washington state agency that was created to provide a ''one-stop'' state licensing agency for certain energy facilities in Washington. As such, EFSEC has siting authority over these energy facilities, and parties proposing to construct and operate any such facility must apply to EFSEC for siting review. In addition, energy facilities that exclusively use alternative energy resources (such as wind, solar, geothermal, landfill gas, wave or tidal action, or biomass energy) can ''opt-in'' to the EFSEC review and certification process. In the case of the Wind Project, WRE elected to opt in to the EFSEC process through submittal of its application.[4] WRE's application identified a proposed wind energy facility consisting of up to 50 wind turbines that could each range in size from 1.2 to 2.5 MW, with a total installed capacity of up to approximately 75 MW. The proposal also included an Operations and Maintenance (O&M) facility, an electrical collector substation, underground collector lines and systems, and other ancillary facilities.

In addition to applying to EFSEC for siting of its Wind Project, WRE submitted a request to BPA to interconnect the Wind Project to the FCRTS. BPA processed the request under its LGIP, including conducting interconnection studies and environmental review of the proposed interconnection.

To meet respective obligations under the State Environmental Policy Act (SEPA) and NEPA, Washington EFSEC and BPA decided to conduct a joint environmental review and prepare a joint EIS under SEPA and NEPA for the Wind Project and proposed interconnection. BPA formally initiated the NEPA EIS process by publishing a Notice of Intent to prepare an EIS in the **Federal Register** (74 FR 18213) in April 2009. The Notice of Intent described the proposal and the respective roles of Washington EFSEC and BPA, and explained the environmental process and how to submit scoping comments for the Draft EIS. At the same time, BPA also sent a letter that also provided this information to approximately 250 individuals. During the EIS scoping period, BPA and EFSEC jointly conducted two public informational and EIS scoping meetings in Stevenson, Washington, and Underwood, Washington. BPA also established a Web site (*www.bpa.gov/go/whistling*) with information about the project and the EIS process. Comments received during scoping are described in more detail in Chapter 1 of the Final EIS and in the EIS Scoping Report (August 2009) prepared by EFSEC in consultation with BPA.[5]

In May 2010, BPA and EFSEC issued the Draft EIS for public review and comment. In addition to distributing the Draft EIS to individuals, organizations, and agencies who had previously requested it, BPA posted the Draft EIS at the BPA project Web site and sent letters announcing its availability to potentially interested parties. A Notice of Availability of the Draft EIS also was published in the **Federal Register** (75 FR 30023) on May 28, 2010. BPA and EFSEC initially established a 45-day review and comment period for the Draft EIS, but later extended the comment period for an additional 39 days (for a total 84-day Draft EIS comment period) based on public requests. During the Draft EIS comment period, BPA and EFSEC held two public meetings in Stevenson and Underwood, Washington to help explain the Draft EIS and to accept public comments.

BPA and EFSEC received a total of 608 comment letters on the Draft EIS. From these letters and the two Draft EIS public meetings, BPA and EFSEC identified approximately 2,100 individual comments. After careful consideration of all of these comments, BPA and EFSEC issued the Final EIS for the Project in August 2011. The Final EIS responded to all comments received on the Draft EIS and made necessary corrections and revisions to the EIS text. As with the Draft EIS, BPA distributed the Final EIS to individuals, organizations, and agencies who had previously requested it, posted it at the BPA project Web site, and sent out letters announcing its availability to potentially interested parties. A Notice of Availability of the Final EIS also was published in the **Federal Register** (76 FR 54767) on September 2, 2011.

EFSEC's Adjudicative Proceeding

Concurrent with preparation of the EIS for the Project, EFSEC also held an adjudicative proceeding for WRE's application under Chapter 34.05 of the Revised Code of Washington (RCW) as part of its siting review process for the Wind Project. EFSEC's adjudicatory proceedings are a formal hearing process similar to a courtroom proceeding, in which the applicant and opponents are allowed the opportunity to present information to support their cases concerning the applicant's proposed project.

As an initial step, EFSEC held a land use hearing for the Wind Project in May 2009. This hearing was held to determine whether the Wind Project was consistent with applicable local and regional land use plans and zoning ordinances. In addition to taking evidence at this hearing, 16 witnesses testified at the hearing concerning the Wind Project. EFSEC also received almost 400 comment letters and evidentiary submissions regarding land use consistency.

EFSEC then conducted its adjudicative proceeding for the Wind Project. After issuing a notice of intent to hold the proceeding, several prehearing conferences were held between July 2009 and December 2010. The formal adjudicative hearing was then held over several days in January 2011. In addition to receiving testimony from 17 parties and 65 witnesses on the adjudication hearing record, EFSEC also received almost 400 written submissions regarding the adjudication.

In October 2011, Washington EFSEC issued its Final Adjudicative Order for the Wind Project that presented its conclusions and findings concerning both the land use hearing and the adjudicative proceeding.[6] Regarding land use consistency, EFSEC noted that the Wind Project site is located in an

[3] WRE is a limited liability company created by SDS Lumber Company.

[4] More information about Washington EFSEC's siting review process for the Whistling Ridge Energy Project is available at the EFSEC Web site at: *http://www.efsec.wa.gov/whistling%20ridge.shtml.*

[5] The EIS Scoping Report is available at the Washington EFSEC Web site at: *http://www.efsec.wa.gov/Whistling%20Ridge/SEPA/WR%20Environmental.shtml.*

[6] EFSEC's Final Adjudicative Order for the Wind Project is available at: *http://www.efsec.wa.gov/Whistling%20Ridge/Adjudication/Orders/WR%20Adj%20Order%20868%2010-7-2011.pdf.*

area within Skamania County that is designated as ''Conservancy'' by the County's Comprehensive Plan and that is unmapped under the County's Zoning Ordinance. After considering several factors, EFSEC determined that the Wind Project is consistent with the Conservancy designation in the Comprehensive Plan, and that the Wind Project is compliant with current zoning in the unmapped zone because wind generation has not been found to be a nuisance by a court.

Regarding the adjudicative proceeding, EFSEC found that need existed for the Wind Project, especially considering RCW 80.50.010's recognition of the ''pressing need for increased energy facilities'' and legislation that required sustainable energy to account for 15 percent of the State's energy supply by 2020. *See* RCW 19.285.010. EFSEC then turned to the issue of whether the Wind Project would create a net benefit after considering its impacts. EFSEC found that the ''most hotly contested'' impact was on the aesthetic and cultural heritage of the area, largely due to the visibility of some of the Wind Project's proposed wind turbines from the Columbia River Gorge National Scenic Area (Scenic Area) as well as other portions of the Columbia River Gorge. EFSEC noted that while the Wind Project is not the first development to occur in the area, as transmission lines, hydroelectric dams, highways, rail lines, and industrial, commercial, and residential development already exist, it nonetheless desires to preserve the views within the Columbia River Gorge as much as possible. EFSEC also noted that while most of the Wind Project's turbines would be only partially visible from only a few viewing locations, two ''strings'' of turbines—string A–1 through A–7 and string C–1 through C–8—would be prominently visible from certain locations within the Columbia River Gorge. Based on these concerns, EFSEC concluded that these two turbine strings should not be approved.

EFSEC's Final Adjudicative Order also addressed concerns regarding the Wind Project's impact on wildlife and wildlife habitat. It recognized that although there was significant wildlife habitat in the general area, the Project site is a managed commercial/industrial timber operation and is not pristine natural land. The Washington Department of Fish and Wildlife (WDFW) acknowledged that with appropriate mitigation measures, the Project would comply with its guidelines. After considering various arguments and evidence, EFSEC determined that with appropriate mitigation measures and monitoring, the project should go forward. Finally, the Final Adjudicative Order addressed several other issues with the Wind Project, such as noise issues, geological challenges, access road issues, cultural and archeological concerns, health and safety planning, and site restoration planning. Based on its evaluation and balancing of all of these considerations, EFSEC concluded that the Wind Project should be approved as proposed with the exception of turbine strings A–1 through A–7 and C–1 through C–8, which should be denied.

EFSEC's Recommendation and the Governor's Approval

In January 2012, Washington EFSEC transmitted its Recommendation Order for the Wind Project and associated relevant materials to the Washington State Governor.[7] Consistent with the Final Adjudicative Order, the Recommendation Order recommended that the Governor approve all aspects of the Wind Project except for turbine strings A–1 through A–7 and C–1 through C–8, which it recommended denying. The Recommendation Order also identified suggested conditions to be imposed if the Governor were to approve the Wind Project. A draft Site Certificate Agreement (SCA) was provided with the Recommendation Order that limited the total maximum number of allowed Wind Project turbines to up to 35 turbines (thereby reflecting the denial of turbine strings A–1 through A–7 and C–1 through C–8) and that included the suggested conditions of approval. However, neither the Recommendation Order nor the draft SCA limited the total installed capacity (up to 75 MW) of the Wind Project.

In March 2012, the Governor of Washington approved the Whistling Ridge Energy Project as recommended by EFSEC in its Recommendation Order. The Governor also executed the Final SCA at that time. In her approval letter to EFSEC, the Governor explained her agreement with EFSEC concerning the denial of the two turbine strings that would be prominently visible from certain locations within the Columbia River Gorge and the balancing of visual impacts with the public interest in approving sites for alternative energy facilities. [8]

Legal Challenge to the Governor's Approval

In April 2012, two environmental groups—Friends of the Columbia Gorge and Save Our Scenic Area (collectively Friends)—filed a petition in Washington state court for judicial review of the Governor's approval and execution of the SCA for the Whistling Ridge Energy Project. Friends had participated in EFSEC's adjudicatory proceedings and had submitted comments during the EIS process for the Wind Project. During both processes, Friends raised various concerns about the Wind Project and urged that approval of the Project be denied.

In its petition for judicial review, Friends primarily challenged the SCA and whether it, and the process leading up to it, complied with various statutory and regulatory requirements. Friends sought invalidation of the SCA and remand to EFSEC for further study and evaluation of the Wind Project. As provided for under RCW 80.50.140, Friends' petition was certified for review directly to the Washington Supreme Court.

In August 2013, the Washington Supreme Court issued its opinion in the Friends' legal challenge to the Wind Project.[9] After reviewing all of Friend's legal claims, the Court found no basis to reverse EFSEC's recommendation or the Governor's approval of the Wind Project. The Court first found that WRE's Application for Site Certification satisfied the requirements of the Washington Administrative Code (WAC) regarding application procedures, more particularly in the areas of assessing nighttime avian collisions, considering wind power guidelines issued by the Washington Department of Fish and Wildlife, and identifying proposed mitigation measures. Next, the Court found that EFSEC had complied with the WAC's fish and wildlife requirements. More specifically, the Court found that EFSEC had not violated the WAC's ''no net loss'' requirement for wildlife habitat and had properly considered the results of wildlife surveys in determining that WAC requirements were met.

The Court then proceeded to reject Friends' remaining claims by finding no fault in how EFSEC had addressed a proposed mitigation parcel; mitigated for aesthetic, heritage, and recreational impacts; made a determination of consistency with Skamania County's zoning code; resolved Washington State

[7] The Recommendation Order (EFSEC Order No. 869) and associated recommendation materials are available at the EFSEC Web site at: *http://www.efsec.wa.gov/whistling%20ridge.shtml.*

[8] The Final SCA and the Governor's approval letter are also available at: *http://www.efsec.wa.gov/whistling%20ridge.shtml.*

[9] The Washington Supreme Court's opinion is available at: *http://www.efsec.wa.gov/Whistling%20Ridge/Appeal/88089-1%20opinion.pdf.*

Forest Practices Act compliance requirements; or treated Forest Practices Act compliance requirements in the SCA.

As a result, the Washington Supreme Court affirmed EFSEC's recommendation and the Governor's approval of the Wind Project.

Alternatives Considered

The Final EIS prepared jointly by Washington EFSEC and BPA considered in detail the Proposed Action and the No Action Alternative. The Final EIS also discussed other alternatives that were considered but eliminated from detailed study in the EIS. The following summarizes the alternatives that were considered in detail in the EIS.

Proposed Action

The Proposed Action involves the State of Washington's approval of WRE's Wind Project and BPA's grant of an interconnection of the Wind Project to the FCRTS. Under the Proposed Action, the Wind Project facilities and the BPA interconnection facilities will be constructed and operated within an approximately 1,150-acre site about 7 miles northwest of the City of White Salmon in Skamania County, Washington. This site is private commercial forestland in an unincorporated area of Skamania County, outside of the Scenic Area. Although the Wind Project site is relatively large, only a small portion of the site will actually be developed with Project facilities. About 56 acres would be permanently developed with these facilities, and another approximately 52 acres would be subject to temporary disturbance primarily from construction activities.[10] As a longstanding commercial forestry site, no old growth forests exist in areas where the Project will be developed.

The Wind Project will have a total installed capacity of up to 75 MW and includes wind turbines, an electrical collector system, other components, and access roads as described below. The BPA interconnection facilities, including a substation and transmission lines, that will be constructed to interconnect the Wind Project are also described below.[11]

Wind Turbines

Up to 35 wind turbines, each ranging from 1.2 to 2.5 MW in generating capacity, will be installed in ''strings'' generally along ridgelines within the Project site.

Turbine towers will be approximately 221 to 265 feet tall at turbine hub height, and up to 426 feet tall including blades. The turbines will all be the same model, although height may vary in response to terrain. The turbine towers will be tapered, hollow tubular structures, approximately 14 feet in diameter at the base and mounted on a concrete foundation with a diameter up to approximately 60 feet. The towers will likely be painted a flat neutral gray or white color. Some of the towers will be furnished with blinking lights visible to aircraft.

In each turbine string, individual turbines will be spaced approximately 350 to 800 feet from the next (or approximately 1.5 to 2.5 times the diameter of the turbine rotor). Specific turbine strings have been identified and approved by the State of Washington through its siting process for the Wind Project. The precise location of each turbine within these limited areas will be determined during EFSEC's ''micro-siting'' process, which is the final technical and engineering process by which WRE will provide EFSEC with the final exact location for each turbine.

The wind turbines will operate at wind speeds from 9 to 56 miles per hour, with a rotor speed range of 10 to 20 rotations per minute. The turbines operate on a variable pitch principal in which the rotor blades rotate to keep them at the optimum angle to maximize output for all wind speeds. At speeds exceeding 56 mph, the blades feather on their axis and the rotor stops turning. Each turbine is equipped with a wind vane that signals wind direction changes to the turbine's electronic controller. The electronic controller operates electric motors (the yaw mechanism), which turn the nacelle and rotor so that each turbine faces into the wind.

As described earlier in this Record of Decision, WRE originally had proposed developing up to 50 wind turbines at the Wind Project site. Accordingly, in order to provide an analysis of the maximum potential development, a maximum 50-turbine wind project was what was described and evaluated in the EIS for the Wind Project. The State of Washington's approval of the Wind Project, however, denied turbine strings A–1 through A–7 and C–1 through C–8, thereby not approving 15 turbine sites out of the original 50 potential sites originally proposed. By authorizing up to 35 turbines, the SCA reflects this denial of these two turbine strings. In all other respects, including the maximum total installed capacity (up to 75 MW), the Wind Project remains the same as described and evaluated in the EIS.

Because the State of Washington's decision to deny turbine strings A–1 through A–7 and C–1 through C–8 occurred after the Final EIS had issued, BPA prepared a Supplement Analysis pursuant to its NEPA Regulations to review whether the resulting authorized turbine limitation constituted a ''substantial change'' in the Proposed Action within the meaning of NEPA.[12] In the Supplement Analysis, BPA determined that the denial of these turbines was not such a change. The Supplement Analysis that BPA has prepared is available at *www.bpa.gov/go/ whistling.*

Electrical Collector System

In addition to wind turbines, the Wind Project includes an electrical collector system to collect and deliver the energy generated at Project turbines to the Project's collector substation. Each turbine will generate energy at approximately 575 volts (V). A 575 V to 34.5–kV transformer will be installed at each turbine, either on a transformer pad adjacent to the turbine or enclosed in the turbine's nacelle, depending on the turbine model. From there, the collected energy will be transmitted to the collector substation via underground 34.5–kV electric cables. Approximately 8.5 miles of underground collector cables will be installed. In areas where environmental constraints, geologic features, or cultural features necessitate, minor above ground placement of collector cables may occur.

All of the underground 34.5–kV electric cables will connect to the Wind Project's collector substation located in the southern portion of the Wind Project site immediately adjacent to the new BPA interconnection substation. The collector substation will include voltage transformers (non-polychlorinated biphenyl oil-filled types) to transform the collected Project energy from 34.5–kV to 230–kV so that it is suitable for delivery to the FCRTS at the new BPA substation. The collector substation will be a graveled, fenced area that would include the voltage transformers, switching equipment, other electrical

[10] The acreages described in this section represent the maximum amounts identified in the Whistling Ridge Energy Project Final EIS; actual acreages for the Project as approved by the State of Washington will be less.

[11] A more detailed discussion of the Proposed Action and the components of the Project is contained in Chapter 2 of the Whistling Ridge Energy Project Final EIS.

[12] U.S. Department of Energy NEPA Regulations, which are applicable to BPA, allow for the preparation of a Supplement Analysis to determine whether a new or supplemental EIS is required for changes to a proposed action covered in an existing EIS, or whether no further NEPA documentation is required. *See* 10 CFR 1021.314.

equipment, and a parking area. A 50-foot cleared area will be maintained around this substation.

Other Wind Project Components

To support the Wind Project, an Operations and Maintenance (O&M) facility will be constructed. The O&M facility will be located on an approximately 5-acre area either adjacent to the Wind Project's collector substation or about one-half mile west of the Wind Project site along West Pit Road. This 5-acre area will be fenced and have a locked gate. The O&M facility will be constructed of sheet metal and be approximately 16 feet tall to the roof peak. The facility will have approximately 3,000 square feet of enclosed space, including office and workshop areas, a kitchen, bathroom, shower, and utility sink. Water for the facility will come from a new on-site well; anticipated water use at this facility is expected to be less than 5,000 gallons per day. Water used by the facility will drain into an on-site septic system. A graveled parking area for employees, visitors, and equipment will be located adjacent to the O&M facility.

In addition, a meteorological tower will be installed to collect and monitor wind speed and direction information as well as temperature, relative humidity and barometric pressure. The location for this tower will be determined during EFSEC's micro-siting process, based on a meteorologist's recommendations for an on-site location that best represents the Wind Project site's meteorological conditions. Meteorological towers are typically un-guyed lattice towers with either three or four corners that taper in size up to the tower's top. These towers are constructed so that the top of the tower—and the meteorological monitoring equipment installed there—is at the same approximate height as the hub of nearby wind turbines (*i.e.,* in the case of the Wind Project, approximately 221 to 262 feet high).

Access Roads

Much of the Wind Project site is accessible through an already existing network of logging roads at the site. Approximately 7.9 miles of existing logging roads at the site will be improved to allow use by Project construction vehicles. These improvements generally will involve road widening and providing a gravel all-weather surface. These roads currently are generally 8 to 12 feet wide, although some are as wide as 20 feet. Most of these roads will be widened to approximately 25 feet (width of finished road), with an additional 5 feet of shoulder on either side.

In portions of the Wind Project site where there are no existing logging roads, approximately 2.4 miles of new permanent access roads will be constructed. To construct these roads, a gravel surface will be installed, compacted to meet all equipment load requirements, and maintained to reduce wind erosion and dust. In addition, some temporary access may be required at some locations. Generally, equipment will be driven across open ground to access these locations, and some minor grading may be required to allow safe access. Any temporary access routes will be re-graded and reseeded as necessary to restore vegetation after construction is completed.

Off of the Wind Project site, access to the site will occur from SR 14 and County roads (Cook-Underwood Road to Willard Road) and then via a new connection to West Pit Road which connects to the Wind Project site. Approximately 2.5 miles of roadway improvements will occur on West Pit Road, which currently varies in width between 20 and 26 feet. To create a drivable surface of 25 feet with 5 feet of clearing on each side, portions of the roadway and some corners will be widened. In addition, an existing culvert that runs along a portion of this road may need some additional lengthening if the roadway is widened over the culvert.

BPA Interconnection Facilities

BPA will construct a new substation (currently referred to as the Little Buck Substation) to interconnect the Wind Project to the FCRTS. The new BPA substation will be located adjacent to the Wind Project's collector substation in the southern portion of the Wind Project site, near the southernmost BPA transmission line corridor that passes through the site. BPA's existing Underwood Tap to Bonneville Powerhouse 1-North Camas 115–kV transmission line runs along the northern side of this corridor, while BPA's existing North Bonneville-Midway 230–kV transmission line runs along the southern side of the corridor.

Overhead lines will connect the Wind Project's collector substation to the BPA substation. The BPA substation will occupy an area of approximately 430 feet by 430 feet or approximately 4.25 acres. This area will be fenced, graded and rocked. Inside the fence, there will be a control house, six 230–kV disconnect switches, three 230–kV power circuit breakers, steel structures and towers, insulators and bus work. The graveled access roads described above will provide access to the BPA substation.

From the BPA substation, two new overhead 230–kV transmission lines will extend south for about 1,000 feet to the interconnection point on BPA's North Bonneville-Midway transmission line. These overhead lines will serve to ''loop in'' the new BPA substation to the North Bonneville-Midway transmission line. Ten transmission structures will be installed to provide this loop-in. Two of these structures will be installed along the North Bonneville-Midway transmission line to create a ''break'' in this line for the loop-in. One of these structures will direct the line north to the new substation and the other will connect it back into the existing alignment. Both structures will be steel lattice dead-end towers that will be installed entirely within the existing transmission line right-of-way. Due to topography, one of these structures will be 50 feet tall and the other will be 85 feet tall.

The other eight transmission structures will be wood pole structures installed in between the BPA substation and the interconnection point to support the two new overhead lines. Each of the two lines will have four structures installed. For each line, the structure closest to the BPA substation will be a three-pole H-frame structure as will the structure closest to the interconnection point. The remaining two structures for each line will be two-pole H-frame structures. The eight structures will be installed in a previously disturbed corridor running from the BPA substation to the interconnection point. The heights of the eight structures will range from 50 to 80 feet, depending on terrain.

In addition, because the loop-in will need to cross underneath the Underwood Tap to Bonneville Powerhouse 1-North Camas transmission line to reach the North Bonneville-Midway transmission line, a new steel lattice structure will be installed along the Underwood Tap to Bonneville Powerhouse 1-North Camas transmission line to raise its conductors such that the loop-in can safely cross underneath. This tower will be approximately 80 feet tall and installed entirely within the existing transmission line right-of-way. This tower and all other BPA interconnection facilities will be located outside of the Scenic Area.

No Action Alternative

The No Action Alternative described in the Final EIS involved the State of Washington denying WRE's Application for Site Certification for the Wind Project and/or BPA not granting

interconnection of the Project to the FCRTS. As a result, the Project and its various components would not be constructed or operated under the No Action Alternative, and the environmental effects associated with Project construction and operation would not occur.[13] Accordingly, under this alternative, the Wind Project's output would not be available to utilities seeking renewable energy resources in order to meet state renewable energy goals, or to meet the region's potential need for additional power in coming years.

While the Project would not be constructed or operated under the No Action Alternative, activities with environmental effects would still continue to occur on the Wind Project site. This site has been in commercial forestry use for the last century, during which the site has been logged over a series of approximately 50-year logging rotations. It is reasonable to expect that SDS Lumber and others will continue to use the site for commercial forestry production—which would include regular tree clearing, harvesting, replanting, and development of additional logging roads as necessary—for the foreseeable future if the Project is not built.

On balance and overall, however, the development of a wind generation facility at the Project site likely will result in greater local environmental impacts than would occur from continued periodic commercial forestry production under the No Action Alternative. The No Action Alternative thus is the environmentally preferable alternative.

Public Comments Received Since Issuance of the Final EIS

Following issuance of the Final EIS, BPA received comments concerning the Project and EIS from various parties. These comments can be viewed on-line at: *www.bpa.gov/go/whistling.* BPA has reviewed and considered all of these comments in making its decision about interconnecting the Project to the FCRTS.

Although NEPA does not require written responses to comments received on a Final EIS, this section of the Record of Decision summarizes and addresses the comments about the Project and EIS that BPA received after issuing the Whistling Ridge Energy Project Final EIS. Some of the comments that BPA received identify post-Final EIS developments that the commenter believes warrant preparation of a supplemental EIS. These post-Final EIS developments include the State of Washington's decision to deny turbine strings A–1 through A–7 and C–1 through C–8, as well as additional environmental information potentially relevant to the Wind Project. As previously indicated in this Record of Decision, BPA has prepared a Supplement Analysis to address the state's denial of certain turbine strings; this Supplement Analysis also addresses additional environmental information potentially relevant to the Wind Project that has been raised by commenters, as well as other additional information and circumstances that BPA has become aware of. For comments that identified post-Final EIS developments, a summary response to each of these comments is provided here, with a more detailed consideration and evaluation of the post-Final EIS developments and whether or not they warrant preparation of a supplemental EIS contained in the Supplement Analysis that BPA has prepared. As previously indicated, the Supplement Analysis is available at *www.bpa.gov/go/whistling.*

Comments were received from the following parties after the release of the Final EIS:

- U.S. Environmental Protection Agency (EPA)
- Skamania County Noxious Weed Control Board
- Confederated Tribes and Bands of the Yakama Nation (Yakama Nation)
- Seattle Audubon
- Friends of the Columbia Gorge (Friends)

EPA's letter stated that the Final EIS was responsive to and addressed the comments that they had submitted on the Draft EIS. The EPA expressed appreciation for additional clarifying environmental resource information provided in the Final EIS, other EIS changes in response to public comments, and BPA's commitment to continue to work with Tribes, state agencies, and other Federal agencies. BPA appreciates the EPA's feedback in these areas.

The Skamania County Noxious Weed Control Board sent an email to BPA that provided updated contact information and a corrected Web site link. BPA has revised its contact list for the Project to include the updated contact information, and acknowledges that the correct Board Web site link is *http://www.skamaniacounty.org/noxious-weeds/.*

The Yakama Nation's letter raised three main issues. BPA responded to these issues in an October 2011 letter to the Yakama Nation; the following summarizes the issues raised and BPA's responses. First, the Yakama Nation raised concerns about potential impacts to an archaeological object found in May 2011 on Chemawa Hill within the Wind Project site that was not identified in the Final EIS. Although not specifically identified in the Final EIS, the Final EIS addressed the cultural significance of Chemawa Hill and BPA acknowledges and respects that cultural significance. Additionally, the State of Washington's approval of the Wind Project did not approve the turbine strings that would have been located on Chemawa Hill, thereby eliminating the potential for impacts to any cultural resources at Chemawa Hill. Furthermore, WRE has committed to continued collaboration with the Yakama Nation regarding construction activities in potential culturally sensitive areas.

Second, the Yakama Nation's letter reminded BPA of a tribal resolution specifying that only the Yakama Nation Cultural Resource Program is authorized to represent the Yakama Nation in discussions concerning placement of Wind Project turbines in culturally sensitive areas. BPA acknowledges and respects this tribal resolution. Accordingly, although BPA is not involved in the turbine siting, in carrying out its interconnection actions, BPA has and will continue to consult with the Yakama Nation Cultural Resource Program as the designated representative for the Tribe with respect to the Project.

Third, the Yakama Nation's letter stated views on the scope of BPA's review under NEPA and the National Historic Preservation Act (NHPA) for the Project. While BPA respects the Yakama Nation's views, BPA believes the Final EIS properly identifies the scope of BPA's action for the Whistling Ridge Energy Project and that BPA has appropriately considered its action under NEPA and the NHPA, as well as its federal trust responsibilities. BPA also notes that it fully participated in the preparation of the joint NEPA/SEPA EIS that included analysis of the environmental impacts of the entire

[13] At this point in time, the conclusion that the Wind Project would not be constructed and operated if BPA were to deny interconnection may no longer be true, given that the State of Washington has approved the Wind Project and granted a SCA to WRE. This state approval allows WRE to build its Wind Project regardless of BPA's action on the interconnection request. Thus, it is conceivable that even if BPA denied interconnection, WRE could still build its Wind Project and seek interconnection of the Wind Project to the transmission lines of another transmission provider, such as Klickitat or Skamania PUD. Nonetheless, for the purposes of this Record of Decision and the NEPA analysis, BPA continues to presume that the Wind Project would not be constructed and operated under the No Action Alternative, as is stated in the Final EIS.

Project. Accordingly, in making a decision to allow interconnection of the Wind Project to the FCRTS, BPA considered all of the environmental information about the Project that is contained in the Final EIS.

The letter from the Seattle Audubon on behalf of itself and other groups requested that BPA and the U.S. Fish and Wildlife Service (FWS) reinitiate Section 7 consultation under the Endangered Species Act (ESA) for the Project. In its letter, Seattle Audubon stated that reinitiation of consultation was needed because conclusions made by the FWS in its July 2010 concurrence letter about the Project's effect on northern spotted owl (NSO) appeared to be based on inaccurate information, the FWS failed to evaluate key NSO information, and the FWS's June 2011 Revised Recovery Plan for the NSO needed to be evaluated.

BPA responded in a November 2011 letter in which BPA explained the standards for reinitiating consultation and found that any misstatements or possible omissions were not substantial enough to justify reinitiation of consultation, and that it was unlikely that further consideration of any corrections or omissions would change the outcome of the FWS's final determination. In a December 2011 letter, the FWS also responded to Seattle Audubon by agreeing with BPA and concluding that, based on a review of the additional information provided by Seattle Audubon as well as the Revised Recovery Plan, they were not recommending reinitiation of Section 7 consultation for the Project. In February 2012, the FWS sent BPA a letter under Section 7(a)(2) of the ESA to review and address potentially inaccurate information and possible omissions that had been identified. The FWS concluded its letter by reaffirming the determination made in its July 2010 concurrence letter that the Project is not likely to adversely affect the NSO. Additional information concerning Section 7 consultation and coordination activities for the Project after issuance of the Final EIS is provided in the Supplemental Analysis that has been prepared for the EIS.

Finally, BPA received several letters from Friends after issuance of the Final EIS that raised a variety of issues about BPA's proposed interconnection of the Wind Project and the EIS. To begin with, Friends urged BPA to deny WRE's interconnection request because Friends believes WRE has not sufficiently defined the details of the Wind Project, as approved by the State of Washington, and thus has not satisfied the BPA's information requirements for interconnections. BPA notes that it considers the information it received from WRE as part of the initial interconnection request by WRE as sufficient and at an appropriate level of detail to assess the impacts of the interconnection and complete the study phase of the interconnection process. In addition, the decision by the State of Washington to not approve certain turbines strings did not materially alter the sufficiency of this information for the purposes of interconnection studies, given that the Wind Project's maximum total installed capacity did not change, and neither did the plan of service for interconnecting the Wind Project to the FCRTS. The information requirements cited by Friends describe typical information that BPA requires, to the extent that it is applicable and necessary, at various points in the interconnection process. Consistent with BPA's normal process, BPA will obtain the more detailed technical information about Wind Project components relevant to its interconnection requirements as it refines the technical design for the BPA interconnection facilities, but it is fully expected that these refinements will not alter the basic plan of service that has already been developed. Accordingly, BPA has sufficient certainty about the Wind Project and its details to grant WRE's interconnection request.

Friends also urged BPA to not act on WRE's interconnection request until BPA updates a 2008 system impact study with Wind Project details and changes in system conditions since the study was completed. To clarify, BPA performed the 2008 system impact study in response to requests for transmission service, not a request for interconnection. Transmission service requests are handled separately and independently from interconnection requests such as the one being granted as a result of this ROD. Moreover, the 2008 system impact study was performed for transmission service requests that were effectively withdrawn from consideration soon after the 2008 study was completed. When WRE submits a transmission service request, BPA will conduct a new system impact study specific to whatever that request entails. The results of that study are not necessary for making a decision concerning the requested interconnection, and BPA believes it has a sufficient understanding at this time of potential system impacts from interconnecting the Wind Project. In addition, in recent years BPA has built new transmission facilities and made other infrastructure improvements that have helped address previously identified transmission constraints in this portion of BPA's transmission system.

Friends also believes that BPA should not act on WRE's interconnection request until WRE signs the Final SCA for the Wind Project that the Washington Governor has already signed, to ensure acceptance of the Final SCA's term and conditions by WRE. BPA notes that WRE signed the Final SCA in November 2013. Accordingly, the terms and conditions in the Final SCA, including those that serve as environmental mitigation measures, are fully binding on WRE.

A final grounds urged by Friends for denying WRE's interconnection request is that the Wind Project, as approved by the State of Washington, is not economically viable based on statements from WRE during the state's siting review process. BPA contacted WRE about this issue, and WRE recently provided BPA with a letter addressing it. In its letter, WRE affirms that the Wind Project continues to be an economically viable project for a variety of reasons. The letter points to Oregon and Washington state requirements for increasing use of renewable energy resources in utility portfolios in coming years, other state as well as federal proposals that likely would result in increased pressure to shift from fossil fuel energy sources to renewable energy, and the potential for increased demand from California for renewable energy. The letter notes that demand for renewables occurs in periodic waves, and these factors are expected to significantly increase renewable demand in coming years. WRE also attached a 2012 Declaration in Washington state court made by Jason Spadaro, President of WRE, that further elaborates on the reasons why the Wind Project is economically viable and affirms that WRE is committed to the Wind Project. This information from WRE sufficiently addresses the economic viability issue raised by Friends.

Regarding the EIS for the Project, Friends asserted in its letters that BPA should prepare a supplemental EIS for a variety of reasons. To begin with, Friends stated a supplemental EIS is necessary to address the limitation on the maximum number of wind turbines resulting from the State of Washington's approval of the Wind Project. As previously discussed in this Record of Decision, BPA reviewed this limitation through the Supplement Analysis it has prepared. In the Supplement Analysis, BPA determined that the turbine limitation did not constitute a

''substantial change'' in the Proposed Action within the meaning of NEPA, and that preparation of a supplemental EIS therefore was not required.

Another reason to supplement the EIS stated by Friends is that Friends believes the State of Washington's approval requires BPA to reexamine its need for action identified in the Final EIS, as well as the identified BPA purposes. As discussed in the EIS, BPA's need for action is a need to decide whether or not to grant the requested interconnection of the Wind Project to the FCRTS. This need has not changed. Furthermore, the identified BPA purposes remain the same for the state-approved Wind Project. These purposes are considered in detail below in the ''BPA's Rationale for Decision'' section of this Record of Decision.

Another reason stated by Friends is that increases in regional wind energy since the Final EIS was completed have affected BPA's need for action identified in the Final EIS, as well as the identified BPA purposes. As with the State of Washington's decision to limit the maximum number of turbines, the increase in regional wind energy has not changed the BPA need for action or its identified purposes. Consideration of the purposes in light of increased regional wind energy is provided in the ''BPA's Rationale for Decision'' section of this Record of Decision.

Another reason stated by Friends is that the summary in the Final EIS of the Applicant-identified needs for the Wind Project requires reevaluation for several reasons. To clarify, these Applicant-identified needs are not BPA's need. Nonetheless, the description of regional renewable energy needs—and more importantly for BPA's decision, project transmission needs—remains reasonably accurate today and helps provide useful context for why WRE has proposed its Wind Project. This includes the description of the Northwest Power and Conservation Council's draft Sixth Northwest Power Plan (Power Plan), which was subsequently finalized. BPA has reviewed the final Power Plan and finds that portions of the draft Power Plan that are summarized in the Final EIS remained substantially similar in the final version of the Power Plan.

Another reason stated by Friends is that BPA and EFSEC need to review several aspects of the Project under NEPA and SEPA that Friends believes are unresolved or undecided. Friends states that these aspects include technical details, mitigation measures, and construction and operational plans that are yet to be resolved and approved. Current information about the Project is sufficient to analyze its environmental impacts and meet the requirements of NEPA. If there is a change in the Project or its potential impacts at some point in the future as a result of further Project refinement, BPA would conduct appropriate additional NEPA review at that time depending on the nature and scope of any change.

Another reason stated by Friends is that the Final EIS failed to adequately evaluate wildlife impacts in the areas of quantification of bird and bat mortality from blade strikes, evaluation of the relative abundance of sensitive-status species, inclusion of critical info on impacts to bats, and disclosure of mitigation measures for wildlife impacts. The Final EIS provides sufficient consideration and analyses of these areas to meet the requirements of NEPA.

Another reason stated by Friends is that the EIS should address the FWS's June 2011 Revised Recovery Plan for the NSO. As discussed above, BPA and the FWS have determined that reinitiation of Section 7(2)(a) consultation is not needed as a result of the Revised Recovery Plan. In addition, BPA has reviewed the Revised Recovery Plan, and any additional information concerning NSO provided by the Plan does not alter the conclusions made in the final EIS about potential impacts to NSO. Correspondingly, no additional analysis concerning the Revised Recovery Plan is needed in the EIS.

Another reason stated by Friends is that additional EIS analysis of impacts to bald and golden eagles is needed to comply with the FWS's ''Land-Based Wind Energy Guidelines'' issued in 2012 and ''Eagle Conservation Plan Guidance'' issued in 2013, both of which have been reviewed by BPA. The surveys that were conducted for the Wind Project generally comport with the FWS guidance in these documents and, regardless, are sufficient for the purposes of NEPA analysis. Furthermore, BPA notes that both of these documents are intended to be guidelines to be followed only voluntarily; in other words, they are not required or mandatory. Just as importantly, both of these FWS documents provide that projects for which planning is already underway should comply with the recommendations going forward rather than conducting restudies to apply the guidance retroactively. Accordingly, additional EIS restudy is not required to address these two guidance documents.

Another reason stated by Friends is that EIS review is needed of a 2012 report entitled ''Synthesis of Wind Energy Development and Potential Impacts on Wildlife in the Pacific Northwest, Oregon and Washington'' by the U.S. Department of Agriculture (USDA). BPA has reviewed this report, and the analysis of wildlife impacts contained in the Final EIS remains sufficient under NEPA in light of the report. In addition, additional information provided by the report does not alter the conclusions made in the Final EIS about potential wildlife impacts. Thus, preparation of a supplemental EIS on the basis of the USDA report is not necessary.

Another reason stated by Friends is that the Final EIS fails to consider the effects of noise impacts on wildlife. BPA notes first that the Final EIS does consider disturbance of wildlife by Project construction, including through changes to the noise environment. In addition, BPA has reviewed information sources cited by Friends concerning potential operational noise impacts to wildlife and has determined that this information does not significantly alter the conclusions made in the Final EIS concerning potential operation impacts to wildlife. As discussed in the Supplement Analysis that has been prepared, the project's operational noise would occur in a landscape of managed timber land that is, and will continue to be, fragmented with ongoing disturbance. Any operational noise impacts to wildlife thus would fall within the bandwidth of overall degradation of wildlife habitat already discussed in the Final EIS.

Another reason stated by Friends is that EIS review is needed of a bibliography of noise impacts to wildlife that was published by the National Park Service in 2011. BPA has reviewed the sources included in this bibliography that are relevant to wind projects and has determined that the source reports do not alter the conclusions made in the Final EIS about potential wildlife impacts.

Another reason stated by Friends is that EIS review is needed to address recent studies on the effects of noise from operating wind turbines on human health and the human environment. BPA has reviewed these studies and determined that the analysis of potential impacts to human health from wind turbine noise that is contained in the Final EIS remains sufficient under NEPA. The studies cited by Friends largely are consistent with the discussion of potential noise impacts to humans from wind turbine operations that is contained in Section 3.7.2 of the EIS, and do not alter the conclusions made in the Final EIS about these impacts. BPA also notes EFSEC's findings that construction and operation

of the Wind Project will comply with all applicable noise regulations in the State of Washington. Accordingly, a supplemental EIS is not needed to address these studies.

Another reason stated by Friends is that the EIS needs to address information from EFSEC's Final Adjudicative Order and Recommendation Order concerning the significance of impacts to scenic resources from the Wind Project. EFSEC provided a letter in December 2011 to Friends that largely addressed this issue. EFSEC's letter explained that EFSEC did not perform or use any new analysis or data for scenic impacts from what was considered in the Final EIS. EFSEC further explained that it simply duplicated the review process utilized in the EIS in making its determination concerning the significance of viewscape change for the Wind Project from various viewing sites. In so doing, EFSEC emphasized that it did not find any serious flaws in the Final EIS's analysis of scenic impacts, did not discredit any conclusions made in the EIS about these impacts, and found nothing that would violate state law. Accordingly, while EFSEC members may have developed their own opinion on scenic impacts, they did not alter or undermine the analysis of scenic impacts contained in the Final EIS. BPA concurs with EFSEC's response and believes that the Final EIS does not need to be supplemented on the basis of this issue.

Another reason stated by Friends is that the EIS understates the Project's likely scenic impacts. First, as Friends notes, the Final EIS acknowledges the scenic impacts of the Project. While Friends may disagree about the degree of those impacts, the Final EIS provides a reasonable analysis of potential scenic impacts and draws reasonable conclusions about their significance. Second, the denial by the State of Washington of turbine strings A–1 through A–7 and C–1 through C–8 served to substantially reduce the overall scenic impact of the Wind Project from various viewing points in the Columbia River Gorge, include those within the Scenic Area. The denial of these turbines thus further mitigated scenic impacts to ensure that potential levels of visual impacts would not be higher than low to moderate at any of the viewpoints examined. As a result, the conclusions in the FEIS concerning the level of potential visual impacts at various viewpoints remains relatively accurate, and the Final EIS does not need to be supplemented on the basis of this issue.

Another reason stated by Friends is that the EIS needs to address the May 2011 discovery of an archaeological object on Chemawa Hill. As is discussed above, the Final EIS adequately addresses the cultural significance of Chemawa Hill and impacts to cultural resources at this location are being avoided.

Another reason stated by Friends is that the cumulative impacts analysis in the Final EIS is outdated and inadequate, because additional wind energy resources and other development have been completed or are proposed within the cumulative impact study area since the Final EIS was issued. BPA's Supplement Analysis discusses this additional development and concludes that it either has no cumulative impacts beyond those already described in the Final EIS or has resulted in only negligible increases in cumulative impacts within the scope of those already discussed in the Final EIS. For these reasons, a supplemental EIS to further consider cumulative impacts is not necessary.

In its letters, Friends also states that it believes BPA must obtain permits under the Bald and Golden Eagle Protection Act (BGEPA) and the Migratory Bird Treaty Act (MBTA) in order to approve the interconnection. As discussed in the Final EIS, the Wind Project would not involve intentional acts in wanton disregard of bald or golden eagles under the BGEPA and would not be expected to result in a take or killing of migratory bird species within the meaning of the MBTA. Moreover, the Final SCA between the State of Washington and WRE makes WRE responsible for completing a plan to comply with requirements of these statutes. It is BPA's understanding that if a permit is required for the Wind Project under either statute, that will be the responsibility of WRE, as the owner and operator of the Wind Project, to obtain. Accordingly, it is not necessary for BPA to seek permits under the BGEPA and MBTA under these circumstances.

In addition, Friends asks BPA to consider evaluating recent information concerning an enforcement action under the MBTA related to wind projects in Wyoming and deaths of golden eagles at the Wild Horse Wind Project in central Washington State. BPA has reviewed available information concerning the Wyoming wind project enforcement action, including the U.S. Department of Justice (DOJ) press release regarding the enforcement. The Final EIS sufficiently addresses and analyzes the potential for impacts to migratory birds and eagles in a manner consistent with the recommendations of the FWS and DOJ concerning pre-construction evaluations. In addition, as discussed in the Final EIS and pursuant to the Final SCA, pre-construction raptor nest surveys will be conducted during the nesting season immediately prior to beginning site preparation, and a Technical Advisory Committee of agency professionals and other bird experts will be convened to assist with developing measures to ensure that risks to migratory birds and eagles are minimized as much as possible. Furthermore, as discussed above, the Final SCA requires that a golden eagle and bald eagle plan be completed before the Wind Project begins operations. The Final SCA also requires that this plan be completed in consultation with the FWS and WDFW, which BPA expects will ensure that these agencies are in agreement with the approach being taken. Accordingly, the information concerning the Wyoming enforcement action does not significantly change the analysis or conclusions concerning migratory birds and eagles in the Final EIS.

BPA also has reviewed available information concerning the golden eagle deaths at the Wild Horse Wind Project. The analysis of potential impacts to golden eagles completed for the Whistling Ridge Energy Project Final EIS remains sufficiently accurate even in light of this information. Furthermore, the consultation that will occur with the FWS for the golden eagle and bald eagle plan for the Wind Project will ensure that all impacts to golden eagles are appropriately considered and addressed. As part of that consultation, it is expected that WRE and the FWS will coordinate as necessary concerning whether an eagle take permit is needed for the Wind Project.

Finally, Friends has provided BPA with a petition from citizens opposed to the Wind Project. On behalf of these citizens, Friends' letter transmitting the petition urges BPA to deny the requested interconnection for a variety of reasons, largely similar to those expressed in other letters from Friends and addressed above. BPA respects the viewpoints and opinions expressed in the petition and understands that there are some who are opposed to the Wind Project given its location. BPA has included consideration of the petition in making its decision (see ''BPA's Rationale for Decision'' section below).

BPA'S Rationale for Decision

In making its decision to implement its part of the Proposed Action, BPA has considered and balanced a variety of relevant factors. BPA considered how

well each alternative under consideration—the Proposed Action alternative and the No Action alternative—would fit with BPA's statutory missions and relevant policies and procedures. BPA also considered the environmental impacts described in the Final EIS. In addition, BPA considered new environmental information and other circumstances, including the State of Washington's denial of certain turbine strings, addressed in the Supplement Analysis. BPA also considered public comments received throughout the NEPA process for the Project, including those received on the Draft and Final EISs. Another consideration was the extent to which each alternative under consideration would meet the following BPA purposes (*i.e.*, objectives) identified in the Final EIS:

- Maintain the electrical stability and reliability of the FCRTS;
- Continue to meet BPA's statutory and contractual obligations;
- Act consistently with BPA's environmental and social responsibilities; and
- Provide for cost and administrative efficiency.

Finally, BPA took into consideration the State of Washington's siting authority and regulatory jurisdiction over the Wind Project, the information from the state's lengthy and extremely thorough siting process for the Wind Project, and the unanimous Washington Supreme Court decision upholding the Governor's approval of the Wind Project. The entire record of EFSEC's administrative proceedings for the Wind Project—including the EIS process and the adjudication—was certified to the Washington Supreme Court. BPA has considered that record in making its decision.

After considering and balancing all of these factors, BPA has decided to grant the requested interconnection and offer an LGIA to WRE. Approving this interconnection is consistent with the policies embodied in BPA's transmission tariff, which is based on allowing open access to transmission and interconnection services on the FCRTS. BPA has adopted its tariff to be consistent with national policy promulgated by FERC that directs transmission providers to provide open access to their transmission systems. Because WRE has complied with the established tariff procedures for proposed interconnections, BPA believes it is appropriate under its tariff to grant WRE's interconnection request.

Granting the requested interconnection will not interfere with or otherwise affect BPA's ability to maintain the stability and reliability of its transmission system. The physical interconnection of the Wind Project to the FCRTS will be designed and constructed to meet applicable reliability criteria and standards intended to maintain system stability, and the LGIA will include operating parameters and other provisions to ensure that operation of the Wind Project will not impair system reliability. Furthermore, BPA's implementation of its part of the Proposed Action will not interfere with BPA's ability to meet its statutory and contractual obligations. Although BPA has no express statutory or contractual obligation to construct the new substation that will be built for this interconnection, constructing the substation is consistent with BPA's statutory directive to make additions to the transmission system, as appropriate, in order to integrate and transmit electric power and maintain system stability and reliability.

BPA has adopted measures to ensure that granting the requested interconnection will not contribute to issues caused by generation oversupply conditions on BPA's transmission system at certain times of the year. To address these issues, BPA developed an Oversupply Management Protocol (Protocol) as an amendment to its transmission tariff. This Protocol provides a set of policies and operational practices that allow for the management of oversupply events while complying with environmental responsibilities as well as satisfying statutory and contractual obligations and maintaining reliability and stability. These Protocol goals align with BPA's purposes identified in the Final EIS. The Protocol was approved by FERC late last year, which has provided certainty with respect to BPA's approach to the management of oversupply events. Because the Wind Project will be subject to the Protocol through its LGIA, the Wind Project will not exacerbate operational and reliability issues associated with future oversupply events that may occur.

Granting the requested interconnection will serve to integrate a new renewable generating resource. This will be consistent with certain FERC interconnection policies intended to help facilitate the integration of new renewable resources, which in turn are consistent with the Obama Administration's policies and action plan to address climate change by increasing reliance on renewable resources to reduce greenhouse gas emissions.

In planning and designing the Wind Project, it is clear that WRE attempted to minimize potential environmental impacts where possible. In addition, EFSEC and BPA have identified numerous mitigation measures in the Final EIS to further reduce, avoid, or compensate for Project impacts. These measures are also included as conditions in the Final SCA for the Wind Project that EFSEC has found will ensure that the Project will produce minimal adverse environmental impacts. Nonetheless, it is acknowledged that the Project will create a number of environmental impacts even with the implementation of mitigation. These impacts, which are fully disclosed in the Final EIS, primarily include disturbance of soils, conversion of habitat, direct mortality of birds, increases in noise and traffic in the vicinity, and—characterized by EFSEC as the ''most hotly contested''—impacts to scenic resources.

BPA understands the sensitivities of many individuals to these impacts, and recognizes that the prospect of these impacts has led certain individuals—as well as some groups such as Friends—to oppose the Wind Project. BPA also appreciates that the Columbia River Gorge is a special place to many people and is one of the landscapes that makes the Pacific Northwest great. However, with the extensive mitigation measures that have been identified and SCA conditions that have been imposed, BPA believes that the Project will be implemented in an environmentally responsible manner. In addition, in making a decision to grant the requested interconnection, BPA believes it has fully carried out its environmental responsibilities under NEPA, the ESA, and other applicable environmental laws.

Concerning impacts to scenic resources, BPA recognizes that the State of Washington's decision to deny turbine strings A–1 through A–7 and C–1 through C–8 served to mitigate the most significant visual impacts of the Wind Project. Accordingly, these impacts have been substantially reduced from those depicted in the visual simulations included in the Final EIS. BPA respects and appreciates the sentiments expressed by Governor Gregoire in her March 2012 approval letter concerning the evaluation of visual impacts that led to the state's decision to not approve the most visually prominent turbines associated with the Wind Project. BPA agrees that the Columbia River Gorge is a unique and beautiful landscape, and that proposed development within view of the Columbia River Gorge—even if

outside of the Scenic Area as is the case with the Wind Project—warrants thoughtful and careful consideration of its potential to impact scenic resources. BPA believes that such consideration has been amply demonstrated in this case, and that definite and effective action has been taken by the State of Washington to reasonably help protect views as a result of this consideration. Furthermore, BPA agrees with the Governor that the state-approved Wind Project strikes an effective balance between minimizing visual impacts while still carrying out the public interest of the State of Washington in approving sites for alternative energy facilities.

The total cost of the BPA interconnection facilities is estimated at $12.6 million. All costs associated with these facilities will be advance funded by WRE and administration of contracts with WRE will follow normal, established procedures. In accordance with BPA's open access transmission tariff, WRE will be eligible to receive transmission credits for any portion of the interconnection facilities that constitute network upgrades. BPA believes that this approach provides for both cost and administrative efficiencies.

Finally, in deciding to grant the requested interconnection, BPA believes it is being appropriately respectful of state authorities concerning the siting of non-federal generation projects. As has been mentioned previously in this Record of Decision, BPA does not have siting authority or regulatory jurisdiction over these facilities. That is the purview of appropriate state and local entities, in this case Washington EFSEC and, ultimately, the Washington Governor. BPA notes that the siting process conducted by the State of Washington for the Wind Project was both lengthy and extremely thorough, and addressed many of the same environmental issues also considered in the Final EIS for the Project. BPA also notes that the State of Washington decided to approve construction and operation of the Wind Project on the basis of the siting process and Final EIS. Finally, BPA notes that this approval was upheld by the Washington Supreme Court in a legal challenge of the siting process brought against the State of Washington. In light of this, granting the requested interconnection provides the appropriate comity to the State of Washington's legally executed overall authorities concerning the siting of the Wind Project.

Mitigation

All the mitigation measures described in the Draft EIS and updated in the Final EIS have been adopted. A complete list of these measures can be found in the Mitigation Action Plan. WRE will be responsible for executing mitigation measures identified for the Wind Project, while BPA will be responsible for executing the mitigation measures associated with the BPA interconnection facilities.

In addition to identifying mitigation measures in the EIS, the State of Washington has included numerous conditions in the Final SCA for the Wind Project that are intended to ensure that the Wind Project is built and operated in a way that preserves and protects the quality of the environment. As environmental mitigation, Washington EFSEC has found that these conditions will ensure that the Project will produce minimal adverse environmental effects. WRE will be required to comply with these Final SCA conditions. As discussed above, the Final SCA is available at *http://www.efsec.wa.gov/whistling%20ridge.shtml.*

Issued in Portland, Oregon.

Dated: June 24, 2015.

Elliot E. Mainzer,

Administrator and Chief Executive Officer.

[FR Doc. 2015–17087 Filed 7–13–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–413]

Application to Export Electric Energy; Elan Energy Services, LLC

AGENCY: Office of Electricity Delivery and Energy Reliability, DOE.

ACTION: Notice of application.

SUMMARY: Elan Energy Services, LLC (Applicant) has applied for authority to transmit electric energy from the United States to Mexico pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before August 13, 2015.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed to: Office of Electricity Delivery and Energy Reliability, Mail Code: OE–20, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0350. Because of delays in handling conventional mail, it is recommended that documents be transmitted by overnight mail, by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to 202–586–8008.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated by the Department of Energy (DOE) pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b), 7172(f)) and require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On June 5, 2015, DOE received an application from the Applicant for authority to transmit electric energy from the United States to Mexico as a power marketer for a five-year term using existing international transmission facilities. The Applicant will register as a Power Marketer with the Texas Public Utilities Commission (PUCT.) The Applicant will also register as a Purchasing Selling Entity with the Texas Reliability Entity (TRE) and the North American Electric Reliability Corporation (NERC).

In its application, the Applicant states that it does not own or control any electric generation or transmission facilities, and it does not have a franchised service area. The electric energy that the Applicant proposes to export to Mexico would be surplus energy purchased from third parties such as electric utilities and Federal power marketing agencies pursuant to voluntary agreements. The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedures (18 CFR 385.211). Any person desiring to become a party to these proceedings should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214). Five copies of such comments, protests, or motions to intervene should be sent to the address provided above on or before the date listed above.

Comments and other filings concerning the Applicant's application to export electric energy to Mexico should be clearly marked with OE Docket No. EA–413. An additional copy is to be provided directly to Andrew B.

Young, Mayer Brown LLP, 1999 K Street NW., Washington, DC 20006.

A final decision will be made on this application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after a determination is made by DOE that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above, by accessing the program Web site at *http://energy.gov/node/11845,* or by emailing Angela Troy at *Angela.Troy@hq.doe.gov.*

Issued in Washington, DC, on July 7, 2015.

Christopher Lawrence,

Electricity Policy Analyst, Office of Electricity Delivery and Energy Reliability.

[FR Doc. 2015–17082 Filed 7–13–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2464–000]

Gresham Municipal Utilities; Notice Of Authorization for Continued Project Operation

On June 10, 2013 Gresham Municipal Utilities, licensee for the Weed Dam Hydroelectric Project, filed an Application for a New License pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. The Weed Dam Hydroelectric Project is located on Red River, in Shawano County, Wisconsin.

The license for Project No. 2464 was issued for a period ending June 30, 2015. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2464 is issued to the licensee for a period effective July 1, 2015 through June 30, 2016 or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before June 30, 2016, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that the licensee, Gresham Municipal Utilities, is authorized to continue operation of the Weed Dam Hydroelectric Project, until such time as the Commission acts on its application for a subsequent license.

Dated: July 8, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–17223 Filed 7–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–524–000]

Florida Gas Transmission Company, LLC; Notice of Request Under Blanket Authorization

Take notice that on June 29, 2015, Florida Gas Transmission Company, LLC (FGT), 1300 Main St., Houston, Texas 77002, filed in Docket No. CP15–524–000, a prior notice request pursuant to sections 157.205, 157.208(b)/(c), and 157.211(b) of the Commission's regulations under the Natural Gas Act (NGA). FGT seeks authorization to construct, own and operate a new bi-directional measurement and regulation station and an interconnection with Gulfstream Natural Gas System, LLC, located in Martin County, Florida. FGT proposes to perform these activities under its blanket certificate issued in Docket No. CP82–553–000 [21 FERC ¶ 62,235 (1982)], all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to Stephen Veatch, Senior Director of Certificates, Florida Gas Transmission Company, LLC, 1300 Main St., Houston, Texas, 77002, or by calling (713) 989–2024 (telephone) or (713) 989–1205 (fax) *stephen.veatch@energytransfer.com.*

Any person or the Commission's Staff may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this

project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the ''e-Filing'' link. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: July 8, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–17220 Filed 7–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7320–000]

Erie Boulevard Hydropower, L.P.; Notice of Authorization for Continued Project Operation

On July 1, 2013 Erie Boulevard Hydropower, L.P., licensee for the Chasm Hydroelectric Project, filed an Application for a New License pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. The Chasm Hydroelectric Project is located on Salmon River in Franklin County, New York.

The license for Project No. 7320 was issued for a period ending June 30, 2015. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 7320 is issued to the licensee for a period effective July 1, 2015 through June 30, 2016 or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before June 30, 2016, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that the licensee, Erie Boulevard Hydropower, L.P., is authorized to continue operation of the Chasm Hydroelectric Project, until such time as the Commission acts on its application for a subsequent license.

Dated: July 8, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–17224 Filed 7–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER15–1925–000]

Breckinridge Wind Project, 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 Breckinridge Wind Project, 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 July 28, 2015.

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 5 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 electronic 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: July 8, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–17221 Filed 7–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: July 16, 2015 10 a.m.

PLACE: Room 2C, 888 First Street NE., Washington, DC 20426.

STATUS: OPEN.

MATTERS TO BE CONSIDERED: Agenda.

Note: Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's Web site at *http://www.ferc.gov* using the eLibrary link, or may be examined in the Commission's Public Reference Room.

1018TH—MEETING

[Regular Meeting—July 16, 2015, 10:00 a.m.]

Item No.	Docket No.	Company
	ADMINISTRATIVE	
A–1	AD02–7–000	Customer Matters, Reliability, Security and Market Operations.
A–2	AD02–1–000	Agency Business Matters.
	ELECTRIC	
E–1	RM15–14–000	Revised Critical Infrastructure Protection Reliability Standards.
E–2	ER15–1745–000	Midcontinent Independent System Operator, Inc.
E–3	ER12–2170–000	International Transmission Company.
E–4	ER12–2170–001	International Transmission Company.
E–5	RM15–3–000	Revisions to Public Utility Filing Requirements.
E–6	OA08–53–005	Midwest Independent Transmission System Operator, Inc.
	ER15–133–000	Midcontinent Independent System Operator, Inc.
E–7	ER05–1056–008	Chehalis Power Generating, L.P.
E–8	ER14–2553–001, ER14–2553–002	Southwest Power Pool, Inc.
E–9	ER14–1469–002	PJM Interconnection, L.L.C.
E–10	OMITTED.	
E–11	OMITTED.	
E–12	EC15–138–000	DTE Electric Company and DTE East China, LLC.
E–13	EL15–59–000	Navopache Electric Cooperative, Inc.
E–14	EL15–57–000	GenOn Energy Management, LLC v. ISO New England Inc.
	MISCELLANEOUS	
M–1	RM13–17–002	Communication of Operational Information Between Natural Gas Pipelines and Electric Transmission Operators.
	GAS	
G–1	RP14–380–001	National Fuel Gas Supply Corporation and Empire Pipeline, Inc.
G–2	RM96–1–038	Standards for Business Practices of Interstate Natural Gas Pipelines.
G–3	RP12–498–003	Enable Gas Transmission, LLC formerly CenterPoint.
	RP12–498–004	Energy Gas Transmission Company, LLC.
G–4	RP12–816–001, RP12–816–002	EL Paso Natural Gas Company, L.L.C.
G–5	RP08–426–017, RP12–806–000	EL Paso Natural Gas Company, L.L.C.
G–6	PL15–1–001	Cost Recovery Mechanisms for Modernization of Natural Gas Facilities.
G–7	IS12–236–001	Enbridge Energy, Limited Partnership.
	HYDRO	
H–1	P–14245–001	KC Hydro LLC of New Hampshire.
H–2	P–2197–107	Alcoa Power Generating Inc.
	CERTIFICATES	
C–1	CP13–541–000	Floridian Natural Gas Storage Company, LLC.
C–2	CP15–23–000	Southern Natural Gas Company, L.L.C.

1018TH—MEETING—Continued

[Regular Meeting—July 16, 2015, 10:00 a.m.]

Item No.	Docket No.	Company
C–3	RM12–11–003	Revisions to Auxiliary Installations, Replacement Facilities, and Siting and Maintenance Regulations.

Issued: July 9, 2015.

Kimberly D. Bose,

Secretary.

A free webcast of this event is available through *www.ferc.gov.* Anyone with Internet access who desires to view this event can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the free webcasts. It also offers access to this event via television in the DC area and via phone bridge for a fee. If you have any questions, visit *www.CapitolConnection.org* or contact Danelle Springer or David Reininger at 703–993–3100.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters, but will not be telecast through the Capitol Connection service.

[FR Doc. 2015–17305 Filed 7–10–15; 11:15 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER15–2129–000]

Slate Creek Wind Project, 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 Slate Creek Wind Project, 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 July 28, 2015.

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 5 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 electronic 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: July 8, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–17222 Filed 7–13–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2015–0092; FRL–9930–50–OAR]

Notice of Opportunity To Comment on an Analysis of the Greenhouse Gas Emissions Attributable to Production and Transport of Cotton (Gossypium spp.) Seed Oil for Use in Biofuel Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is inviting comment on its analysis of the greenhouse gas (GHG) emissions attributable to the production and transport of *Gossypium spp.* seed oil (''cottonseed oil'') feedstock for use in making biofuels such as biodiesel, renewable diesel, and jet fuel. This document explains EPA's analysis of the feedstock production and transport-related components of the lifecycle GHG emissions of biofuel made from cottonseed oil, including both direct and indirect agricultural and forestry sector emissions. This notice also describes how EPA may apply this analysis in the future to determine whether biofuels produced from cottonseed oil meet the necessary GHG reductions required for qualification as renewable fuel under the Renewable Fuel Standard program. Based on this analysis, we anticipate that biofuels produced from cottonseed oil could qualify as biomass-based diesel or advanced biofuel if typical fuel production process technologies are used.

DATES: Comments must be received on or before August 13, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2015–0092, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov,* Attention Air and Radiation Docket ID No. EPA–HQ–OAR–2015–0092.
- *Mail:* Air and Radiation Docket, Docket No. EPA–HQ–OAR–2015–0092, Environmental Protection Agency, Mail

code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

• *Hand Delivery:* EPA Docket Center, EPA/DC, EPA WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20460, Attention Air and Radiation Docket, ID No. EPA–HQ–OAR–2015–0092. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2015–0092. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means 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 *www.regulations.gov*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air and Radiation Docket, EPA/DC, EPA WJC 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 Public Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Christopher Ramig, Office of Transportation and Air Quality, Mail Code: 6401A, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., 20460; telephone number: (202) 564–1372; fax number: (202) 564–1177; email address: *ramig.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

This document is organized as follows:

I. Introduction
II. Analysis of GHG Emissions Associated With Use of Cottonseed Oil as a Biofuel Feedstock
A. Feedstock Description, Production, and Distribution
1. Production of Cottonseed Oil-Based Biofuels
2. Cottonseed Oil Production Economics
3. Replacement of Cottonseed Oil in Vegetable Oil Markets
4. Upstream GHG Implications of Cottonseed Oil Use as a Biofuel Feedstock
B. Summary of Agricultural Sector GHG Emissions
C. Fuel Production and Distribution
III. Summary

I. Introduction

As part of changes to the Renewable Fuel Standard (RFS) program regulations published on March 26, 2010 [1] (the ''March 2010 rule''), EPA specified the types of renewable fuels eligible to participate in the RFS program through approved fuel pathways. Table 1 to 40 CFR 80.1426 of the RFS regulations lists three critical components of an approved fuel pathway: (1) Fuel type; (2) feedstock; and (3) production process. Fuel produced pursuant to each specific combination of the three components, or fuel pathway, is designated in Table 1 to 40 CFR 80.1426 as eligible for purposes of the Clean Air Act's (CAA) requirements for greenhouse gas (GHG) reductions to qualify as renewable fuel or one of three subsets of renewable fuel (biomass-based diesel, cellulosic biofuel, or advanced biofuel). EPA may also independently approve additional fuel pathways not currently listed in Table 1 to 40 CFR 80.1426 for participation in the RFS program, or a third-party may petition for EPA to evaluate a new fuel pathway in accordance with 40 CFR 80.1416.

Pursuant to 40 CFR 80.1416, EPA received a petition from the National Cottonseed Products Association (NCPA), requesting that EPA evaluate the lifecycle GHG emissions for biofuels produced using *Gossypium spp.* seed oil (''cottonseed oil''), and that EPA provide a determination of the renewable fuel categories, if any, for which such biofuels may be eligible. EPA's lifecycle analyses are used to assess the overall GHG impacts of a fuel throughout each stage of its production and use. The results of these analyses, considering uncertainty and the weight of available evidence, are used to determine whether a fuel meets the necessary GHG reductions required under the CAA for it to be considered renewable fuel or one of the subsets of renewable fuel. Lifecycle analysis includes an assessment of emissions related to the full fuel lifecycle, including feedstock production, feedstock transportation, fuel production, fuel transportation, fuel distribution, and tailpipe emissions. Per the CAA definition of lifecycle GHG emissions, EPA's lifecycle analyses also include an assessment of significant indirect emissions, such as indirect emissions from land use changes, agricultural sector impacts, and production of co-products from biofuel production.

In this document, we are describing EPA's evaluation of the GHG emissions associated with the feedstock production and feedstock transport stages of the lifecycle analysis of cottonseed oil when it is used to produce a biofuel, including the indirect agricultural and forestry sector impacts. We are seeking public comment on the methodology and results of this evaluation. For reasons described in Section II below, we believe that, as a conservative estimate, it is reasonable to apply the GHG emissions estimates we established in the March 2010 rule for the production and transport of soybean oil to cottonseed oil.

If appropriate, EPA will update its evaluation of the feedstock production and transport phases of the lifecycle analysis for cottonseed oil based on comments received in response to this action. EPA will then use this feedstock production and transport information to evaluate facility-specific petitions, received pursuant to 40 CFR 80.1416, that propose to use cottonseed oil as a feedstock for the production of biofuel. In evaluating such petitions, EPA will consider the GHG emissions associated with the production and transport of cottonseed oil feedstock as described in this document, including the potential

[1] See 75 FR 14670.

indirect impacts. In addition, EPA will determine—based on information in the petition and other relevant information, including the petitioner's energy and mass balance data—the GHG emissions associated with petitioners' biofuel production processes, as well as emissions associated with the transport and use of the finished biofuel. We will then combine our assessments into a full lifecycle GHG analysis and determine whether the fuel produced at an individual facility satisfies CAA renewable fuel GHG reduction requirements.

II. Analysis of GHG Emissions Associated With Use of Cottonseed Oil as a Biofuel Feedstock

EPA has evaluated the production and transport portion of the lifecycle GHG impacts of using cottonseed oil as a biofuel feedstock, based on information provided in the petition and other data gathered by EPA. Based on this evaluation, EPA believes that new agricultural sector modeling is not needed to evaluate this portion of the lifecycle GHG impacts of using cottonseed oil as a biofuel feedstock. As explained below, our analysis makes the conservative assumption that cottonseed oil diverted from the vegetable oil markets for food and industrial use to biofuel production will be replaced with soybean oil rather than result in additional production of cottonseed oil or any other vegetable oil. Therefore, in this analysis, we are applying the same agricultural sector impacts for soybean oil to cottonseed oil on a per-pound-of-feedstock basis. Based on this analysis (described below), we propose to evaluate the agricultural sector GHG emissions impacts of using cottonseed oil in responding to petitions received pursuant to 40 CFR 80.1416 by assuming that GHG emissions are similar to those associated with the use of soybean oil for biofuel production. We invite comment on this proposed approach.

A. Feedstock Description, Production, and Distribution

1. Production of Cottonseed Oil-Based Biofuels

Cottonseed oil is the fourth most produced vegetable oil in the U.S., after soybean oil, corn oil, and canola oil respectively. It is the seventh most consumed vegetable oil in the U.S., behind soybean oil, canola oil, palm oil, corn oil, coconut oil, and olive oil respectively. It accounts for about 2.5–4 percent of U.S. production and about 1.5–2.5 percent of U.S. consumption of vegetable oil.[2] Internationally, cottonseed oil is the sixth most produced and consumed vegetable oil, representing about 3–3.5 percent of global production and consumption.[3] Over the last decade, annual U.S. cottonseed oil production has averaged just under 800 million pounds.[4] If this entire supply were used for biodiesel and/or renewable diesel production, which is highly unlikely for reasons discussed below, it would generate approximately 100 million gallons of fuel. Since U.S. biodiesel and renewable diesel production was approximately 1.5 billion gallons in 2014, the potential contribution of cottonseed oil is relatively small in comparison to the overall biodiesel and renewable diesel market.

Cottonseed oil is preferred for a number of specialty uses by certain producers, including the frying of potato chips and the preservation of smoked shellfish. According to industry experts in government and the private sector consulted by EPA, many producers strongly prefer cottonseed oil over its alternatives, believing that the type of oil used for these products has a very significant impact on the quality of the product itself. Market experts also noted to EPA that these producers have historically been willing to pay a significant premium to maintain their supply of cottonseed oil when supplies become limited.[5]

This behavior is supported by available historical data. Figure II.A.1–1 below illustrates one of multiple examples from recent history. In the 2012/13 crop year, cottonseed oil production was near the ten-year average.[6] However, in the 2013/14 crop year, cottonseed oil production was down significantly, about 20 percent below the ten-year average.[7] Conversely, these two crop years were both good for soybean oil, with production levels just above the ten-year average.[8] In 2012/13, when both oilseeds produced around their recent averages, the peak monthly price spread between soybean oil and cottonseed oil was about 3 cents per pound.[9] However, in 2013/14 when cottonseed oil supply was heavily constrained, the monthly average price spread grew to as much as 43.5 cents per pound.[10]

[2] United States Department of Agriculture, ''National Oil Crops Yearbook 2014'', available at: *http://www.ers.usda.gov/data-products/oil-crops-yearbook.aspx* (Last Accessed: January 14th, 2015). United Nations Food and Agriculture Organization, ''FAOSTAT'', available at: *http://faostat.fao.org/* (Last Accessed: January 29th, 2015).

[3] Ibid.

[4] Ibid.

[5] Based on conversations with Michael Dowd of the USDA Agricultural Research Service on December 30th, 2014 and June 17th, 2015.

[6] In the USDA data considered here, crop years begin in October of the first year listed and end in September of the second year listed.

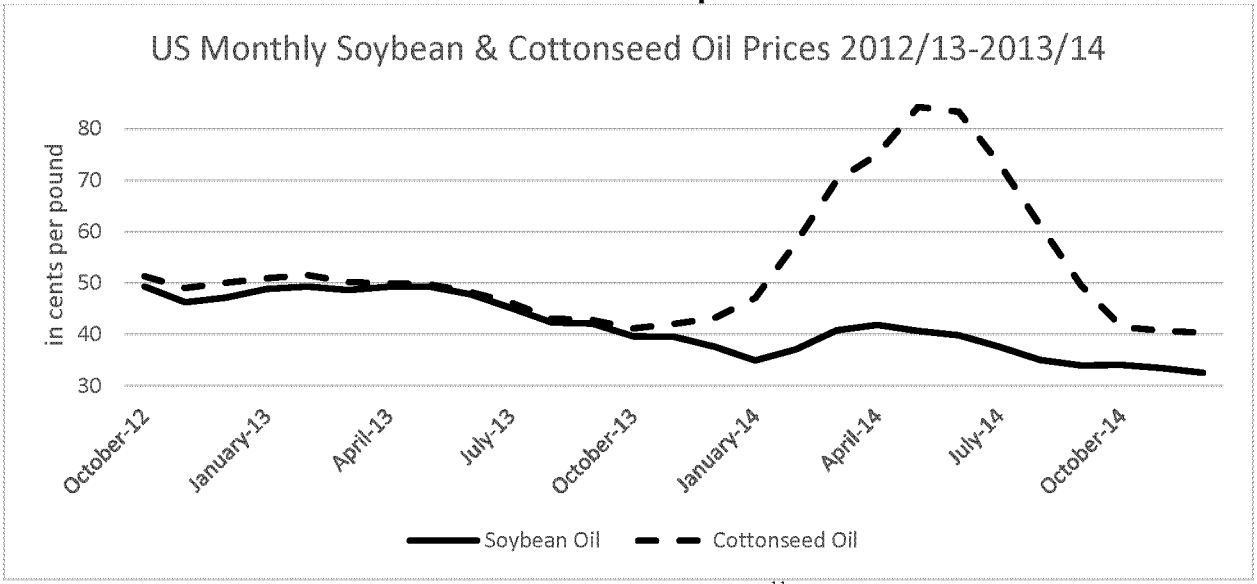
[7] U.S. cottonseed oil production has averaged about 800 million pounds since the 2003/04 crop year. According to the USDA Oil Crops Yearbook 2014, production in 2012/13 was also about 800 million pounds and production in 2013/14 was approximately 630 million pounds.

[8] U.S. soybean oil production has averaged about 19.5 billion pounds since the 2003/04 crop year. According to the USDA Oil Crops Yearbook 2014, production in 2012/13 was about 19.8 billion pounds and production in 2013/14 was approximately 19.7 billion pounds.

[9] This occurred in December 2012, when, according to USDA data, soybean oil averaged 47.16 cents per pound and cottonseed oil averaged 49.05 cents per pound.

[10] This occurred in May of 2014, when, according to USDA data, soybean oil averaged 40.68 cents per pound and cottonseed oil averaged 84.25 cents per pound.

Figure II.A.1-1 – Monthly Average Prices of Soybean Oil and Cottonseed Oil in the 2012/13 and 2013/14 Crop Years



Source: USDA Oil Crops Yearbook[11]

As Figure II.A.1–1 illustrates, cottonseed oil can approach price parity with soybean oil at times of average or above-average supply of cottonseed oil. However, the price trend shown above for 2013 should not be taken as representative of the full historical record. Cottonseed oil does not often achieve actual price parity with soybean oil. According to historical monthly price data from the U.S. Department of Agriculture (USDA), the national average monthly price for cottonseed oil was approximately equal to or below that of soybean oil in only 23 of the last 180 months (15 years).[12] Even in the middle months of 2013, when soybean oil and cottonseed oil prices appear to converge in Figure II.A.1–1, cottonseed oil actually maintained a small premium over soybean oil, though in a few months of 2013 this premium was less than a cent per pound. In only one month out of the last fifteen years, September 2004, was the monthly average price of cottonseed oil more than one cent per pound cheaper than that of soybean oil. For the majority of the recent historical record, cottonseed oil has maintained a significant price premium over soybean oil, averaging approximately 7 cents per pound over the last 15 years.

Based on information from USDA vegetable oil market experts, demand for cottonseed oil for specialty uses like those cited above is extremely inelastic, meaning that demand for this volume of cottonseed oil would not be significantly impacted by an increase in the price of cottonseed oil.[13] It is therefore highly unlikely that biofuel producers could bid cottonseed oil away from such specialty uses. This inelasticity of demand dramatically shrinks the potential amount of cottonseed oil that might be utilized for biofuel production and the potential impact that approving a pathway for cottonseed oil might have on vegetable oil markets. The data suggest that, in most years, cottonseed oil would not be price competitive with soybean oil for biofuel feedstock use in most locations. This suggests that cottonseed oil is unlikely to be used for biofuel production except in years where cottonseed oil prices are significantly lower than normal relative to soybean oil. Even then, as discussed below, cottonseed oil is likely to be used as a feedstock predominantly by biofuel production facilities located near cottonseed crushing facilities.

Conversely, the data also suggest that in some circumstances, cottonseed oil may achieve approximate price parity with soybean oil. This trend in pricing indicates cottonseed oil could compete on price with soybean oil as biofuel feedstock in times of abundant supply, or possibly in a year with low soybean oil production but normal cottonseed oil production, both of which might be expected to narrow the normal price gap. This trend also indicates that, when cottonseed oil prices are relatively low, the U.S. market values cottonseed oil at about the same price as soybean oil, rather than cheaper alternatives like palm oil or waste oils and greases or more expensive alternatives like sunflower seed oil. In other words, the historical pricing data available indicates that the primary competitor of cottonseed oil under these circumstances is soybean oil, since the prices converge, or at least nearly converge, under such circumstances.

Based on consultation with USDA and private sector vegetable oil industry experts and given the historical data presented above, we believe that the actual potential for biodiesel and non-ester renewable diesel production from cottonseed oil is considerably smaller than the 100 million gallons noted above.[14] Based on a conversation with NCPA we believe that the actual potential is more likely in the range of 20 million gallons of biodiesel per year (representing roughly 150–160 million pounds of cottonseed oil), and could be considerably smaller than that

[11] United States Department of Agriculture, ''National Oil Crops Yearbook 2014'', available at: *http://www.ers.usda.gov/data-products/oil-crops-yearbook.aspx* (Last Accessed: January 14th, 2015).

[12] USDA Agricultural Marketing Service, ''Monthly Feedstuff Prices and Milling and Baking News'', multiple editions. In this example, by ''approximately equal'' we mean that there was less than a 1 cent difference between the prices of cottonseed oil and soybean oil.

[13] Based on conversations with Michael Dowd of the USDA Agricultural Research Service on December 30th, 2014 and June 17th, 2015.

[14] Based on conversations with Michael Dowd of the USDA Agricultural Research Service on December 30th, 2014 and June 17th, 2015; based also on memo from NCPA [EPA–HQ–OAR–2015–0092–0001; EPA–HQ–OAR–2015–0092–0002].

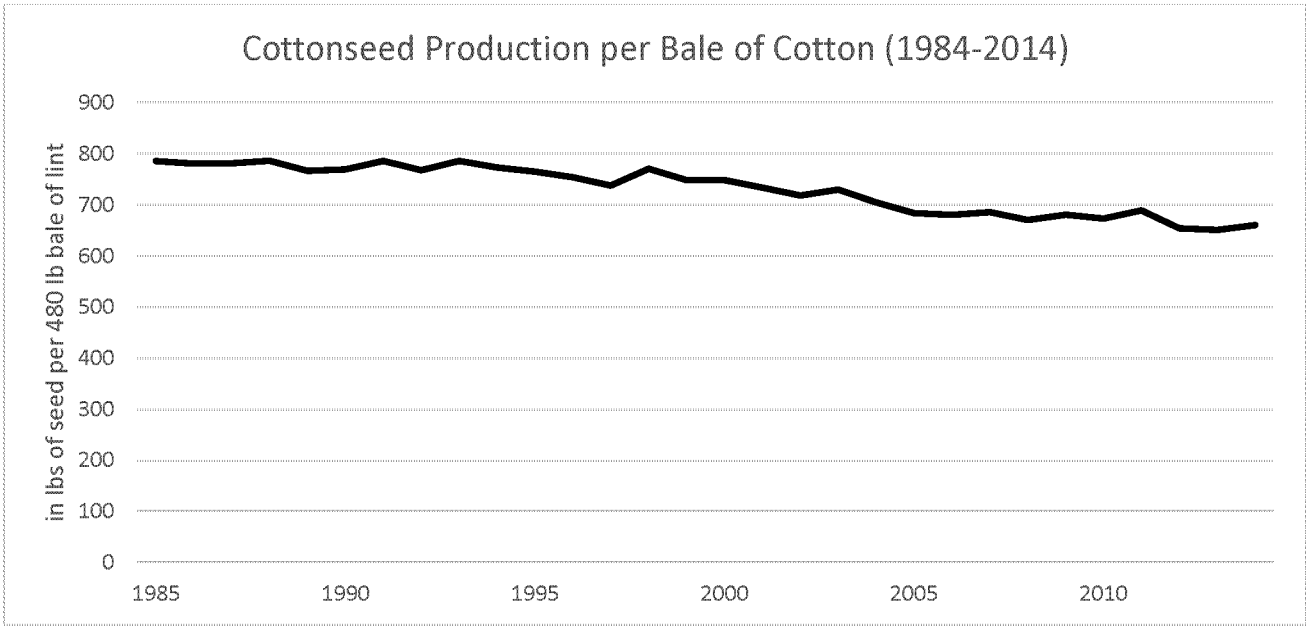
depending on market conditions.[15] As noted above, this is largely due to the inelastic nature of cottonseed oil demand for specialty uses, which have demonstrated their willingness to pay prices for cottonseed oil that would be prohibitive to biofuel producers when forced to compete for limited supplies of cottonseed oil. Except in years with high levels of cottonseed oil production or uncharacteristically low demand from specialty users (for example, if potato chip production were to be unusually low in a particular year), we do not expect that there will be significant quantities of cottonseed oil available at prices that biodiesel producers would consider competitive. As a result, were EPA to approve pathways for cottonseed oil-based fuels and begin registering producers, we would not expect it to have a significant impact on U.S. biofuel production or U.S. vegetable oil production, consumption, and trade patterns.

2. Cottonseed Oil Production Economics

The methods of producing cottonseed oil are nearly identical to those of other vegetable seed oils. The seeds are crushed, oil and meal are separated, and the two products are sold separately into the vegetable oil and animal feed markets respectively. However, the production of the cotton oilseed is unique among major oilseeds because the seed itself is not a primary crop product. Rather, it is generally considered a byproduct of the production of cotton lint for fiber. Fiber production is the primary purpose of cotton farming, representing approximately 85 percent of the value of the average U.S. acre of cotton, and it drives the decisions of farmers regarding whether to plant cotton and what types of farming practices to utilize.[16] The cotton seed and its products represent the remaining approximately 15 percent of average value per acre. Conversely, for soybeans and other major oilseeds, the seed itself comprises nearly 100 percent of the value per acre.

While cottonseed does have value and provides farmers with a secondary revenue stream, most cotton farmers consider it to be a byproduct of producing cotton lint. The efforts of cotton breeders over a long time period to maximize lint yields relative to seed yields, demonstrated by yield trends in cottonseed and cotton lint, support this hypothesis. Since 1985, the U.S. average cottonseed yield per bale of cotton lint produced has declined from nearly 800 pounds per bale to less than 700 pounds per bale (See Figure II.A.2–1 below).

Figure II.A.2-1 – Historical Cottonseed Production per Bale of Cotton



Source: USDA NASS Database[17]

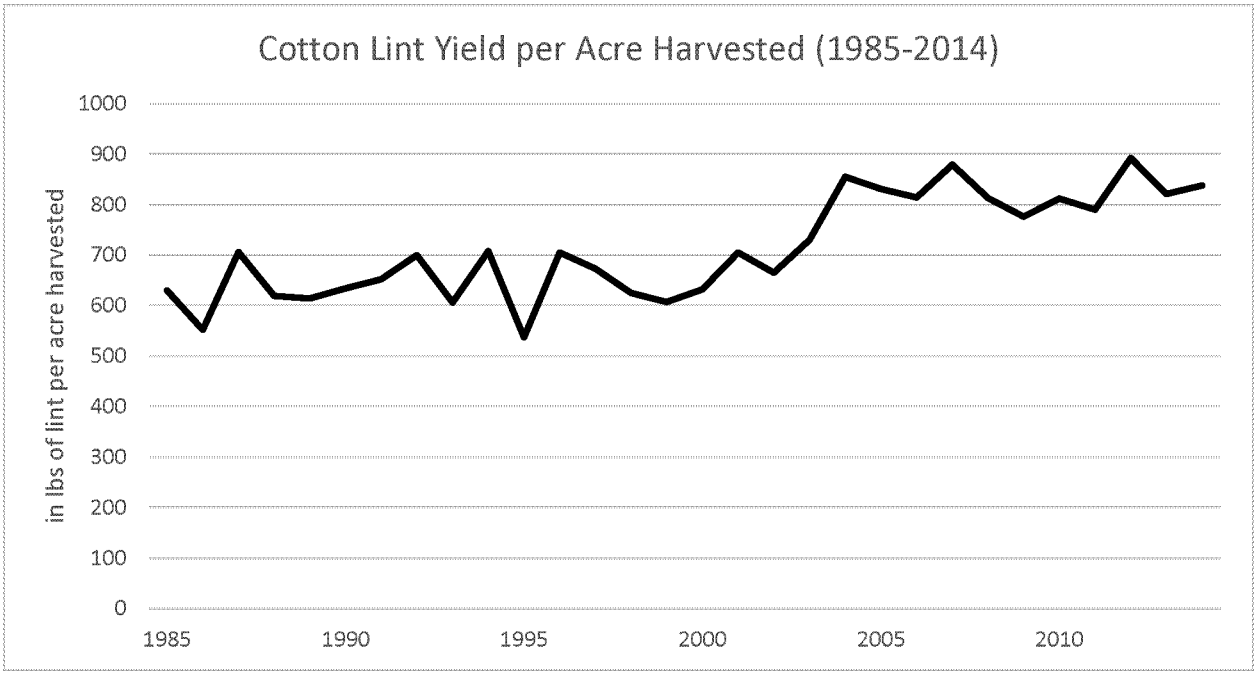
Conversely, over that same period, the U.S. average cotton lint yield has increased from 630 pounds per acre harvested to over 800 pounds per acre harvested.

[15] Based on memo from NCPA [EPA–HQ–OAR–2015–0092–0001; EPA–HQ–OAR–2015–0092–0002].

[16] According to the USDA NASS database, cotton lint has represented about 85 percent of revenue per acre fairly consistently since at least the year 1980. (Source: United States Department of Agriculture, ''National Agricultural Statistical Service Database'', available at: *http://quickstats.nass.usda.gov/* [Last Accessed: January 14th, 2015]).

[17] United States Department of Agriculture, ''National Agricultural Statistical Service Database'', available at: *http://quickstats.nass.usda.gov/* (Last Accessed: January 14th, 2015).

Figure II.A.2-2 – Historical Cotton Lint Yield per Acre



Source: USDA NASS Database[18]

The secondary nature of cottonseed production for cotton farmers has significant implications for our study of the impacts of cottonseed oil production for use in making biofuels. In a given year, weather conditions may reduce lint yields and force farmers to rely more on seed revenue. But when making decisions about what to plant, when to plant, and what types and quantities of crop inputs to utilize, lint yields are the first priority of cotton farmers. Further, the fact that cottonseed oil will only be competitive as a biofuel feedstock under certain relatively uncommon and unpredictable circumstances makes it even more unlikely that establishing pathways for cottonseed oil-based fuels under the RFS would have any impact on planting decisions. While farmers will seek to maximize the price they receive for cottonseed, it is highly unlikely that an increase in cottonseed value would have any significant impact on the behavior of cotton farmers.

Because changes in cottonseed oil prices are unlikely to affect overall cotton production decisions, it is highly unlikely that the use of cottonseed oil as a biofuel feedstock will significantly affect cottonseed production or the supply of cottonseed oil in the U.S. vegetable oil markets. Imports of cottonseed oil are approximately zero. We do not expect demand for cottonseed oil as biofuel feedstock to change this, since the costs of creating and operating new trade routes would make cottonseed oil uncompetitive with alternative oil feedstocks, especially soybean oil. Instead, we expect that, in the rare instances when cottonseed oil prices approach parity with soybean oil prices, biofuel producers might utilize some quantity of cottonseed oil. Since, in most previous historical instances of this near price parity, cottonseed oil is still somewhat more expensive than soybean oil, we would expect to only see this behavior amongst biofuel producers with renewable fuel production facilities near cottonseed crushing locations, since this oil could be sourced with minimal transport costs. If some quantity of cottonseed oil is diverted from the vegetable oil markets to the biofuel market, any unfilled demand for vegetable oil will most likely be met with increased consumption of other vegetable oils, for the reasons outlined in the next section.

3. Replacement of Cottonseed Oil in Vegetable Oil Markets

As noted in Section II.A.1 above, cottonseed oil demand in the U.S. tends to be inelastic until the needs of specialty consumers are fully met, and the amount of cottonseed oil that could be bid away from such users for biofuel production is likely small until that threshold is reached. Whether or not any of this remaining cottonseed oil will actually be used for biofuel production will depend on the price of cottonseed oil relative to soybean oil at that time.

In the event that cottonseed oil is used as a biofuel feedstock, the small volume likely to be available in any given region makes it highly unlikely that cottonseed oil could meet the total feedstock needs of a biofuel production facility. Rather, we expect that U.S. biofuel producers who are already utilizing vegetable oil feedstocks and are located near cottonseed crushing facilities will have the option to include some amount of cottonseed oil in their mix of feedstocks when the price is right.

There are two likely ways that biofuel producers may include some amount of cottonseed oil in their feedstock mix. First, biofuel producers may at times substitute cottonseed oil for some amount of soybean oil and produce the same volume of fuel as before. Second, they may at times use low-priced cottonseed oil to increase their total volume of fuel production. While the market response is likely to be some combination of both scenarios, for this analysis we have assumed the more conservative scenario from a lifecycle

[18] United States Department of Agriculture, ''National Agricultural Statistical Service Database'', available at: *http://quickstats.nass.usda.gov/* (Last Accessed: June 2nd, 2015).

GHG perspective. This second scenario is more conservative because in the first scenario the displaced soybean oil could backfill in other vegetable oil markets for the cottonseed oil consumed for biofuel production and total vegetable oil production is unlikely to change. In the second scenario, where total biofuel production increases, cottonseed oil is being diverted away from some other use, creating a shortfall in vegetable oil supplies for some portion of the market. Either prices for vegetable oil will rise (in which case it is less likely that biofuel producers would still consume the cottonseed oil, since they were only purchasing it because of the low price) or additional vegetable oil will need to be supplied. In either case, the GHG emissions will be greater in the second scenario, where there is an incentive to expand crop production. If the results of analyzing the conservative scenario associated with greater GHG emissions indicates that biofuels produced from cottonseed oil satisfy the 50 percent lifecycle GHG emissions reduction requirement for biomass-based diesel and advanced biofuels, we can conclude that the threshold determination would be the same under the less conservative but more likely scenario.

If the use of cottonseed oil for biofuel does create an increase in total demand for vegetable oil, we believe the direct result will be a corresponding increase in soybean oil consumption in the United States. As we established above, cotton farmers are unlikely to respond to increased demand for cottonseed oil. Instead, we are likely to see an increase in production of the vegetable oil most competitive with the cottonseed oil being diverted to biofuel feedstock use. Based on consultation with oilseed market experts at USDA and recent historical data (see Section II.A.1), which shows cottonseed oil prices tracking soybean oil prices, the marginal users of cottonseed oil are largely indifferent between cottonseed and soybean oil when they approach price parity.[19] Therefore, it follows that if vegetable oil is needed to backfill for cottonseed oil used as biofuel, soybean oil would be the most likely vegetable oil to meet this demand in the United States.

To the extent that soybean oil is used to satisfy U.S. domestic demand for vegetable oil that would have otherwise been met with cottonseed oil, there would likely be secondary impacts on the production and consumption of other vegetable oils internationally and the agricultural sector more broadly. In the modeling we conducted for the March 2010 rule, we projected that the use of soybean oil for biofuel feedstock would cause a global increase in vegetable oil production. In that analysis, we projected that the majority of this increase would come in the form of additional soybean oil production, but that additional canola, palm, peanut, and sunflower oil production would also occur in some parts of the world, with secondary impacts on other parts of the agricultural sector.[20] Therefore, by assuming that cottonseed oil would have similar indirect impacts on other vegetable oils, our analysis takes into account the ripple effects in the vegetable oil and other agricultural markets resulting from an increase in biofuel demand in the U.S. We invite comment on this approach.

4. Upstream GHG Implications of Cottonseed Oil Use as a Biofuel Feedstock

Our analysis indicates that the most likely market impact of the use of cottonseed oil as biofuel feedstock is some feedstock swapping between cottonseed oil and soybean oil and some increase in total biofuel production from vegetable oil, as explained in the previous section. However, as a conservative assumption, we assume in our analysis that any use of cottonseed oil as biofuel feedstock will result in an increase in total biofuel production and that there would be a corresponding increase in U.S. demand for vegetable oil. In such a hypothetical situation, the alternative product used by marginal U.S. consumers of vegetable oil is likely to be soybean oil. We do not expect any shift in the supply of cotton or cottonseed oil. The GHG emissions associated with cottonseed oil at the feedstock production and transport stages of the lifecycle are likely to be similar to or less than those we have previously estimated for soybean oil on a normalized basis.[21] Therefore, we are proposing to use the upstream GHG emissions associated with an increase in soybean oil in our lifecycle analysis for cottonseed oil. In the March 2010 rule, we determined that the GHG emissions associated with soybean oil at the feedstock production and transport stages of the lifecycle were approximately 646 grams of carbon dioxide equivalent (gCO_2e) per pound of soybean oil.[22] Based on our evaluation, we believe that it is reasonable, as a conservative estimate, to apply the same value for the emissions associated with cottonseed oil at the feedstock production and transport stages of the lifecycle. We invite comment on this approach.

B. Summary of Agricultural Sector GHG Emissions

Based on our comparison of cottonseed oil to soybean oil, EPA proposes to apply the estimate of upstream soybean oil feedstock production and transport emissions, including indirect agricultural and forestry sector impacts, to future evaluations of petitions proposing to use cottonseed oil as a feedstock for biofuel production. We believe this approach will provide a conservative estimate of potential emissions associated with the production and transport of cottonseed oil. EPA solicits comment on this proposed approach.

C. Fuel Production and Distribution

Cottonseed oil has physical properties that are similar to soybean oil, and is suitable for the same conversion processes as soybean oil feedstock. In addition, the fuel yield per pound of oil is expected to be the same for each of these feedstocks. After reviewing comments received in response to this action, we will combine our evaluation of agricultural sector GHG emissions associated with the use of cottonseed oil feedstock with our evaluation of the GHG emissions associated with individual producers' production processes and finished fuels to determine whether any proposed pathway satisfies CAA lifecycle GHG emissions reduction requirements for RFS-qualifying renewable fuels. Each

[19] Based on conversations with Michael Dowd of the USDA Agricultural Research Service on December 30th, 2014 and June 17th, 2015.

[20] See EPA–HQ–OAR–2005–0161–3173.9 and EPA–HQ–OAR–2005–0161–3173.10 for more information.

[21] EPA's lifecycle analysis of soybean oil biodiesel for the March 2010 RFS rule evaluated the GHG impacts for a scenario with increased soybean oil biodiesel production compared to a control case. To calculate the results on a normalized basis for the scenario evaluated, we divide the increase in GHG emissions by the increase in the amount of soybean oil used for biodiesel production, which gives the normalized results in units of gCO_2e per pound of soybean oil. The lifecycle GHG analysis that EPA conducted for the March 2010 RFS rule for biofuel derived from soybean oil feedstock is described in section 2.6.1.3 (Biodiesel Results) of the Regulatory Impact Analysis for the March 2010 RFS rule (EPA–420–R–10–006).

[22] EPA's soybean oil biodiesel assessment uses a biodiesel conversion efficiency of 7.76 pounds of soybean oil per gallon of biodiesel, and biodiesel lower heating value of 118,000 British Thermal Units (Btu) per gallon. Therefore, GHG emissions of 646 gCO_2e/lb soybean oil converts to 41,247 gCO2e per million Btu of soybean oil biodiesel. This value includes the emissions associated with soybean oil delivered to a biodiesel production facility, including the emissions from growing and harvesting the soybeans, transporting the soybeans to a crushing facility, extracting the soybean oil, transporting the soybean oil to a biodiesel facility, and all of the significant indirect emissions such as from land use change.

biofuel producer seeking to generate RINs for non-grandfathered volumes of biofuel produced from cottonseed oil will first need to submit a petition requesting EPA's evaluation of their new renewable fuel pathway pursuant to 40 CFR 80.1416 of the RFS regulations, and include all of the information specified at 40 CFR 80.1416(b)(1). Because EPA is evaluating the greenhouse gas emissions associated with the production and transport of cottonseed oil feedstock through this action and comment process, petitions requesting EPA's evaluation of biofuel pathways involving cottonseed oil feedstock will not have to include the information for new feedstocks specified at 40 CFR 80.1416(b)(2).[23] Based on our evaluation of the lifecycle GHG emissions attributable to the production and transport of cottonseed oil feedstock, EPA anticipates that fuel produced from cottonseed oil feedstock through the same transesterification or hydrotreating process technologies that EPA evaluated for the March 2010 RFS rule for biofuel derived from soybean oil and the March 2013 RFS rule for biofuel derived from camelina oil would qualify for biomass-based diesel (D-code 4) renewable identification numbers (RINs) or advanced biofuel (D-code 5) RINs.[24] However, EPA will evaluate petitions for fuel produced from cottonseed oil feedstock on a case-by-case basis.

III. Summary

EPA invites public comment on our analysis of GHG emissions associated with the production and transport of cottonseed oil as a feedstock for biofuel production. EPA will consider public comments received when evaluating the lifecycle GHG emissions of biofuel production pathways described in petitions received pursuant to 40 CFR 80.1416 which use cottonseed oil as a feedstock.

Dated: June 30, 2015.

Christopher Grundler,

Director, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2015–17262 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

[23] For information on how to submit a petition for biofuel produced from cottonseed oil see EPA's Web page titled ''How to Submit a Complete Petition'' (*http://www.epa.gov/otaq/fuels/renewablefuels/new-pathways/how-to-submit.htm*) including the document on that Web page titled ''How to Prepare a Complete Petition.'' Petitions for biofuel produced from cottonseed oil should include all of the applicable information outlined in Section 3 of the ''How to Prepare a Complete Petition'' document, but they do not need to provide the information outlined in section 3(F)(2) (Information for New Feedstocks).

[24] The transesterification process that EPA evaluated for the March 2010 RFS rule for biofuel derived from soybean oil feedstock is described in section 2.4.7.3 (Biodiesel) of the Regulatory Impact Analysis for the March 2010 RFS rule (EPA–420–R–10–006). The hydrotreating process that EPA evaluated for the March 2013 rule for biofuel derived from camelina oil feedstock is described in section II.A.3.b of the March 2013 rule (78 FR 14190).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2013–0677; FRL–9929–99]

Receipt of Test Data Under the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing its receipt of test data submitted pursuant to a test rule issued by EPA under the Toxic Substances Control Act (TSCA). As required by TSCA, this document identifies each chemical substance and/or mixture for which test data have been received; the uses or intended uses of such chemical substance and/or mixture; and describes the nature of the test data received. Each chemical substance and/or mixture related to this announcement is identified in Unit I. under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kathy Calvo, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8089; email address: *calvo.kathy@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. Chemical Substances and/or Mixtures

Information about the following chemical substances and/or mixtures is provided in Unit IV.:

D-gluco-heptonic acid, monosodium salt, (2.xi.)—(*CAS RN 31138–65–5*).

II. Federal Register Publication Requirement

Section 4(d) of TSCA (15 U.S.C. 2603(d)) requires EPA to publish a notice in the **Federal Register** reporting the receipt of test data submitted pursuant to test rules promulgated under TSCA section 4 (15 U.S.C. 2603).

III. Docket Information

A docket, identified by the docket identification (ID) number EPA–HQ–OPPT–2013–0677, has been established for this **Federal Register** document that announces the receipt of data. Upon EPA's completion of its quality assurance review, the test data received will be added to the docket for the TSCA section 4 test rule that required the test data. Use the docket ID number provided in Unit IV. to access the test data in the docket for the related TSCA section 4 test rule.

The docket for this **Federal Register** document and the docket for each related TSCA section 4 test rule is available electronically at *http://www.regulations.gov* or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 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 Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

IV. Test Data Received

This unit contains the information required by TSCA section 4(d) for the test data received by EPA.

D-gluco-heptonic acid, monosodium salt, (2.xi.)—(*CAS RN 31138–65–5*).

1. *Chemical Uses:* Organic salt used as a chelating agent in cosmetics, dairy cleaners, bottle cleaners, food contact paper and paperboard, manufacturing, metal cleaning, kier boiling, caustic boil-off, paint stripping, boiler water additive for food processing, and as an ingredient in aluminum etchant. This chemical is also used as a sequestrant, latex stabilizer, and in intravenous pharmaceuticals.

2. *Applicable Test Rule:* Chemical testing requirements for second group of high production volume chemicals (HPV2), 40 CFR 799.5087.

3. *Test Data Received:* The following listing describes the nature of the test data received. The test data will be added to the docket for the applicable TSCA section 4 test rule and can be found by referencing the docket ID number provided. EPA reviews of test data will be added to the same docket upon completion.

Aquatic Toxicity (Fish) (C1). The docket ID number assigned to this data is EPA–HQ–OPPT–2007–0531.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: July 7, 2015.

Mari J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2015–17256 Filed 7–13–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0824]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid 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 and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before September 14, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0824.

Title: Service Provider and Billed Entity Identification Number and Contact Information Form.

Form Number: FCC Form 498.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit and not-for-profit institutions.

Number of Respondents: 26,000 respondents; 26,000 responses.

Estimated Time per Response: 0.75 hours.

Frequency of Response: On occasion reporting requirements and third party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154 and 254 the Communications Act of 1934, as amended.

Total Annual Burden: 19,500 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission notes that the Universal Service Administrative Company (USAC) who administers the universal service program must preserve the confidentiality of all data obtained from respondents and contributors to the universal service programs, must not use the data except for purposes of administering the universal service programs, and must not disclose data in company-specific form unless directed to do so by the Commission. With respect to the FCC Form 498, USAC shall publish each participant's name, SPIN, and contact information via USAC's Web site. All other information, including financial institution account numbers or routing information, shall remain confidential.

Needs and Uses: One of the functions of the Universal Service Administrative Company (USAC) is to provide a means for the billing, collection and disbursement of funds for the universal service support mechanisms. On October 1998, the OMB approved FCC Form 498, the ''Service Provider Information Form'' to enable USAC to collect service provider name and address, telephone number, Federal Employer Identification Number (EIN), contact names, contact telephone numbers, and remittance information. FCC Form 498 enables participants to request a Service Provider Identification Number (SPIN) and provides the official record for participation in the universal service support mechanisms. The remittance information provided by participants on FCC Form 498 enables USAC to make payments to participants in the universal service support mechanisms.

The following proposed revisions have been made to the FCC Form 498 for which we seek OMB approval:

- Form name changed to ''Service Provider and Billed Entity Identification Number and Contact Information Form'';
- Added an additional field in block 3 for a company's Federal Registration Number (FRN);
- Added a column for the Study Area Code Company Name in block 8;
- Added the ability for a carrier to designate an alternate bank account for the payment of BEAR funds in block 11;
- Added a box in block 1 and a supplemental information sheet to allow respondents to include information about affiliates;
- Updated the Principal Communications Types in block 14 to include additional business types as listed on the FCC Form 499–A; and
- Added a box after every program on the form that will allow service providers to cease participation in the associated program without having to deactivate their entire SPIN.

Corresponding adjustments were made to the instructions to reflect the proposed changes to the FCC Form 498. The information collected on the FCC Form 498 is used by USAC to disburse federal universal service support consistent with the specifications of eligible participants in the universal service programs. FCC Form 498 submissions also provide USAC with updated contact information so that USAC can contact universal service fund participants when necessary. Without such information, USAC would not be able to distribute support to the proper entities and this would prevent the Commission from fulfilling its statutory responsibilities under the Act to preserve and advance universal service.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–17187 Filed 7–13–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The 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 August 7, 2015.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Green Bancorp, Inc.,* Houston, Texas; to merge with Patriot Bancshares, Inc., and thereby indirectly acquire Patriot Bank, and Patriot Texas Holdings, Inc., all in Houston, Texas.

Board of Governors of the Federal Reserve System, July 9, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–17197 Filed 7–13–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the notices must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 7, 2015.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Parkway Bancorp, Inc.,* Harwood Heights, Illinois; to acquire 100 percent of the voting shares of Park Bancorp, Inc., and indirectly acquire Park Federal Savings Bank, both in Chicago, Illinois, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4)(ii).

Board of Governors of the Federal Reserve System, July 9, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–17198 Filed 7–13–15; 8:45 am]

BILLING CODE 6210–01–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 July 29, 2015.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Sandra Holig and John Holig, trustees of Trust B, created under Article V of the Robert J. Holig Revocable Trust dated July 2, 1992, an Irrevocable Trust,* all of Swanville, Minnesota; a group acting in concert, to acquire and retain voting shares of Swanville Bancshares, Inc., and thereby indirectly acquire and retain voting shares of First State Bank of Swanville, both in Swanville, Minnesota.

Board of Governors of the Federal Reserve System, July 9, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–17199 Filed 7–13–15; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10492]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *August 13, 2015.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Data Submission for the Federally-faciliated Exchange User Fee Adjustment; *Use:* The final rule ''Coverage of Certain Preventive Services Under the Affordable Care Act'' published by the Departments of Health and Human Services (HHS), the Treasury, and Labor on July 2, 2013, sets forth regulations regarding coverage for certain preventive services under section 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the Public Health Service Act requires coverage without cost sharing of certain preventive health services, including certain contraceptive services, in non-exempt, non-grandfathered group health plans and health insurance coverage. The final rules establish accommodations with respect to group health plans established or maintained by eligible organizations (and group health insurance coverage offered in connection with such plans). Eligible organizations are required to self-certify that they are eligible for this accommodation and provide a copy of such self-certification to their third party administrators. The final rules also set forth processes and standards to fund the payments for the contraceptive services that are provided for participants and beneficiaries in self-insured plans of eligible organizations under the accommodation described previously, through an adjustment in the Federally-facilitated Exchange (FFE) user fee payable by an issuer participating in an FFE.

In order to facilitate the FFE user fee adjustment, and ensure that these user fee adjustments reflect payments for contraceptive services provided under this accommodation and that the adjustment is applied to the appropriate participating issuer in an FFE, the final rule requires an information collection from applicable participating issuers and third party administrators. In particular, the final regulations at 45 CFR 156.50(d)(2)(i) provide that a participating issuer who seeks an FFE user fee adjustment must submit to HHS in the year following the benefit year in which payments for contraceptive services were made under the previously mentioned accomodation, identifying information for the participating issuer, each third party administrator, and each self-insured group health plan, as well as the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year under the accommodation. The final regulation at 45 CFR 156.50(d)(2)(iii) also requires the third party administrator to submit to HHS identifying information for the third party administrator, the participating issuer, and each self-insured group health plan, as well as the total number of participants and beneficiaries in each self-insured group health plan during the applicable calendar year, the total dollar amount of payments made for contraceptive services, and an attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

Furthermore, to determine the potential number of submissions provided by third party administrators and allow HHS to prepare to receive submissions in calendar year 2015, the final regulation at 45 CFR 156.50(d)(2)(ii) requires third party administrators to submit to HHS a notification that the third party administrator intends for a participating issuer to seek an FFE user fee adjustment, by the later of January 1, 2014, or the 60th calendar day following the date on which the third party administrator receives a copy of a self-certification from an eligible organization. Additionally, a health insurance issuer providing payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations to provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments.

The burden associated with these processes includes the time for applicable participating issuers and third party administrators to submit identifying information and total payments made for contraceptive services in the prior calendar year, and for third party administrators to notify HHS of their intent to seek the user fee adjustment. HHS estimates 488 third party administrators, 48 QHP issuers, and 325 fully insured issuers of eligible organizations will submit this information. HHS anticipates that participating issuers in an FFE seeking a user fee adjustment and third party administrators with respect to which the FFE user fee adjustment is received will submit this information electronically. *Form Number:* CMS–10492 (OMB control number: 0938—NEW); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 861; *Total*

Annual Responses: 861; *Total Annual Hours:* 12,930. (For policy questions regarding this collection contact Jaya Ghildiyal at (301) 492–5149.)

Dated: July 9, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–17285 Filed 7–10–15; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Annual Report on Households Assisted by the Low Income Home Energy Assistance Program (LIHEAP)

OMB No.: 0970–0060.

Description: This statistical report is an annual activity required by statute (42 U.S.C. 8629) and Federal regulations (45 CFR 96.92) for the Low Income Home Energy Assistance Program (LIHEAP). Submission of the completed report is one requirement for LIHEAP grantees applying for Federal LIHEAP block grant funds. States, the District of Columbia, and the Commonwealth of Puerto Rico are required to report statistics for the previous Federal fiscal year on the number and income levels of LIHEAP applicants and assisted households, as well as the number of LIHEAP-assisted households with at least one member who is elderly, disabled, or a young child.

The statistical report requires States, the District of Columbia, and the Commonwealth of Puerto Rico to report on assisted households having at least one elderly person who is homebound; an unduplicated count of assisted households having at least one member who is elderly, disabled, or a young child; and an unduplicated count of assisted households receiving one or more types of LIHEAP assistance.

Insular areas receiving less than $200,000 annually in LIHEAP funds and Indian Tribal Grantees are required to submit data only on the number of households receiving heating, cooling, energy crisis, or weatherization benefits. The information is being collected for the Department's annual LIHEAP report to Congress. The data also provides information about the need for LIHEAP funds. Finally, the data are used in the calculation of LIHEAP performance measures under the Government Performance and Results Act of 1993. The additional data elements will improve the accuracy of measuring LIHEAP targeting performance and LIHEAP cost efficiency.

Respondents: State Governments, Tribal Governments, Insular Areas, the District of Columbia, and the Commonwealth of Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Assisted household Report-Long Form	52	1	25	1,300
Assisted Household Report-Short Form	155	1	1	155
Applicant Household Report	52	1	13	676

Estimated Total Annual Burden Hours: 2,131.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project , Email: *OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–17166 Filed 7–13–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0597]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach To Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information concerning the development of comprehensive monitoring plans in the guidance.

DATES: Submit either electronic or written comments on the collection of information by September 14, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455

Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach To Monitoring

(OMB Control Number 0910–0733)—Extension

The guidance is intended to assist sponsors of clinical investigations in developing strategies for risk-based monitoring and plans for clinical investigations of human drug and biological products, medical devices, and combinations thereof. The guidance describes strategies for monitoring activities performed by sponsors, or by contract research organizations (CROs), that focus on the conduct, oversight, and reporting of findings of an investigation by clinical investigators. The guidance also recommends strategies that reflect a risk-based approach to monitoring that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. The guidance specifically encourages greater reliance on centralized monitoring methods where appropriate.

Under parts 312 and 812 (21 CFR parts 312 and 812), sponsors are required to provide appropriate oversight of their clinical investigations to ensure adequate protection of the rights, welfare, and safety of human subjects and to ensure the quality and integrity of the resulting data submitted to FDA. As part of this oversight, sponsors of clinical investigations are required to monitor the conduct and progress of their clinical investigations. The regulations do not specify how sponsors are to conduct monitoring of clinical investigations and, therefore, are compatible with a range of approaches to monitoring. FDA currently has OMB approval for the information collection required under part 812 (OMB control number 0910–0078) and part 312, including certain provisions under subpart D (OMB control number 0910–0014).

The collection of information associated with this guidance that approved under OMB control number 0910–0733 is as follows:

Development of Comprehensive Monitoring Plan: Section IV.D ''Monitoring Plan'' of the guidance recommends that sponsors develop a prospective, detailed monitoring plan that describes the monitoring methods, responsibilities, and requirements for each clinical trial. The plan should provide adequate information to those involved with monitoring to effectively carry out their duties. All sponsor personnel and CRO personnel who may be involved with monitoring (including those who review appropriate action, determine appropriate action, or both regarding potential issues identified through monitoring) should review the monitoring plan. The components of a monitoring plan are described in the guidance, including monitoring plan amendments (*i.e.,* the review and revision of monitoring plans and processes for timely updates).

FDA understands that sponsors currently develop monitoring plans; however, not all monitoring plans contain all the elements described in the guidance. Therefore, our burden estimate provides the additional time that a sponsor would expend in developing a comprehensive monitoring plan based on the recommendations in the guidance. FDA estimates that approximately 88 sponsors will develop approximately 132 comprehensive monitoring plans in accordance with the guidance and that the added burden for each plan will be approximately 4 hours to develop, including the time needed to prepare monitoring plan amendments when appropriate (a total of 528 hours).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Development of Comprehensive Monitoring Plan	88	1.5	132	4	528

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17318 Filed 7–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2148]

Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices.'' This draft guidance provides a detailed description of the information that should be included in a premarket notification for a magnetic resonance diagnostic device (MRDD). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 13, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jana Delfino, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4236, Silver Spring, MD 20993–0002, 301–796–6503; or Sunder Rajan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1113, Silver Spring, MD 20993–0002, 301–796–4194.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this document is to provide a detailed description of the information that should be included in a premarket notification for an MRDD. This document is an elaboration of the general requirements contained in 21 CFR 807.87 and is intended to be used in conjunction with general information regarding the content and format of a 510(k) premarket notification. The approach outlined in this guidance document is intended to facilitate the timely review and marketing clearance of MRDDs.

This draft guidance is applicable to MRDDs as defined in 21 CFR 892.1000. An MRDD is intended for general diagnostic use to present images that reflect the spatial distribution and/or magnetic resonance spectra that reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information). MRDDs are class II medical devices that require premarket notification and an agency determination of substantial equivalence prior to marketing.

The principal components of current MRDDs include the main magnet, shim and gradient systems, radiofrequency transmitter and receiver, transmit and receive coils, power supplies, computer, and software. This draft guidance document is applicable to premarket notifications for new magnetic resonance imaging (MRI) and magnetic resonance spectroscopy systems, new components, and modifications to systems and components that have a significant impact on safety or effectiveness of the magnetic resonance diagnostic device. The information in this draft guidance document is also applicable to the MRI system components of dual-modality devices, such as positron emission tomography/MRI systems.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. Persons unable to download an electronic copy of ''Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 340 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the

heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: July 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17250 Filed 7–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences 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 Environmental Health Sciences Special Emphasis Panel; Undergraduate Research Training in Environmental Health Sciences.

Date: August 6, 2015.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Room 3118, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, 919/541–0670, *worth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 7, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17164 Filed 7–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scientific Advisory Committee on Alternative Toxicological Methods; Announcement of Meeting; Request for Comments

SUMMARY: This notice announces a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). SACATM advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. The meeting is open to the public. Registration is requested for both public attendance and oral comment and required to access the webcast. Information about the meeting and registration is available at *http://ntp.niehs.nih.gov/go/32822.*

DATES: Meeting: September 2, 2015, beginning at 8:30 a.m. Eastern Daylight Time (EDT) and continuing until adjournment at approximately 5:00 p.m.

Written Public Comments Submissions: Deadline is August 19, 2015.

Registration for Meeting and/or Oral Comments: Deadline is August 26, 2015.

Registration to View Webcast: Deadline is September 2, 2015. Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709

Meeting Web page: The preliminary agenda, registration, and other meeting materials will be at *http://ntp.niehs.nih.gov/go/32822.*

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, Designated Federal Officer for SACATM, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 919–541–9834, fax: (301) 480–3272, email: *whiteld@niehs.nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2136, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Preliminary Agenda and Other Meeting Information: A preliminary agenda, roster of SACATM members, background materials, public comments, and any additional information, when available, will be posted on the SACATM meeting Web site (*http://ntp.niehs.nih.gov/go/32822*) or is available upon request from the Designated Federal Officer. Following the meeting, summary minutes will be prepared and available on the SACATM Web site or upon request.

Meeting and Registration: This meeting is open to the public with time scheduled for oral public comments. The public may attend the meeting at NIEHS, where attendance is limited only by the space available, or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to attend and/or provide oral comments are encouraged to register at *http://ntp.niehs.nih.gov/go/32822* by August 26, 2015, to facilitate planning for the meeting. Individuals interested in the meeting are encouraged to access this Web site to stay abreast of the most current information regarding the meeting. Visitor and security information for those attending in person is available at *niehs.nih.gov/about/visiting/index.cfm.* Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (919) 541–4363 or email: *guyr2@niehs.nih.gov.* TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Request for Comments: Both written and oral public input on the agenda topics is invited. Written comments submitted in response to this notice should be received by August 19, 2015. Comments will be posted on the meeting Web site and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), and sponsoring organization (if any) with the document. Time is allotted during the meeting for presentation of oral comments and each organization (sponsoring organization or affiliation) is allowed one time slot per

topic. At least 7 minutes will be allotted for each speaker, and if time permits, may be extended up to 10 minutes at the discretion of the chair. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than for registered speakers and will be determined by the number of persons who register at the meeting. In addition to in-person oral comments at the meeting, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The lines will be open from 8:30 a.m. until approximately 5:00 p.m., although public comments will be received only during the formal public comment periods, which will be indicated on the preliminary agenda. The access number for the teleconference line will be provided to registrants by email prior to the meeting.

Persons wishing to present oral comments are encouraged to register using the SACATM meeting registration form (*http://ntp.niehs.nih.gov/go/32822*), indicate the topic(s) on which they plan to comment, and, if possible, send a copy of their statement to *whiteld@niehs.nih.gov* by August 26, 2015, to enable review by SACATM, NICEATM, ICCVAM, and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 20 copies of the statement for distribution and to supplement the record.

Background Information on ICCVAM, NICEATM, and SACATM: ICCVAM is an interagency committee composed of representatives from 15 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety-testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found at *http://ntp.niehs.nih.gov/go/iccvam* and *http://ntp.niehs.nih.gov/go/niceatm.*

SACATM was established in response to the ICCVAM Authorization Act [Section 285*l*–3(d)] and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167.*

Dated: July 8, 2015.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2015–17165 Filed 7–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implantation Grant (R01).

Date: August 17, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 5061 Fishers Lane, Conference Room 3F100, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Paul Roberts, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G22, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852, 240–669–5053, *paul.roberts@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implantation Grant (R01).

Date: August 18, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 5601 Fishers Lane, Conference Room 3F100, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Paul Roberts, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G22, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852, 240–669–5053, *paul.roberts@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implantation Cooperative Agreement (U01).

Date: August 19, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 5601 Fishers Lane, Conference Room 3F100, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Paul Roberts, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G22, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852, 240–669–5053, *paul.roberts@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 8, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17160 Filed 7–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA grant applications: Toxicology and Digestive, Kidney and Urological Systems.

Date: July 29, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301–435–1169, *greenwep@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Mechano-Sensing and Transduction by Epithelial Cell Junctions.

Date: August 6, 2015.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Janet M Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7840, Bethesda, MD 20892, 301–806–2765, *larkinja@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Resource Review: Imaging Mass Spectrometry Research Resource.

Date: August 10–12, 2015.

Time: 6:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Nashville at Vanderbilt, 1811 Broadway, Nashville, TN 37203.

Contact Person: Vonda K Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7892, Bethesda, MD 20892, 301–435–1789, *smithvo@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 8, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17162 Filed 7–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel; Regional Consortia for High Resolution Cryoelectron Microscopy.

Date: August 5, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Margaret J. Weidman, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room, 3An.12N, Bethesda, MD 20892, 301–594–2048, *weidmanma@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: July 9, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17219 Filed 7–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 14–050: Virtual Consortium for Translational/Transdisciplinary, Environmental Research (ViCTER).

Date: July 21, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301–435–1169, *greenwep@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts and Continuous Submission: Angiogenesis, Vascular, Inflammation and Dysfunction.

Date: August 6–7, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–435–1206, *komissar@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Reproductive Sciences Topics.

Date: August 7, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Genes, Genomes, and Genetics IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, MSC 7890, Bethesda, MD 20892, 301 435–2514, *riverase@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 8, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17159 Filed 7–13–15; 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 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: Center for Scientific Review Special Emphasis Panel; Small Business-Hematology- Rump.

Date: July 13, 2015.

Time: 8:00 a.m. to 5:00 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: Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301–435–0912, *Katherine_Malinda@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: July 8, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17158 Filed 7–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the Council of Councils.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov*).

A portion of 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: Council of Councils.

Open: September 1, 2015.

Time: 8:15 a.m. to 11:45 a.m.

Agenda: Call to Order and Introductions; Announcements; Update on the Office of AIDS Research; Data Science at NIH: Opportunities and Challenges; NIH Update; Discussion; Concept Clearance #1: Planning for FY16 New Directions in Environmental Influences on Child Health and Development Program.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C-Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Closed: September 1, 2015.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C-Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Open: September 1, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: Council Operating Procedures; Draft Framework for NIH Strategic Plan; Concept Clearance #2: Two G20 concepts; Update on the Early Independence Awards; Potential Concept Clearance #3: OAR/ORIP—HIV Vaccine Research Education Program; Retiring Council Member Perspectives; and Closing Remarks.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C-Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Franziska Grieder, D.V.M., Ph.D., Executive Secretary, Director, Office of Research Infrastructure Programs, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, 6701 Democracy Boulevard, Room 948, Bethesda, MD 20892, *GriederF@mail.nih.gov*, 301–435–0744.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/* where an agenda will be posted before the meeting date.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: July 7, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17163 Filed 7–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; 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 Eye Institute Special Emphasis Panel; NEI Mentored Training Grant Applications (K08, K23) .

Date: August 3–4, 2015.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Anne E. Schaffner, Ph.D., Chief, Scientific Review Branch Division of Extramural Research National Eye Institute, 5635 Fishers Lane, Suite 1300, Msc 9300, Bethesda, MD 20892–9300, (301) 451–2020, *aes@nei.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 8, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17161 Filed 7–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2005–20118]

Extension of Agency Information Collection Activity Under OMB Review: Maryland Three Airports: Enhanced Security Procedures for Operations at Certain Airports in the Washington, DC, Metropolitan Area Flight Restricted Zone

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0029, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day period soliciting comments, of the following collection of information on April 7, 2015, 80 FR 18643. This collection requires individuals to successfully complete a security threat assessment (1) to operate an aircraft to or from the three Maryland airports (Maryland Three Airports) that are located within the Washington, DC, Metropolitan Area Flight Restricted Zone (FRZ), or (2) to serve as an airport security coordinator at one of the three airports.

DATES: Send your comments by August 13, 2015. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (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 unless it displays a valid OMB control number. The ICR documentation is available at *http://www.reginfo.gov.* Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Maryland Three Airports: Enhanced Security Procedures for Operations at Certain Airports in the Washington, DC, Metropolitan Area Flight Restricted Zone.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 1652–0029.

Forms(s): TSA Form No. 418, MD–3 PIN Application.

Affected Public: Maryland Three airports and pilots operating an aircraft to or from one of the three Maryland airports, and airport employees who serve as an airport security coordinator at one of these three airports.

Abstract: 49 CFR part 1562 sets forth security measures that apply to flight operations at the Maryland Three airports (College Park Airport, Potomac Airfield, and Washington Executive/Hyde Field). TSA requires pilots who fly to or from, including flight operations between the Maryland Three airports, or airport employees who serve as security coordinators at one of these airports, to submit personal information and fingerprints. TSA will use the information and fingerprints to conduct a security threat assessment. A successful security threat assessment is required for a pilot to fly to or from the Maryland Three airports, or for an airport employee to serve as a security coordinator at one of these airports.

Number of Respondents: 312.

Estimated Annual Burden Hours: An estimated 4,290 [1] hours annually.

Dated: July 7, 2015.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2015–17183 Filed 7–13–15; 8:45 am]

BILLING CODE 9110–05–P

[1] TSA overestimated the burden reported in the 60-day notice, 28,080 annual hours. Current data indicates the estimated annual burden hours is 4,290.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2014–N141; FXES11120000–156–FF08ECAR00]

Endangered and Threatened Wildlife and Plants; Incidental Take Permit Application; Proposed Diversified Pacific Low-Effect Habitat Conservation Plan and Associated Documents, City of Redlands, San Bernardino County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application from Diversified Pacific (Applicant), for a 5-year incidental take permit (permit). The application includes the Applicant's proposed habitat conservation plan (HCP), as required by the Endangered Species Act of 1973, as amended (Act). If approved, the permit would authorize incidental take of the endangered San Bernardino Merriam's kangaroo rat in the course of routine construction activities associated with the development of residential houses in the City of Redlands. We invite public comment on the permit application and the proposed HCP, and on our preliminary determination that the HCP qualifies as ''low-effect'' for a categorical exclusion under the National Environmental Policy Act. To make this determination, we used our environmental action statement and low-effect screening form, which are also available for review.

DATES: To ensure consideration, please send your written comments by August 13, 2015.

ADDRESSES:

Obtaining Documents: You may request a copy of the incidental take permit application, draft EA, and proposed HCP by email, telephone, fax, or U.S. mail (see below). These documents are also available for public inspection by appointment during normal business hours at the office below. Please send your requests or comments by any one of the following methods, and specify ''Diversified Pacific Low-Effect HCP'' in your request or comment.

Submitting Comments: You may submit comments or requests for more information by any of the following methods:

Email: karin_cleary-rose@fws.gov. Include ''Diversified Pacific Low-Effect HCP'' in the subject line of your message.

Telephone: Karin Cleary-Rose, Palm Springs Fish and Wildlife Office, 760–322–2070 extension 206.

Fax: Karin Cleary-Rose, Palm Springs Fish and Wildlife Office, 760–322–4648, Attn.: Diversified Pacific Low-Effect HCP.

U.S. Mail: Karin Cleary-Rose, Palm Springs Fish and Wildlife Office, Attn.: Diversified Pacific Low-Effect HCP, U.S. Fish and Wildlife Service, 777 East Tahquitz Canyon Way, Suite 208, Palm Springs, CA 92262.

In-Person Viewing or Pickup of Documents, or Delivery of Comments: Call 760–322–2070 to make an appointment during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Karin Cleary-Rose, Inland Division Chief, Palm Springs Fish and Wildlife Office; telephone 760–332–2070 extension 206. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Introduction

The Applicant, Diversified Pacific, requests an incidental take permit under section 10(a)(1)(B) of the Act. If we approve the permit, the Applicant anticipates taking San Bernardino Merriam's kangaroo rat (*Dipodomys merriami parvus;* SBKR) as a result of permanent impacts to habitat that the species uses for breeding, feeding, and sheltering. Take of SBKR would be incidental to the Applicant's activities associated with the construction of residential houses in the City of Redlands, San Bernardino County, California. We published a final rule to list SBKR as endangered on September 24, 1998 (63 FR 51005). The rule became effective September 24, 1998. Final designation of Critical Habitat was published on April 23, 2002 (67 FR 19812). A 5-year review of the species was published on May 21, 2010 (75 FR 28636).

Background

Section 9 of the Act and our implementing Federal regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17 prohibit the ''take'' of wildlife species listed as endangered or threatened. Take of listed wildlife is defined under the Act as ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect listed species, or to attempt to engage in any such conduct'' (16 U.S.C. 1538). ''Harm'' includes significant habitat modification or degradation that actually kills or injures listed wildlife by significantly impairing essential behavioral patterns such as breeding, feeding, or sheltering (50 CFR 17.3). Under limited circumstances, we may issue permits to authorize incidental take of listed wildlife species, which the Act defines as take that is incidental to, and not the purpose of, the carrying out of otherwise lawful activities.

Regulations governing incidental take permits for threatened and endangered species are at 50 CFR 17.32 and 17.22, respectively. In addition to meeting other criteria, activities covered by an incidental take permit must not jeopardize the continued existence in the wild of federally listed wildlife or plants.

Applicant's Proposal

The Applicant requests a 5-year permit under section 10(a)(1)(B) of the Act. If we approve the permit, the Applicant anticipates taking SBKR as a result of the construction activities which will permanently impact 7.7 acres (ac) (3.12 hectares (ha)) of habitat the species uses for breeding, feeding, and sheltering. The take would be incidental to the Applicant's routine construction activities associated with the development of residential houses. The site is located southwest and southeast of the intersection of Pioneer Avenue and Judson Street in the City of Redlands, San Bernardino County, California. The proposed project site is surrounded by residential development and a mix of active and abandoned citrus orchards. An active municipal airport is located approximately 0.25 mile northeast of the project site.

Based upon focused surveys (2003, 2010, 2013, and 2015), 7.7 ac (3.12 ha) of the project site are occupied by SBKR. The Service has determined that the proposed development would result in incidental take of SBKR. No other federally listed species are known to occupy the project site.

To mitigate take of SBKR at the project site, the Applicant proposes one of two mitigation options.

Option A:

- SBKR captured prior to ground disturbance on the project site will be translocated to Cajon Creek Conservation Bank in the City of Muscoy, San Bernardino County, California. These animals will augment the current low-density population of SBKR found in the portion of the Bank where the relocation will occur. These animals will be monitored for 5 years, including annual reporting.
- The Applicant will provide funding for the perpetual maintenance and monitoring of approximately 20.9 ac of

occupied high-quality SBKR habitat in the City of Redlands, owned and conserved by the Redlands Land Conservancy into perpetuity.

Option B:

▪ SBKR captured prior to ground disturbance on the project site will be relocated to conserved habitat owned and managed by the Redlands Land Conservancy or other conserved property managed for the benefit of SBKR.

▪ The Applicant will provide funding for the perpetual maintenance and monitoring of 23.1 ac of occupied high-quality SBKR habitat in the City of Redlands, owned and conserved by the Redlands Land Conservancy for the benefit SBKR in perpetuity.

The determination as to which mitigation option will be implemented will be based upon the suitability of conserved site to receive the translocated population. This decision will be made by the Service prior to the initiation of ground disturbance on the project site.

Proposed Habitat Conservation Plan Alternatives

In the proposed HCP, the Applicant considers alternatives to the taking SBKR under the proposed action. Our proposed action is to issue an incidental take permit to the Applicant, who would implement the HCP. If we approve the permit, take of SBKR would be authorized for the Applicant's routine construction activities associated with the development of residential houses, in the City of Redlands. The Applicant's proposed HCP does identify a no-build alternative that would not result in incidental take of SBKR, but it is infeasible for the Applicant to accept this alternative as it would result in no development of the land or associated infrastructure improvements necessary to the City of Redlands and surrounding community. The proposed HCP also examined participation in a regional HCP as an alternative to an individual HCP. This alternative plan is infeasible because there is currently no completed regional plan, and the timing for completion of a regional plan is unknown.

Our Preliminary Determination

We invite comments on our preliminary determination that our proposed action, based on the Applicant's proposed activities, including the proposed minimization and mitigation measures, would have a minor or negligible effect on SBKR, and that the HCP qualifies as ''low effect'' as defined by our *Habitat Conservation Planning Handbook* (November 1996).

We base our determination that a HCP qualifies as a low-effect plan on the following three criteria:

(1) Implementation of the HCP would result in minor or negligible effects on federally listed, proposed, and candidate species and their habitats;

(2) Implementation of the HCP would result in minor or negligible effects on other environmental values or resources; and

(3) Impacts of the HCP, considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not result, over time, in cumulative effects to environmental values or resources that would be considered significant.

As more fully explained in our environmental action statement and associated low-effect screening form, the Applicant's proposed HCP qualifies as a low-effect HCP for the following reasons:

• The project is small in size and does not jeopardize the continued existence of the SBKR.

• The Applicant will mitigate impacts to the SBKR by translocating HCP individuals to a conserved property, monitoring those translocated individuals for 5 years, and funding the perpetual management of up to 23.1 acres of high-quality SBKR habitat at the conserved 100-acre Redlands Conservancy property in Redlands, California.

• This project proposes to increase the genetic diversity of SBKR at the translocation receiver site, fund the long-term management of conserved and occupied habitat, and increase the quality of habitat, in areas found outside of the 100-year floodplain, in two of the three designated critical habitat units for the species.

Therefore, our proposed issuance of the requested incidental take permit qualifies as a categorical exclusion under the National Environmental Policy Act, as provided by the Department of the Interior Manual (516 DM 2 Appendix 1, 516 DM 6 Appendix 1, and 516 DM 8.5(C)(2)). Based on our review of public comments we receive in response to this notice, we may revise this preliminary determination.

Public Review

The Service invites the public to comment on the permit application, including the proposed HCP, during the public comment period. Copies of the documents will be available during a 30-day public comment period (see **DATES**). If you wish to comment, you may submit your comments to the address listed in **ADDRESSES**. 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 may 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.

Next Steps

We will evaluate the proposed HCP and comments we receive to determine whether the permit application meets the requirements and issuance criteria under section 10(a) of the Act (16 U.S.C. 1531 *et seq.*). We will also evaluate whether issuance of a section 10(a)(1)(B) incidental take permit would comply with section 7 of the Act by conducting an intra-Service consultation. We will use the results of this consultation, in combination with the above findings, in our final analysis to determine whether or not to issue a permit. If the requirements and issuance criteria under section 10(a) are met, we will issue the permit to the Applicant for incidental take of SBKR.

G. Mendel Stewart,

Field Supervisor, Carlsbad Fish and Wildlife Office, Carlsbad, California.

[FR Doc. 2015–17209 Filed 7–13–15; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX15AE6000C1000]

Notice of Intent To Grant an Exclusive License

AGENCY: Geological Survey, Department of the Interior.

ACTION: Notice of intent to grant an exclusive license.

SUMMARY: The Notice is hereby given that the U.S. Geological Survey intends to grant to Glosten Associates, 1201 Western Avenue, Suite 200, Seattle, WA 98101, an exclusive license to practice the following: A system, method, and apparatus for treating ship ballast water.

DATES: Comments must be received fifteen (15) days from the effective date of this notice.

FOR FURTHER INFORMATION CONTACT: Benjamin Henry, Technology Enterprise Specialist, Office of Policy & Analysis, U.S. Geological Survey, 12201 Sunrise Valley Dr., MS 153, Reston, VA 20192, 703–648–4344.

SUPPLEMENTARY INFORMATION: It is in the public interest to license this invention, as Glosten Associates, submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen(15) days from the date of this published Notice, the U.S. Geological Survey Office of Policy & Analysis receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Katherine McCulloch,

Deputy Associate Director for Administration.

[FR Doc. 2015–17247 Filed 7–13–15; 8:45 am]

BILLING CODE 4311–AM–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[156A2100DD/AAKC001030/ A0A501010.999900 253G]

Renewal of Agency Information Collection for Loan Guarantee, Insurance and Interest Subsidy Program

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Assistant Secretary—Indian Affairs is seeking comments on the renewal of Office of Management and Budget (OMB) approval for the collection of information for the Loan Guarantee, Insurance, and Interest Subsidy Program authorized by OMB Control Number 1076–0020. This information collection expires October 31, 2015.

DATES: Submit comments on or before September 14, 2015.

ADDRESSES: You may submit comments on the information collection to: Mr. James West, Division of Capital Investment, Office of Indian Energy and Economic Development, U.S. Department of the Interior, 1951 Constitution Avenue NW., MS–20–SIB, Washington, DC 20245; email: *JamesR.West@bia.gov.*

FOR FURTHER INFORMATION CONTACT: David Johnson, phone: (202) 208–7253.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Office of Indian Energy and Economic Development (IEED) is seeking renewal of the approval for the information collection conducted under 25 CFR 103, implementing the Loan Guarantee, Insurance, and Interest Subsidy Program, established by 25 U.S.C. 1451 *et seq.* The information collection allows IEED to determine the eligibility and credit-worthiness of respondents and loans and otherwise ensure compliance with Program requirements. This information collection includes the use of several forms. A response is required to obtain and/or retain a benefit.

II. Request for Comments

The IEED requests your comments on this collection concerning: (a) The necessity of this information collection 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 (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) Ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. 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.

III. Data

OMB Control Number: 1076–0020.

Title: Loan Guarantee, Insurance, and Interest Subsidy, 25 CFR 103.

Brief Description of Collection: Submission of this information allows IEED to implement the Loan Guarantee, Insurance, and Interest Subsidy Program, 25 U.S.C. 1451 *et seq.,* the purpose of which is to encourage private lending to individual Indians and Indian organizations by providing lenders with loan guarantees or loan insurance to reduce their potential risk. The information collection allows IEED to determine the eligibility and credit-worthiness of respondents and loans and otherwise ensure compliance with Program requirements. This information collection includes the use of several forms. A response is required to obtain and/or retain a benefit.

Type of Review: Extension of currently approved collection.

Respondents: Lenders, including commercial banks, and borrowers, including individual Indians and Indian organizations.

Number of Respondents: 295.

Frequency of Response: On occasion, as needed.

Estimated Time per Response: Ranging from 0.5 to 2 hours.

Estimated Total Annual Hour Burden: 2,644 hours.

Estimated Total Annual Non-Hour Dollar Cost: $0.

Dated: July 8, 2015.

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2015–17065 Filed 7–13–15; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[15X L1109AF LLUTW000000 L14400000.FR0000; UTU–89553 24–1A]

Notice of Realty Action; Recreation and Public Purposes Act Classification for Conveyance of Public Lands in Utah County, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) has examined and found suitable for classification for conveyance under the Taylor Grazing Act, and the provisions of the Recreation and Public Purposes (R&PP) Act, as amended, 160 acres of public land in Utah County, Utah. Utah County proposes to develop a public shooting range facility on the land.

DATES: Comments regarding the proposed classification for conveyance of public land must be submitted to the Field Manager, Salt Lake Field Office, at the address below on or before August 28, 2015.

ADDRESSES: Written comments should be addressed to the Bureau of Land Management, Field Manager, Salt Lake Field Office, 2370 South Decker Lake Blvd., West Valley City, UT 84119. Comments may also be submitted by email at *ut_sl_comments@blm.gov* or fax 801–977–4397. Please reference

''Conveyance of Public Lands to Utah County for Establishment of a Public Shooting Range'' on all correspondence.

FOR FURTHER INFORMATION CONTACT: David Watson, Realty Specialist, Salt Lake Field Office, 801–977–4368, email: *dswatson@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 for the above individual. Replies are provided during normal business hours.

SUPPLEMENTARY INFORMATION: The following described public land has been examined and found suitable for classification for conveyance under Section 7 of the Taylor Grazing Act, 43 U.S.C. 315f, and the provisions of the R&PP Act as amended:

Salt Lake Meridian

T. 7 S., R. 1 W.,
Sec. 28, SW1/4.

The area described contains 160 acres in Utah County, Utah.

The land is not needed for any Federal purpose and is not of national significance. Conveyance is consistent with the BLM Pony Express Resource Management Plan—1990, and would be in the public interest. The BLM conducted a Phase II Environmental Site Assessment in November 2014, and no hazardous substances, petroleum products, or recognized environmental conditions were identified on the parcel. An Environmental Assessment (EA) was prepared to analyze Utah County's proposed plan of development and management for the shooting range facility.

The conveyance document, if issued, would be subject to the provisions of the R&PP Act and applicable regulations of the Secretary of the Interior and will contain the following reservations, terms, and conditions:

1. A right-of-way thereon for ditches or canals constructed by authority of the United States pursuant to the Act of August 30, 1890, 43 U.S.C. 945.

2. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove the minerals under applicable laws and such regulations as the Secretary of the Interior may prescribe, including all necessary access and exit rights.

3. The purchaser, by accepting the patent, agrees to indemnify, defend, and hold the United States harmless from any costs, damages, claims, causes of action, penalties, fines, liabilities, and judgments of any kind arising from the past, present, or future acts or omissions of the patentee, its employees, agents, contractors, or lessees, or any third party arising out of, or in connection with, the patentee's use, occupancy or operations on the patented real property. This indemnification and hold-harmless agreement includes, but is not limited to, acts and omissions of the patentee, its employees, agents, contractors, or lessees, or third party arising out of or in connection with the use and/or occupancy of the patented real property resulting in: (1) Violations of Federal, State, and local laws and regulations that are now, or in the future become, applicable to the real property; (2) Judgments, claims, or demands of any kind assessed against the United States; (3) Costs, expenses, or damages of any kind incurred by the United States; (4) Releases or threatened releases of solid or hazardous waste(s) and/or hazardous substances(s), as defined by Federal or State environmental laws, off, on, into, or under land, property, and other interests of the United States; (5) Other activities by which solid or hazardous substances or wastes, as defined by Federal and State environmental laws are generated, released, stored, used, or otherwise disposed of on the patented real property, and any cleanup response, remedial action, or other actions related in any manner to said solid or hazardous substances or wastes; or (6) Natural resource damages as defined by Federal and State law. This covenant will run with the patented real property and may be enforced by the United States in a court of competent jurisdiction.

4. A limited reversionary provision stating that the title shall revert to the United States upon a finding, after notice and opportunity for a hearing, that the patentee has not substantially developed the lands in accordance with the approved plan of development on or before the date 5 years after the date of conveyance. No portion of the land shall under any circumstance revert to the United States if any such portion has been used for solid waste disposal or for any other purpose which may result in the disposal, placement, or release of any hazardous substance.

5. Any other terms or conditions that the Authorized Officer determines appropriate to ensure public access and proper management of the Federal land and interests therein. Detailed information concerning this proposed project, including, but not limited to documentation relating to compliance with applicable environmental and cultural resource laws, is available for review at the BLM-Salt Lake Field Office at the address above.

On July 14, 2015, the public land described above is segregated from all forms of appropriation under the public land laws, including the general mining laws, except for conveyance under the R&PP Act.

Classification Comments: Interested parties may submit comments involving the suitability of the land for the proposed facility. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use (or uses) of the land, whether the use is consistent with local planning and zoning, or whether the use is consistent with State and Federal programs.

Application Comments: Interested parties may submit comments regarding the specific use proposed in the application and plan of development and management, and whether the BLM followed proper administrative procedures in reaching the decision to convey under the R&PP Act.

The BLM-Utah State Director will review any adverse comments and may sustain, vacate or modify this realty action. In the absence of any adverse comments, the classification of the land described in this notice will become effective September 14, 2015. The land will not be available for conveyance until after the decision becomes effective.

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.

Authority: 43 CFR 2741.5.

Lance C. Porter,

Acting Associate State Director.

[FR Doc. 2015–17233 Filed 7–13–15; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM EQD SSB–LLWO250000.L12200000.PM0000]

Proposed Information Collection: Surveys and Focus Groups To Support Outcomes-Focused Management

AGENCY: Bureau of Land Management, Interior.

ACTION: 60-day notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act, the Bureau of Land Management (BLM) will ask the Office of Management and Budget (OMB) to approve a collection of information to support recreation planning and management on public lands. The respondents will be recreationists visiting BLM-managed areas and members of communities near BLM-managed areas. The BLM invites public comments on this proposed collection. 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.

DATES: Please submit comments on the proposed information collection by September 14, 2015.

ADDRESSES: Comments may be submitted by mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Anna Atkinson, Washington, DC 20240.

Fax: to Anna Atkinson at 202–245–0050.

Electronic mail: amatkinson@blm.gov.

Please indicate ''Attn: 1004–XXXX'' regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Dr. Peter J. Fix, University of Alaska Fairbanks, Department of Natural Resources Management, Fairbanks, AK 99775–7200; email: *pjfix@alaska.edu*; or phone: 907–474–6926.

SUPPLEMENTARY INFORMATION:

I. Abstract

The BLM's recently issued planning and management guidelines for outdoor recreation in Handbook 8320–1 require managers to consider recreational visitors' and local community members' perspectives on the preferred characteristics of the resource area (*e.g.,* the type and amount of facilities/development, the number of other visitors present, etc.), the desired recreational experience, and longer-term benefits that might be realized. Information on these topics would assist with the development of a Land Use Plan (LUP) and monitor implementation of that LUP. The BLM proposes to collect information regarding these topics from two populations, recreational visitors and local community members, utilizing both surveys and focus groups.

For the surveys, the BLM would ask onsite, randomly selected recreational visitors 10 questions related to specific areas visited, activity participation, and basic demographics. After completion of those questions, the BLM would ask if they are interested in participating in a more in-depth mailback or internet survey. The mailback/internet survey would ask approximately 25 detailed questions about the trip, including: specific areas and attractions visited, activity participation, reasons for visiting and expected outcomes, evaluation of their visit, preferences for management of the area. Demographic questions would also be included. A reminder postcard/email will be sent after one week and a second survey will be sent to those who did not respond after two weeks. Surveys would be conducted at no more than 108 field offices.

As a random sample is not the goal of the focus groups, participants would be solicited through a variety of methods including agency lists of key stakeholder groups; outreach to BLM partners; BLM field office Web sites; flyers at visitor centers, information kiosks, BLM offices, public spaces of gateway communities, and local hotels and restaurants; and local newspaper articles. During the focus group, the BLM staff would lead participants through a series of topics regarding how often participants visit the site in question, what makes the site special to them/the local community, reasons for visiting, desired outcomes from the site, perceived positive/negative changes to the site, and the participants' thoughts on partnerships and management. Questions asked of participants would include a mix of open-ended and fixed-choice responses. Answers will be recorded by electronic clickers and/or paper forms. The BLM field offices would be selected to administer a visitor survey based on one of two conditions: (1) A forthcoming Land Use Plan (LUP) in which Special Recreation Management Areas (SRMA) might be considered (*e.g.,* high visitation, unique recreation opportunities, and unique natural features); or (2) a recently completed LUP in which SRMAs were designated. Gateway communities selected for focus groups would be those near a BLM field office with a forthcoming or recently completed LUP in which SRMAs will be considered or have been designated. The BLM would conduct a maximum of 648 focus groups over a 3-year period within the 12 states in which the BLM manages public lands.

The information gathered would be used to:

(1) Identify onsite experiences and longer-term outcomes desired/attained by visitors, local residents, and other relevant local stakeholders (*e.g.,* improved health, improved family bonding, economic diversity).

(2) Determine the field office's ability to respond to identified recreational issues and opportunities and understand the relationships among desirable/attained outcomes, activities, setting characteristics, and service delivery systems (within BLM-administered and other public lands as well as those provided by local communities) which those outcomes and activities depend on.

(3) Develop LUPs that ensure visitor services and facilities are appropriate to provide desired experiences, settings and longer-term outcomes.

(4) Monitor progress towards meeting SRMA objectives put forth in the LUP.

(5) Prepare and maintain a continuing inventory of outdoor recreation values, kept current so as to reflect changing conditions and identify new and emerging values.

II. Data

OMB Control Number: This is a new collection; 1004–XXXX.

Title: Surveys and Focus Groups to Support Outcomes-Focused Management.

Affected Public: Visitors to BLM resource areas, residents and other relevant stakeholders (*e.g.,* representatives of the business community, local government, etc.) of communities near BLM resource areas.

Respondent Obligation: Voluntary.

Frequency of Collection: Annually, no more than 36 BLM field offices would be surveyed (32 would be pre-LUP inventory/needs assessment surveys and 4 would be post-LUP monitoring surveys) and no more than 216 focus groups would be conducted.

Estimated Number of Annual Responses: pre-LUP inventory/needs assessment visitor surveys: 12,800; post-LUP monitoring visitor surveys: 1,600; focus groups: 5,400

Annual Burden Hours: We estimate the public reporting burden to be approximately 30 minutes per completed inventory/needs assessment visitor survey, 10 minutes per

monitoring survey, and 90 minutes per focus group meeting participant. Total annual burden hours: 14,772.

A. Type of response	B. Number of responses	C. Time per response (minutes)	D. Total hours (Col. B × Col. C/60 min)
Pre-RMP, onsite contact	20729	0.5	173
Pre-RMP, onsite survey (95% of above)	19692	5	1641
Pre-RMP follow-up contacts (100% of above)	19692	1	328
Pre-RMP follow-up completion of survey (65% of above)	12800	20	4267
Total for Pre-RMP			6409

A. Type of response	B. Number of responses	C. Time per response (minutes)	D. Total hours (Col. B × Col. C/60 min)
Post-RMP, onsite contact	2591	0.5	22
Post-RMP, onsite survey (95% of above)	2462	1	41
Post-RMP follow-up contacts (100% of above)	2462	1	41
Post-RMP follow-up completion of survey (65% of above)	1600	6	160
Total for Post-RMP			264

A. Type of response	B. Number of responses	C. Time per response (minutes)	D. Total hours (Col. B × Col. C/60 min)
Focus group	5400	90	8100

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: There are no identified ''non-hour cost'' burdens associated with this collection of information.

III. Request for Comments

Comments are invited on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including use of automated information techniques or other forms of information technology.

Please note that the comments submitted in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. 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 BLM in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Anna Atkinson,

Bureau of Land Management, Information Collection Clearance Officer (Acting).

[FR Doc. 2015–17231 Filed 7–13–15; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LL WO31000.L13100000.PB0000.15X]

Renewal of Approved Information Collection; OMB Control No. 1004–0185

AGENCY: Bureau of Land Management, Interior.

ACTION: 60-day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act, the Bureau of Land Management (BLM) invites public comments on, and plans to request approval to continue, the collection of information pertaining to Federal and Indian oil and gas leasing and drainage protection (except on the Osage Reservation). The Office of Management and Budget (OMB) has assigned control number 1004–0185 to this information collection.

DATES: Submit comments on the proposed information collection by September 14, 2015.

ADDRESSES: Comments may be submitted by mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: to Anna Atkinson at 202–245–0050.

Electronic mail: amatkinson@blm.gov.

Please indicate ''Attn: 1004–0185'' regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Jennifer Spencer, Division of Fluid Minerals, at 202–912–7146. Persons who use a telecommunication device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, to leave a message for Ms. Spencer.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act, 44 U.S.C. 3501–3521, require that interested members of the public and affected agencies be given an opportunity to comment on information

collection and recordkeeping activities (see 5 CFR 1320.8 (d) and 1320.12(a)). This notice identifies an information collection that the BLM plans to submit to OMB for approval. The Paperwork Reduction Act provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

The BLM will request a 3-year term of approval for this information collection activity. Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany our submission of the information collection requests to OMB.

The following information is provided for the information collection:

Title: Onshore Oil and Gas Leasing and Drainage Protection (43 CFR parts 3100, 3120, 3150, and Subpart 3162).

Forms: This is a nonform collection.

OMB Control Number: 1004–0185.

Abstract: The BLM proposes to extend the currently approved collection of information. The collection enables the BLM to monitor and enforce compliance with requirements pertaining to:

1. Statutory acreage limitations;
2. Waiver, suspension, or reduction of rental or royalty payments;
3. Various types of agreements, contracts, consolidations and combinations;
4. Subsurface storage of oil and gas;
5. Transfers, name changes, and corporate mergers;
6. Lease renewal, relinquishment, termination, and cancellation;
7. Leasing under railroads and certain other types of rights-of-way;
8. Lands available for competitive leasing; and
9. Drainage protection.

Frequency of Collection: All responses are submitted on occasion under this control number and are required to obtain or retain an oil and gas lease benefit.

Estimated Number and Description of Respondents Annually: 6,165 Federal and Indian oil and gas lessees, operators, record title owners, and holders of options to acquire an interest in Federal or Indian leases.

Estimated Reporting and Recordkeeping ''Hour'' Burden Annually: 25,395 hours.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden Annually: $462,284.

The following table details the individual components and respective hour burdens of this information collection request:

A. Type of response	B. Number of responses	C. Hours per response	D. Total hours (Column B × Column C)
Notice of option holdings 43 CFR 3100.3–1(b)	1	1	1
Option statement 43 CFR 3100.3–3	1	1	1
Proof of acreage reduction 43 CFR 3101.2–4(a)	1	1	1
Excess acreage petition 43 CFR 3101.2–4(a)	1	1	1
Ad hoc acreage statement 43 CFR 3101.2–6	1	1	1
Joinder evidence statement 43 CFR 3101.3–1	50	1	50
Waiver, suspension, or reduction of rental or royalty 43 CFR 3103.4–1	130	2	260
Communitization or drilling agreements 43 CFR 3105.2	535	2	1,070
Operating, drilling, or development contracts 43 CFR 3105.3	1	1	1
Joint operations, transportation of oil application 43 CFR 3105.4	1	1	1
Subsurface storage application 43 CFR 3105.5	1	1	1
Consolidation of leases 43 CFR 3105.6	35	1	35
Heirs and devisees statement 43 CFR 3106.8–1	90	1	90
Change of name 43 CFR 3106.8–2	160	1	160
Corporate merger 43 CFR 3106.8–3	1,755	1	1,755
Lease renewal application 43 CFR 3107.8	1	1	1
Relinquishment 43 CFR 3108.1	90	1	90
Class I reinstatement petition 43 CFR 3108.2–2	35	3	105
Class II reinstatement petition 43 CFR 3108.2–3	30	3	90
Class III reinstatement petition 43 CFR 3108.2–4	1	1	1
Application for lease under right-of-way 43 CFR 3109.1	5	8	40
Lands available for competitive leasing 43 CFR 3120.1–1(e)	1,750	8	14,000
Protests and appeals 43 CFR 3120.1–3	380	8	3,040
Preliminary drainage protection report 43 CFR 3162.2–9	1,000	2	2,000
Detailed drainage protection report 43 CFR 3162.2–9	100	24	2,400
Additional drainage protection report 43 CFR 3162.2–9	10	20	200
Totals	6,165	.....	25,395

Before including your address, phone number, email address, or other person identifying information in your comment, you should be aware that your entire comment—including your person 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.

Anna Atkinson,

Acting Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2015–17230 Filed 7–13–15; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO350000.L14400000.PN0000]

Renewal of Approved Information Collection

AGENCY: Bureau of Land Management, Interior.

ACTION: 30-day notice and request for comments.

SUMMARY: The Bureau of Land Management (BLM) has submitted an information collection request to the Office of Management and Budget (OMB) to continue the collection of information from individuals who want to make a desert land entry to reclaim, irrigate, and cultivate arid and semiarid public lands administered by the BLM in the western States. The Office of Management and Budget (OMB) previously approved this information collection activity, and assigned it control number 1004–0004.

DATES: The OMB is required to respond to this information collection request within 60 days but may respond after 30 days. For maximum consideration, written comments should be received on or before August 13, 2015.

ADDRESSES: Please submit comments directly to the Desk Officer for the Department of the Interior (OMB #1004–0004), Office of Management and Budget, Office of Information and Regulatory Affairs, fax 202–395–5806, or by electronic mail at *OIRA_submission@omb.eop.gov.* Please provide a copy of your comments to the BLM. You may do so via mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Anna Atkinson, Washington, DC 20240.

Fax: to Anna Atkinson at 202–245–0050.

Electronic mail: amatkinson@blm.gov.

Please indicate ''Attn: 1004–0004'' regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Flora Bell, at 202–912–7347. Persons who use a telecommunication device for the deaf may call the Federal Information Relay Service at 1–800–877–8339, to leave a message for Ms. Bell. You may also review the information collection request online at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act (44 U.S.C. 3501–3521) and OMB regulations at 5 CFR part 1320 provide that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond. In order to obtain and renew an OMB control number, Federal agencies are required to seek public comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d) and 1320.12(a)).

As required at 5 CFR 1320.8(d), the BLM published a 60-day notice in the **Federal Register** on February 11, 2015 (80 FR 7631), and the comment period ended April 13, 2015. The BLM received no comments. The BLM now requests comments on the following subjects:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;

2. The accuracy of the BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;

3. The quality, utility and clarity of the information to be collected; and

4. How to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Please send comments as directed under **ADDRESSES** and **DATES**. Please refer to OMB control number 1004–0004 in your correspondence. 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.

The following information pertains to this request:

Title: Desert Land Entry Application (43 CFR part 2520).

Form: Form 2520–1, Desert Land Entry Application.

OMB Control Number: 1004–0004.

Abstract: The BLM needs to collect the information in order to determine if an applicant is eligible to make a desert land entry to reclaim, irrigate, and cultivate arid and semiarid public lands in the States of Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, North Dakota, South Dakota, Utah, Washington, and Wyoming.

Frequency: On occasion.

Description of Respondents: 3 applicants for desert land entries annually.

Estimated Number of Responses Annually: 6 hours annually.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden Annually: $45 annually.

The estimated burdens are itemized in the following table:

A. Type of response	B. Number of responses	C. Hours per response	D. Total hours (Column B × Column C)
Desert Land Entry Application 43 CFR Part 2520 Form 2520–1	3	2	6

Anna Atkinson,

Acting Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2015–17232 Filed 7–13–15; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–WARO–14100; PPNEWARO00/ PPMPSAS1Z.YP0000]

Official Trail Marker for the Washington-Rochambeau Revolutionary Route National Historic Trail

AGENCY: National Park Service, Interior.

ACTION: Notice of designation.

SUMMARY: This notice prescribes the official trail marker insignia of the Washington-Rochambeau Revolutionary Route National Historic Trail. The original graphic image was developed in 2010. It first came into public use in 2011. This publication accomplishes the official designation of the insignia now in use by the National Park Service.

FOR FURTHER INFORMATION CONTACT: Joe DiBello, Superintendent; Washington-Rochambeau Revolutionary Route National Historic Trail; National Park Service; 200 Chestnut Street; Philadelphia, PA 19106; *joe_dibello@nps.gov;* (215) 597–1581.

SUPPLEMENTARY INFORMATION: The primary author of this document is Joe DiBello, Superintendent of the Washington-Rochambeau Revolutionary Route National Historic Trail.

The insignia depicted below is prescribed as the official trail marker logo for the Washington-Rochambeau Revolutionary Route National Historic Trail, administered by the National Park Service, Washington-Rochambeau Revolutionary Route National Historic Trail office, Philadelphia PA. ''Authorization to use this trail marker is controlled by the Secretary of the Interior, acting through the Superintendent of the national historic trail.''

In making this prescription, notice is hereby given that whoever manufactures, sells, or possesses this insignia, or any colorable imitation thereof, or photographs or prints or in any other manner makes or executes any engraving, photograph or print, or impression in the likeness of this insignia, or any colorable imitation thereof, without written authorization from the United States Department of the Interior is subject to the penalty provisions of section 701 of Title 18 of the United States Code.

Authority: Section 5204 of the Omnibus Public Land Management Act of 2009, Pub. L. 111–11, 123 Stat. 991, 1158; National Trails System Act, 161246(c); and Protection of Official Badges, Insignia, etc., 18 U.S.C. 701.

Dated: December 30, 2014.

Joseph DiBello,

Superintendent, Washington-Rochambeau Revolutionary Route National Historic Trail.

Editorial Note: This document was received for publication by the Office of the Federal Register on July 9, 2015.

[FR Doc. 2015–17234 Filed 7–13–15; 8:45 am]

BILLING CODE 4310–WV–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–CAJO–18378; PPNCCHOHS0–PPMPSPD1Z.YM0000]

Request for Nominations for the Captain John Smith Chesapeake National Historic Trail Advisory Council

AGENCY: National Park Service, Interior.

ACTION: Request for nominations.

SUMMARY: The National Park Service, U.S. Department of the Interior, is seeking nominations for individuals to be considered for appointment to the Captain John Smith Chesapeake National Historic Trail Advisory Council (Council).

DATES: Written nominations must be received by August 13, 2015.

ADDRESSES: Send nominations to: Christine Lucero, Partnership Coordinator, Captain John Smith Chesapeake NHT, P.O. Box 374, Yorktown, VA 23690 or via email at *christine_lucero@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Christine Lucero, Partnership Coordinator, Captain John Smith Chesapeake NHT, P.O. Box 374, Yorktown, VA 23690 or via email at *christine_lucero@nps.gov.*

SUPPLEMENTARY INFORMATION: The Council was established under the National Trails System Act (16 U.S.C. 1241 to 1251, as amended).

The purpose of the Council is to consult with the Secretary of the Interior on matters relating to the Captain John Smith Chesapeake National Historic Trail, including, but not limited to, the selection of rights-of-way, standards for the erection and maintenance of markers along the Trail, and interpretation and administration of the Trail.

The Council shall not exceed 35 members and will be appointed by the Secretary as follows:

a. The head of each Federal department or independent agency administering lands through which the trail route passes, or a designee;

b. A member to represent each State through which the trail passes, and such appointments will be made from recommendations of the Governors of such States; and

c. One or more members to represent private organizations, including corporate and individual landowners and land users, which, in the opinion of the Secretary, have an established and recognized interest in the trail. Such appointments will be made from recommendations of the heads of such organizations.

Members will be appointed by the Secretary of the Interior for a term of two years. Members of the Council receive no pay, allowances, or benefits by reason of their service on the Council. However, while away from their homes or regular places of business in the performance of services for the Council as approved by the Designated Federal Officer (DFO), members may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in Government service are allowed such expenses under Section 5703 of Title 5 of the United State Code.

Some Council members may serve as Special Government Employees, which requires the completion of an annual financial disclosure report and annual ethics training.

Individuals who are federally registered lobbyists are ineligible to serve on all FACA and non-FACA boards, committees, or councils in an individual capacity. The term ''individual capacity'' refers to individuals who are appointed to exercise their own individual best judgment on behalf of the government, such as when they are designated Special Government Employees, rather than being appointed to represent a particular interest.

Meetings will take place at such times as designated by the DFO. Members are expected to make every effort to attend all meetings. Members may not appoint deputies or alternates.

Seeking Nominations for Membership

We are seeking nominations for Council members in all categories. The terms of the majority of the 26 members will expire on July 9, 2015. All those interested in membership, including current members whose terms are expiring, must follow the same nomination process.

Nominations should include a resume providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to make an informed decision regarding meeting the membership requirements of the Council, and to permit the Department to contact a potential member.

Dated: June 19, 2015.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2015–17215 Filed 7–13–15; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR02312000, 15XR0680A3, RX.04167000.6000000,]

Notice of Intent To Prepare a Draft Environmental Impact Statement for the Long-Term Plan To Protect Adult Salmon in the Lower Klamath River, Humboldt County, California

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of intent and scoping meetings.

SUMMARY: The Bureau of Reclamation will prepare an Environmental Impact Statement (EIS) to evaluate the effects of the Long-Term Plan for the Protection of Adult Salmon in the lower Klamath River. The proposed action is to increase lower Klamath River flows to reduce the likelihood, and potentially reduce the severity, of any fish die-off in future years due to crowded holding conditions for pre-spawn adults, warm water temperatures, and presence of disease pathogens as the likely major factors contributing to the adult mortalities. The proposed increased flows would be provided primarily from releases of water stored in Trinity Reservoir on the main stem of the Trinity River, with the potential for some of the flows to be derived from the Klamath River above the confluence with the Trinity River depending on existing hydrologic and related environmental conditions. The purpose of the proposed action is to reduce the likelihood, and potentially reduce the severity, of any Ich epizootic event that could lead to an associated fish die-off in future years. The need is based on the past extensive fish die-off in 2002.

DATES: Submit written comments on the scope of the draft EIS by August 20, 2015. Four public scoping meetings will be held on the following dates and times:

- Wednesday, August 5, 2015, 5:30 to 7 p.m., Arcata, CA.
- Thursday, August 6, 2015, 5:30 to 7 p.m., Weaverville, CA.
- Tuesday, August 11, 2015, 5:30 to 7 p.m., Klamath Falls, OR.
- Wednesday, August 12, 2015, 5:30 to 7 p.m., Sacramento, CA.

ADDRESSES: Send written comments on the scope of the draft EIS, or requests to be added to the EIS mailing list, to Mr. Paul Zedonis, Northern California Area Office, Bureau of Reclamation, 16349 Shasta Dam Boulevard, Shasta Lake, CA 96019; or by email to *sha-slo-klamath-LTP@usbr.gov.* Environmental documents for the Long-Term Plan EIS will be available for review and download at *http://www.usbr.gov/mp/nepa/nepa_projdetails.cfm?Project_ID=22021.*

The public scoping meetings will be held at the following locations:

- Arcata—Red Roof Inn, 4975 Valley W Blvd., Arcata, CA 95521.
- Weaverville—Trinity County Library, 351 Main Street, Weaverville, CA 96093.
- Klamath Falls—Shilo Inn, 2500 Almond Street, Klamath Falls, OR 97601.
- Sacramento—Cafeteria Conference Rooms 1001 & 1002, 2800 Cottage Way, Sacramento, CA 95825.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Zedonis, Bureau of Reclamation, 530–275–1554; or by email at *sha-slo-klamath@usbr.gov.*

SUPPLEMENTARY INFORMATION:

Background

In August and September 2002, an estimated 170,000 fall-run Chinook salmon returned to the Klamath River, and a significant number of adult Chinook salmon (~33,000) and other salmonids died prematurely in the lower Klamath River. This included an estimated 344 coho salmon listed as threatened under the Endangered Species Act. Federal, tribal, and state biologists studying the die-off concluded that: (1) Pathogens *Ichthyophthirius multifiliis* (Ich) and *Flavobacterium columnare* (Columnaris) were the primary causes of death to fish; and (2) warm water temperatures, low water velocities and volumes, high fish density, and long fish residence times likely contributed to the disease outbreaks and subsequent mortalities. Flows in the lower Klamath averaged about 2,000 cubic feet per second (cfs) during September 2002.

In 2003, 2004, 2012, and 2013 predictions of large runs of fall-run Chinook salmon to the Klamath River Basin and drier than normal hydrologic conditions prompted the Bureau of Reclamation (Reclamation) to arrange for late-summer flow augmentation to improve environmental conditions in the lower Klamath River to reduce the probability of a disease outbreak. The State Water Resources Board has advised Reclamation that, as the operator of Trinity Dam, Reclamation may bypass and/or release water for various purposes, including releases made to improve instream conditions for the benefit of aquatic resources, without State Board approval. In these years, 38 thousand acre-feet (TAF) of supplemental water was released from Trinity Reservoir in 2003, 36 TAF in 2004, 39 TAF in 2012, and 17.5 TAF in 2013. In 2013 a legal challenge occurred over implementing the flow augmentation action, which subsequently resulted in a delay. Also, accretions were greater than forecasted and ultimately lead to the smaller volume used in that year. General observations regarding the effectiveness of the sustained higher releases are that no significant disease or adult mortalities occurred suggesting flow augmentation was effective at meeting its intended purpose. National Environmental Policy Act (NEPA) reviews (Environmental Assessments) were conducted in each of these years concluding in Findings of No Significant Impacts.

The initial decision in 2014 was to not provide augmentation flows on a preventive basis due to the small run size and lack of any disease outbreak. However, during the first half of August, hydrologic conditions and observed fish health worsened. It was reported the adult return began much earlier than expected, and thousands of fish were stalled at the mouth of Blue Creek on the lower Klamath River mainstem. After consulting with fish agencies, Reclamation determined that an emergency release from Trinity Reservoir was necessary to avert a potentially significant fish loss. In response to a continued and unprecedented concern that a fish die-off was imminent, Reclamation

extended the release of augmentation flows on an emergency basis for a longer duration (and higher magnitude) than in prior years based on the emergency criteria established for the releases. In 2014 the total volume released was 64 TAF. As in prior years of implementing flow augmentation, and despite the unprecedented high incidence of infection, no significant mortalities of fish occurred. In 2014 due to the rapid worsening of conditions in the lower Klamath River and the documented occurrence of disease, NEPA compliance was implemented through the ''Emergency'' provisions as identified by the Council of Environmental Quality.

In response to the need to provide augmentation flows in several of the past years, and the indication that such flows will be needed in future years, Reclamation committed to developing a long-term plan to address this need along with the appropriate NEPA compliance. Reclamation has determined an EIS is the appropriate level of NEPA compliance for the Long-Term Plan, and will serve as the Lead Agency.

Additional Information

The purpose of the scoping process is to solicit early input from the public regarding the development of reasonable alternatives and potential environmental impacts to be addressed in the EIS for the lower Klamath River Long-Term Plan. Written comments are requested to help identify alternatives and issues that should be analyzed in the EIS. Federal, State and local agencies, Tribes, and the general public are invited to participate in the environmental review process.

Special Assistance for Public Scoping Meetings

Requests for sign language interpretation for the hearing impaired and all other special assistance needs to participate in the meetings may be submitted by any of the following methods at least five working days before the meeting:

- *Email to:* Mr. Paul Zedonis, *sha-slo-klamath-LTP@usbr.gov*.
- *U.S. Mail to:* Mr. Paul Zedonis, Northern California Area Office, Bureau of Reclamation, 16349 Shasta Dam Boulevard, Shasta Lake, CA 96019.
- *Telephone:* Mr. Paul Zedonis, 530–275–1554.

Public Disclosure

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.

Dated: June 12, 2015.

Pablo R. Arroyave,

Deputy Regional Director, Mid-Pacific Region.

[FR Doc. 2015–17208 Filed 7–13–15; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–15–021]

Government in the Sunshine Act Meeting Notice; Change of Time to Government in the Sunshine Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

DATE: July 16, 2015.

ORIGINAL TIME: 2 p.m.

NEW TIME: 3 p.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

In accordance with 19 CFR 201.35(d)(2)(i), the Commission hereby gives notice that the Commission has determined to change the time of the meeting of July 16, 2015, from 2 p.m. to 3 p.m.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting. Earlier notification of this change was not possible.

By order of the Commission.

Issued: July 10, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–17378 Filed 7–10–15; 4:30 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09–62]

Odette L. Campbell, M.D.; Decision and Order

On October 26, 2010, an Agency Administrative Law Judge issued the attached Recommended Decision.[1] Therein, the ALJ rejected, as unsupported by substantial evidence, the Government's allegations that: (1) Respondent had unlawfully prescribed methadone to a patient for the purpose of treating the patient's opioid addiction; (2) Respondent had issued a controlled substance prescription to an employee for the purpose of obtaining the controlled substance for her own use; and (3) Respondent could not account for 13 bottles or 390 dosage units of Suboxone. R.D., at 32–43.

However, the ALJ also found that the Government had proved several allegations. These included that: (1) Respondent possessed controlled substances at an unregistered location when she moved her office without obtaining a modification of her registration; (2) Respondent occasionally allowed patients to return controlled substances to her if they did not like the medication or had an adverse reaction to it; and (3) Respondent failed to keep required records (including DEA Form-222s) for her receipts of Demerol, a schedule II controlled substance, as well as both inventories and dispensing logs for Ambien (zolpidem) and Provigil (modafinil), both being schedule IV controlled substances.[2] *Id.* at 30–32; 44; 46–49.

With respect to the latter finding, the ALJ noted that while recordkeeping violations alone can support an order of revocation, Respondent's violations ''occurred over a comparatively short period of time, with substantially fewer controlled substances [than in those cases where revocation was ordered], and with no evidence of actual diversion of any controlled substances.'' *Id.* at 52. The ALJ thus concluded that while ''Respondent's errors and conduct clearly were neglectful and serious during the relevant time period,'' he then reasoned that they were ''likely due in part to ongoing issues including eviction from her registered office, employee problems, and an office break-in and theft'' and that an order of revocation would be disproportionate to the misconduct which was proved. *Id.*

[1] All citations to the Recommended Decision are to the slip opinion as issued by the ALJ.

[2] The ALJ also noted that ''the evidence indicates that Respondent did not follow adequate security procedures'' in that the controlled substance were not stored ''in a securely locked, substantially constructed cabinet'' and ''Respondent did not maintain control over the key.'' R.D. at 45. However, the ALJ declined to consider the evidence on the ground that the Government did not provide adequate notice in either the Show Cause Order or its Prehearing Statement, notwithstanding that Respondent did not object to the testimony. While the record arguably support a finding that the issue was litigated by consent, *see CBS Wholesale Distributors,* 74 FR 36746, 36750 (2009), the Government did not take exception to the ALJ's ruling. I therefore do not consider the evidence.

The ALJ did not explain why these issues prevented Respondent from maintaining proper records for all of the controlled substances she obtained and dispensed or for ensuring that she obtained a new registration after she moved into her new office.

The ALJ further found that ''Respondent's testimony as a whole demonstrates that she has sufficiently accepted responsibility for her actions and omission with regard to a revocation penalty.'' *Id.* However, he then found that her ''explanation of past errors and demonstrated plan to avoid future violations is insufficient to support an unconditional registration.'' *Id.*

The ALJ thus recommended that Respondent's registration not be revoked and that she be granted a registration subject to the conditions that she submit, no later than one year after issuance of a new registration, documentation reflecting that she had successfully completed ''accredited training . . . in the proper maintenance, inventory, and recordkeeping requirements for controlled substances.'' *Id.* at 52–53. The ALJ also recommended that Respondent's registration be subject to the condition that for one year after the issuance of a new registration, she submit a log of all controlled substances ''received, maintained and dispensed'' by her each quarter. *Id.* at 53.

The Government filed an Exception to the ALJ's decision. Thereafter, the record was forwarded to this Office for final agency action.

On review, it was noted that Respondent's registration was due to expire on August 31, 2010, one week after the hearing in this matter was conducted. GX 1. Moreover, at the hearing, the Government argued that the proceeding was moot because under an agency regulation, Respondent was required to file her renewal application at least 45 days before her registration expired in order for her registration to remain in existence past its expiration date. Tr. 9. The Government further argued that Respondent had not filed a renewal application for a Texas Controlled Substances Registration with the Texas Department of Public Safety (DPS), and thus, even if Respondent prevailed in the DEA hearing, she would not be entitled to be registered because she lacked state authority as a result of her failing to file for a renewal of her DPS registration.[3] *Id.* at 9–10. Respondent disputed the Government's contention, asserting that she had filed an application with DPS six months earlier as well as the day before the hearing; she also asserted that she could not obtain a new DPS registration without a DEA registration. *Id.* at 10.

The Government then noted that Respondent had not even attempted to submit a renewal application. *Id.* The Government further argued that because Respondent would still not possess a state license after the DEA proceeding was concluded, there were no collateral consequences which would preclude a finding of mootness. *Id.* at 11. Respondent then offered to ''file a DEA application today after the hearing.'' *Id.* at 12. The ALJ then denied the Government's motion and proceeded to conduct a hearing.

Several months later, Respondent's counsel faxed to the ALJ a copy of a printout from the DPS's Web site which showed that on November 15, 2010, Respondent had been granted a new DPS registration. However, because there was no evidence that Respondent had filed a renewal application, the Administrator ordered the parties to address whether the case was moot. Order, at 2. (June 28, 2011).

Also, having taken official notice that on August 27, 2010, the Texas Medical Board had issued a formal complaint against Respondent charging her with multiple violations of Texas laws based on her prescribing of controlled substances to 19 patients,[4] the Administrator ordered the parties to address the status of the Board proceedings. *Id.* Thereafter, the Government notified this Office that Respondent had, in fact, finally filed a renewal application on November 19, 2010, seven days after it filed its Exception and before the ALJ forwarded the record. Gov. Submission in Response to Order, at 2. The Government further notified this Office that the Medical Board matter was still pending and had gone to mediation, but that further mediation had been postponed and that a date had not been set for further mediation. In her filing, Respondent denied having engaged in non-therapeutic prescribing and asserted that the State's allegation were ''unsubstantiated.''

In its filing, the Government further notified this Office that Respondent had been indicted for health care fraud and was schedule to go to trial in October 2011. Gov.'s Submission at 2 n.1. This Office subsequently determined that on August 19, 2010—approximately one week before the DEA hearing—Respondent was indicted on 30 counts of Health Care Fraud, as well as five counts of altering records during a federal investigation. *See* Docket Sheet at 1, *United States* v. *Campbell,* No. 4:10cr182 (E.D. Tx.).[5]

[3] This proceeding commenced with the issuance of an Order to Show Cause and Immediate Suspension of Registration. Thereafter, both the Texas Medical Board and the Texas Department of Public Safety suspended Respondent's medical license and state controlled substance registration. Accordingly, the Government moved for summary disposition on the ground that because she lacked state authority, she could not be registered with DEA, and thus, her DEA registration should be revoked. The ALJ granted the Government's motion, recommended that her DEA registration be revoked, and thereafter forwarded the then-existing record to this Office for final agency action.

While the matter was under review, Respondent submitted a letter to the ALJ (which was then forwarded to this Office) asserting that the medical board had reinstated her medical license. The Government argued, however, that Respondent was still without state authority because her DPS registration had been revoked and she had not filed a new application. Respondent then submitted a letter in which her counsel asserted that she could not be reinstated by the DPS unless DEA reinstated her registration.

While the parties had engaged in an exchange of letters with each other and the ALJ, neither party filed a motion seeking relief from this Office notwithstanding that the record had since been forwarded to it. The Administrator therefore ordered that if the Government still sought a final order based on Respondent's lack of state authority, it should file a properly supported motion seeking such relief and serve it on Respondent.

Thereafter, the Government filed a request for final agency action, noting that Respondent's DPS registration had not been reinstated, which it supported with appropriate evidence. In opposition, Respondent argued that it was fundamentally unfair and a denial of due process to revoke her DEA registration based on the DPS's action, because the DPS's action was based on the unsubstantiated allegations of the DEA Immediate Suspension Order.

On review, the Administrator noted that it appeared that under Texas law and regulations, Respondent was not entitled to a hearing before the DPS to challenge either the DPS's suspension or the denial of her application for a new registration. *See* Tex. Health & Safety Code § 481.063(e)(3) & (h); *id.* § 481.066(g); *see also* Tex. Admin Code § 13.272(h). Because, if this was so, revoking her registration based on her lack of state authority would preclude her from ever being able to challenge the basis of the Immediate Suspension Order, the Administrator remanded the case to the ALJ with the instruction to first determine whether the DPS would provide her with a hearing on the allegations. The Administrator further instructed that if the DPS had provided or would provide a hearing, the Government could renew its motion for summary disposition; however, in the event DPS would not provide a hearing, the ALJ was to conduct a hearing on the allegations of the Order to Show Cause and Immediate Suspension of Registration.

[4] While the Medical Board had restored Respondent's medical license in October 2009, on August 30, 2010, the Board had filed a formal complaint against her which charged her, *inter alia,* with engaging '' 'in a pattern of non-therapeutic prescribing of controlled substances and/or dangerous drugs.' '' Respondent's Resp. to the Govt's Req. for Status Update, at 6 (quoting Complaint at 2, *In re Campbell,* No 10–6060.MD (Tex. Med. Bd., Aug. 27, 2010)). This proceeding was, however, resolved through mediation and dismissed on the motion of the Texas Medical Board. *See* Order No. 3, *In re Campbell* (Tex. SOAH. Mar 19, 2012).

[5] This Office has also taken Official Notice of the Docket Sheet Entries in this proceeding, as well as

Continued

Under 42 U.S.C. 1320a–7(a)(3), had Respondent been convicted of even a single count of Health Care Fraud, she would have been subject to mandatory exclusion ''from participation in any Federal health care program.'' Moreover, just as a mandatory exclusion is a ground to suspend or revoke an existing registration, it is also ground to deny an application. *See* 21 U.S.C. 824(a)(5) (authorizing suspension or revocation of a registration ''upon a finding that the registrant . . . has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–(7)(a) of Title 42''); *see also Pamela Monterosso,* 73 FR 11146, 11148 (2008) (noting that ''the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered in deciding whether to grant or deny an application under section 303'') (citing cases). Accordingly, this case was held in abeyance pending the final disposition of the Health Care Fraud charges against Respondent.

On March 27, 2013, the United States Attorney offered Respondent a pre-trial diversion agreement, pursuant to which prosecution of the charges would be deferred for a period of 12 months provided she complied with the agreement. The United States Attorney further agreed that upon her ''fulfilling all the terms and conditions of the Agreement'' for the 12-month period, the charges would be dismissed. The Government does not dispute that Respondent complied with the agreement and even submitted a copy of the Certification of Completion of Pretrial Diversion Program, which recommended that the charges against her be dismissed when the diversion agreement expired on March 26, 2014. However, months later, the case still remained open according to the district court docket sheet.

Moreover, during the preparation of this decision, this Office determined that on September 19, 2014, the Texas Medical Board filed a new formal complaint against Respondent seeking the revocation of her medical license. The complaint was based in part on the 2010 indictment for health care fraud and her subsequent entrance into the pre-trial diversion agreement, as well as the results of a July 2013 Lifeguard assessment which found that she ''lacked the fitness to safely practice medicine'' in that she ''displayed a less than adequate knowledge base with many of the practice-based competencies tested, as well as deficiencies in prescriptive practices.'' Mediated Agreed Order, at 1 & 4; *In re Campbell,* (Tx. Med. Bd. Feb. 13, 2015). Because possessing state authority to dispense controlled substances is a prerequisite for holding a DEA registration, *see* 21 U.S.C. 802(21) & 823(f), this proceeding was again held in abeyance pending the resolution of the Board proceeding.

Thereafter, the matter was referred to mediation, and on February 13, 2015, the Board and Respondent entered into a Mediated Agreed Order. *Id.* Therein, the Board found that Respondent has successfully completed the pre-trial diversion agreement, that she had ''complied with all recommendations made as a result of the Lifeguard assessment,'' and that she had ''produced evidence of her ongoing efforts to advance her medical knowledge.'' *Id.* Respondent was thus allowed to retain her state license.

The Government's Exception

As noted above, the Government filed an Exception to the ALJ's Recommended Decision. Because Respondent had allowed her registration to expire and had not filed a renewal application, the Government argued that the Agency should reject the ALJ's ultimate recommendation that Respondent's registration should not be revoked and that she should be granted a restricted registration. Exception, at 2. Noting that the ALJ cited no precedent for maintaining a DEA registration beyond its expiration date where the registrant failed to file a timely renewal application, the Government argued that ''the only possible recommendation to be made by the ALJ is whether the Deputy Administrator should affirm the Immediate Suspension Order issued simultaneously with the Order to Show Cause.'' *Id.* at 1–2. However, as found above, Respondent filed an application for a new registration prior to the ALJ's forwarding of the record to this Office. Thus, notwithstanding that Respondent's registration expired on August 31, 2010, there is an application to act upon.

The Government further contended that ''the issuance of the Immediate Suspension Order'' should be affirmed ''for the reasons discussed in the Government's Post-Hearing Brief.'' Exception, at 2. While Respondent did not file her application until after she received the ALJ's largely favorable decision and the Government filed its Exception, I assume that the Government would likewise seek denial of the application ''for the reasons discussed in the Government's Post-Hearing Brief.'' *Id.*

However, the Agency regulation on Exceptions is quite specific in requiring that a ''party shall include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcripts and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66(a). The purpose of Exceptions is to allow a party to identify the specific factual findings and legal conclusions of the ALJ which it believes to be erroneous. *Cf. The Attorney General's Manual on the Administrative Procedure Act* 87 n.5 (1947) (quoting *Final Report of the Attorney General's Committee on Administrative Procedure,* at 52) (''Too often . . . exceptions are blanket in character, without reference to pages in the record and without in any way narrowing the issues. They simply seek to impose upon the agency the burden of complete reexamination. Review of the hearing commissioner's decision should in general and in the absence of clear error be limited to grounds specified in the appeal.'').

Here, the ALJ previously considered the Government's post-hearing brief and found its evidence unpersuasive on several critical issues, including the allegations that Respondent had issued a prescription to an employee that was actually for her own use and that Respondent was prescribing methadone to treat opioid addiction. With respect to each allegation, the Government relied on unsworn hearsay statements, which the ALJ found were not sufficiently reliable when weighed against the testimony of witnesses which he found credible and the documentary evidence. Because the Government has failed to identify in its Exception why the ALJ erred in reaching these findings, I adopt the ALJ's findings.

As noted above, the ALJ also rejected the Government's evidence regarding the accountability audit. Here again, the Government has failed to identify in its Exception why the ALJ erred in reaching his finding. Indeed, the Government did not even submit the audit computation chart, let alone such documentation as the closing inventory taken by the Investigator. Thus, I must reject the Government's contention.

The ALJ did, however, find that Respondent relocated her practice and possessed and distributed controlled substances at her new location without

Document #27, which sets forth the disposition of an October 6, 2011 hearing conducted by the district court on Respondent's violation of the conditions of her pretrial release, wherein the Court modified the conditions of her release to prohibit her from writing any controlled substance prescriptions.

being registered there. R.D. at 30–32. The ALJ found that this conduct constituted a violation of 21 U.S.C. 822(e) and 827(g), as well as 21 CFR 1301.51. *Id.* at 32. The ALJ found, however, that there was evidence that mitigated the violations as Respondent had notified the Texas DPS that she had changed her practice location and concluded that her failure to notify the Agency of her address change was not ''intentionally deceitful'' but the result of an ''omission.'' *Id.*

The ALJ further found that Respondent admitted that she occasionally accepted controlled substances from patients which she then destroyed, notwithstanding that no provision in the CSA or DEA regulations permits this. R.D. at 44. However, the ALJ also found that there was no evidence that this was a frequent occurrence or evidence that the drugs were diverted; rather, ''the un-rebutted testimony was that the drugs were destroyed.'' *Id.* Be that as it may, it is still a violation of the CSA. *See* 21 U.S.C. 844(a) (''It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter.'').

Next, the ALJ found that Respondent failed to keep proper controlled substance records. Specifically, the ALJ credited the testimony of the Diversion Investigators that Respondent's records showed that she had dispensed Demerol, a schedule II controlled substance. R.D. at 47. Because it is a schedule II drug, Respondent was required to document her purchases and receipts of the drug on DEA Form 222. 21 CFR 1305.04(a); *id.* § 1305.12; *id.* § 1305.13(a) & (e). She was also required to retain a copy of the form for at least two years from the date of the order. *Id.* § 1305.17; 21 CFR 1304.04(a). However, during a search of Respondent's registered and non-registered locations (as well as her home), no Form 222s were found. R.D. at 47. Nor were there any invoices for the Demerol.

Moreover, while the Investigators found that Respondent was dispensing other controlled substances, including Ambien (zolpidem) and Provigil (modafinil), each of which is a schedule IV drug, *see* 21 CFR 1308.14 (c) & (e); there were no inventories or dispensing logs for either drug. R.D. at 47.

In mitigation, the ALJ credited Respondent's testimony that she had never been the subject of a prior DEA investigation; that she had been evicted from her office at the time of the events at issue; that she also had issues with employees, ''to include alleged misuse of prescription pads, theft, and related financial matters''; and that she was a workaholic. R.D. at 49. While finding her testimony to be generally credible, the ALJ concluded that the Government had made out a *prima facie* case, noting that ''[o]n balance . . . Respondent's recordkeeping violations, handling of returned controlled substances and failure to properly change her registered address weigh significantly in favor of revocation'' or the denial of her application. *Id.* at 50.[6]

Turning to whether Respondent had produced sufficient evidence to rebut the Government's *prima facie* case, the ALJ noted that under the Agency's rule, ''where a registrant has committed acts inconsistent with the public interest, a registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct.'' *Patrick W. Stodola,* 74 FR 10083, 10094 (2009). Moreover, in setting the appropriate sanction, the Agency also considers the egregiousness of the proven misconduct and the need to deter future violations by both the Applicant and members of the regulated community. *Fred Samimi,* 79 FR 18698, 18713 (2014) (citing *Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011)).

As for her failure to update her registered address, the ALJ noted that Respondent had updated her address with the Texas DPS and had ''made various efforts to do so with DEA.'' R.D. at 51. However, the ALJ found that Respondent's explanation for her recordkeeping violations was ''less specific.'' *Id.* Noting her testimony that Respondent ''believed she 'had very effective oversight' of controlled substances,'' the ALJ found that her ''belief is contradicted by [her] own testimony.'' *Id.* Specifically, the ALJ noted that ''Respondent testified that she relied heavily on her staff with regard to inventory and maintenance of controlled substances and . . . did very little herself.'' *Id.* While the ALJ concluded that her ''testimony as a whole demonstrated that she understood the seriousness and importance of recordkeeping requirements,'' *id.,* at no point in her testimony did she acknowledge that as a DEA registrant, she was the person ultimately responsible for maintaining the required records.

Noting that Respondent's recordkeeping violations ''occurred over a comparatively short period of time, with substantially fewer controlled substances, and with no evidence of actual diversion,'' the ALJ rejected the Government's contention that revocation was the appropriate sanction, reasoning that it was disproportionate to her misconduct. *Id.* at 52. However, he also found that while ''Respondent's testimony as a whole demonstrates that she has sufficiently accepted responsibility for her actions and omissions . . . [her] explanation of past errors and demonstrated plan to avoid future violations is insufficient to support an unconditional registration.'' *Id.*

Indeed, Respondent offered no plan to avoid future recordkeeping violations. And while I agree that the *proven* misconduct would not support a sanction of revocation (in the event she had not allowed her registration to expire), consistent with other cases it does support a period of outright suspension. *See Kenneth Harold Bull,* 78 FR 62666, 62676 (2013) (imposing six-month suspension based on physician's failure to maintain records where his dispensing activity appeared to be limited and there was no evidence of diversion); *see also Paul Weir Battershell,* 76 FR 44359, 44368–69 (2011). Moreover, while the ALJ explained that ''[t]he Respondent's errors were neglectful and serious during the relevant time period, and likely due in part to ongoing issues including eviction from her registered office, employee problems, and an office break-in and theft,'' R.D. at 52, none of these explain why she was missing records documenting her controlled substance activities even months after her eviction and when she was continuing to possess and dispense controlled substances.[7]

The ALJ recommended that Respondent be granted a restricted registration subject to the conditions that: (1) ''no later than one (1) year after issuance'' of a registration, she provide documentation that she has successfully completed a course in controlled substance recordkeeping, and (2) that she submit to the nearest DEA Field Division Office, on a quarterly basis, a

[6] As explained above, as of the date of the hearing, Respondent had not filed a timely renewal application and her registration expired one week after the hearing and before the record was forwarded.

[7] While Respondent maintained that she was locked out of her first location (4851 I–35 East, Denton, TX.), she also testified that her staff had packed up the medical records prior to her eviction. Tr. 200. Moreover, in her testimony, Respondent stated that the judge in the eviction case granted her ''a brief period of time'' to retrieve her medications. *Id.* Unexplained is why she would not have also retrieved any controlled substance records at this time.

log of all controlled substances received, maintained and dispensed.

I reject these conditions as insufficient to protect the public interest. As explained above, Respondent offered no plan to address the recordkeeping violations that were proved on the record. In the absence of evidence that Respondent has successfully completed a course in controlled substance recordkeeping, allowing Respondent to possess, dispense and administer controlled substance would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f).

Accordingly, while I will grant Respondent's application, upon the issuance of her registration, it shall be suspended for a period of six months. I will further order that her registration be restricted to authorize her to engage in only the prescribing of controlled substances. Respondent shall not be allowed to possess any controlled substance unless she obtains it pursuant to the lawful order of a practitioner to treat a legitimate medical condition. Moreover, Respondent may not accept any manufacturer's or distributor's sample of any controlled substance other than those provided to her by a duly authorized medical professional in the course of treating her for a legitimate medical condition.[8]

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Odette L. Campbell, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, granted subject to the conditions set forth above. I further order that upon the granting of the application, the registration shall be suspended for a period of six months. This Order is effective August 13, 2015.

Dated: July 6, 2015.

Chuck Rosenberg,

Acting Administrator.

Larry P. Cote, Esq., for the Government.
Jeffrey C. Grass, Esq., for Respondent.

[8] In the event Respondent provides evidence that she has completed a course in controlled substance recordkeeping, these conditions will be removed from her registration one year from the effective date of this Order. However, in the event Respondent is granted authority to possess, administer and dispense controlled substances, she shall provide, on a quarterly basis, a log of all controlled substances she receives, possesses, dispenses, or otherwise disposes of, to the nearest DEA Field Division Office. Said log shall be submitted no later than ten (10) calendar days following March 31st, June 30th, September 30th, and December 31st. This requirement shall remain in effect for the duration of the initial period of re-registration. However, if Respondent fully complies with this condition, this requirement shall be removed upon the renewal of her registration.

Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge

Introduction

Timothy D. Wing, Administrative Law Judge. This proceeding is an adjudication governed by the Administrative Procedure Act, 5 U.S.C. 551 *et seq.,* to determine whether Respondent's Certificate of Registration (COR) with the Drug Enforcement Administration (DEA) should be revoked and any pending applications for renewal or modification of that registration should be denied. Without this registration, Respondent, Odette L. Campbell, M.D., of Denton, Texas, would be unable to lawfully possess, prescribe, dispense or otherwise handle controlled substances.

On August 4, 2009, the Deputy Administrator of the DEA immediately suspended Respondent's registration on grounds that Respondent had failed to comply with a standard referenced in 21 U.S.C. 823(g)(1) and that her continued registration during the pendency of these proceedings would constitute an immediate danger to the public health and safety. The Deputy Administrator simultaneously issued an Order to Show Cause (OSC) why DEA should not revoke Respondent's DEA COR as a practitioner pursuant to 21 U.S.C. 824(a)(4) because her continued registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f) and (g)(2)(E)(i). The OSC further alleged, in substance, that:

1. Respondent is currently registered with the DEA as a practitioner in Denton, Texas. Respondent is also authorized to treat no more than thirty narcotic-dependant patients at any one time with Schedule III through V narcotic controlled substances that are approved by the Food and Drug Administration for that indication. Respondent's current DEA registration was set to expire by its own terms on August 31, 2010.

2. Respondent moved her practice to another location in Denton without notifying the DEA and possessed and dispensed controlled substances at an unregistered location in violation of Federal law.[1]

3. On January 30, 2009, Respondent prescribed the Schedule II controlled substance methadone to an individual to treat opioid addiction.[2]

4. In March 2009 Respondent prescribed controlled substances to an employee for other than legitimate medical purposes.[3] At Respondent's request a local pharmacy filled the prescription and the controlled substances were returned to Respondent for her personal use.[4]

5. An accountability audit conducted at Respondent's medical office in April 2009 revealed an unexplained shortage of approximately thirteen bottles, or 390 dosage units, of Suboxone. Respondent's dispensing log indicated that she dispensed other controlled substances, such as Demerol, but she was unable to provide investigators with records showing receipt of these controlled substances.[5]

The Order to Show Cause and Immediate Suspension of Registration (OSC/IS) advised Respondent of her right to a hearing in this matter, and further advised that if she requested a hearing, it would be held on September 21, 2009, at DEA headquarters in Arlington, Virginia. Respondent timely filed a request for a hearing on the issues identified in the OSC/IS and referred all future correspondence to counsel.

On September 8, 2009, counsel for the Government filed a motion for summary disposition, asserting, in substance, that Respondent currently lacked authority to handle controlled substances in Texas, the jurisdiction in which she is licensed to practice medicine and in which she holds a DEA registration, and that the DEA does not have statutory authority to maintain a registration if the registrant does not have state authority to handle controlled substances in the state in which she conducts business.[6] Counsel for the Government further asserted that even if the suspension of Respondent's Texas medical license is temporary or there is the potential for Respondent's state controlled substance privileges to be reinstated, ''summary disposition is warranted because revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement.''[7] Counsel for the Government attached to his motion a copy of an Order of Temporary Suspension (Without Notice of Hearing) dated August 19, 2009, in which a Disciplinary Panel of the Texas Medical Board suspended Respondent's medical license. (ALJ Ex. 10.)

On September 11, 2009, counsel for Respondent[8] entered his appearance in this matter and filed a response to the Government's motion. Counsel for Respondent asserted that the Texas Medical Board action required that Respondent's DEA registration be suspended, but requested a stay in the instant proceedings pending resolution of the state proceedings.

On September 14, 2009, Administrative Law Judge (ALJ) Mary Ellen Bittner[9] issued an Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (Recommended Decision), which granted the Government's motion for summary disposition and recommended that Respondent's DEA registration be revoked and any pending applications denied on the basis that Respondent's state medical license had been suspended and she was therefore

[1] Citing 21 U.S.C. 841(a)(1), 822(3) and 827(g).

[2] Citing 21 U.S.C. 823(g)(1); 21 CFR 1306.04(c).

[3] Citing 21 CFR 1306.04.

[4] Citing 21 U.S.C. 843(a)(3).

[5] Citing 21 CFR 1304.21.

[6] Citing *Roy Chi Lung, M.D.,* 74 FR 20,346 (DEA 2009); *Michael Chait,* 73 FR 40,382 (DEA 2008); *Shahi Musud Siddiqui, M.D.,* 61 FR 14,818 (DEA 1996); *Michael D. Lawton, M.D.,* 59 FR 17,792 (DEA 1994); and *Abraham A. Chaplan, M.D.,* 57 FR 55,280 (DEA 1992).

[7] ALJ Ex. 10 at 2 (citing *Stuart A. Bergman, M.D.,* 70 FR 33,193 (DEA 2005); *Roger A. Rodriguez, M.D.,* 70 FR 33,206 (DEA 2005)).

[8] Richard Alley, Esq.

[9] ALJ Bittner was designated the presiding officer in this matter from August 28, 2009, until June 8, 2010.

without state authority to handle controlled substances. (ALJ Ex. 3.)

On October 29, 2009, Government counsel submitted a letter to the ALJ noting Respondent's request that the matter be set for hearing because Respondent's medical license had been restored by the Texas Medical Board. While the Government conceded the medical license had been restored, the Government maintained that Respondent ''nonetheless still does not have authority to prescribe controlled substances in Texas'' because ''Respondent's state controlled substance registration was revoked by the Texas Department of Public Safety on August 4, 2009, and that there are no applications currently pending for Respondent.'' (ALJ Ex. 12.)

On November 3, 2009, Counsel for Respondent again requested a hearing, noting that ''in speaking with the Texas Department of Public Safety (DPS) . . . attorneys, they have stated that Dr. Campbell cannot be reinstated unless DEA reinstates her license . . . [o]bviously this reasoning is a tautological chicken and the egg quandary and denies Dr. Campbell her due process rights.'' (ALJ Ex. 13.)

On January 19, 2010, the Deputy Administrator issued an Order outlining the procedural history of the matter and inviting the parties to submit a motion, properly supported, that seeks the particular relief requested. (ALJ Ex. 4.)

On January 29, 2010, Government filed a Request for Final Agency Action and on February 8, 2010, Respondent filed her Response. (ALJ Exs. 14, 15.)

On May 11, 2010, the Deputy Administrator remanded the matter to the ALJ for further proceedings. The Deputy Administrator found that although Respondent's Texas medical license had been restored, Respondent's state controlled substance registration was terminated on August 4, 2009, and Respondent was therefore without state authority to handle controlled substances. The Deputy Administrator further found that the applicable Texas statutes and regulations may not permit Respondent to challenge the termination of her state controlled substance registration because the termination was based on the immediate suspension of Respondent's DEA registration. If that is the case, Respondent will be denied the opportunity to challenge the revocation of her DEA registration and her state controlled substance registration, which will effectively deny Respondent her right to due process. The Remand Order therefore directed the ALJ to determine what action the Texas Department of Public Safety (DPS) has taken on Respondent's application for a state registration and whether the DPS has provided or will provide Respondent with a hearing; if not, Respondent is entitled to an expedited hearing on the allegations of the OSC/IS. (ALJ Ex. 5.)

I. Procedural Issue

What action the Texas Department of Public Safety (DPS) has taken on Respondent's application for state registration to handle controlled substances and whether the DPS has provided or will provide Respondent with a hearing; and, if the DPS has determined that Respondent is not entitled to a hearing, to conduct an expedited hearing on the allegations of the OSC/IS served on Respondent on August 4, 2009.

A. The Government's Contentions

The Government first contends that Respondent's alleged due process violations and the failure of the Texas DPS to provide Respondent with a hearing regarding the revocation of her state controlled substance license are beyond the jurisdiction of this agency to adjudicate and would properly be heard by the Texas courts and the DPS.

The Government further argues that because Respondent currently lacks authority to handle controlled substances in Texas, the jurisdiction in which she is licensed to practice medicine and in which she holds a DEA registration, ''any fact-finding proceeding regarding the original basis for the Order to Show Cause [is] moot.'' [10] Citing 37 Tex. Admin. Code § 13.274(b), the Government contends that the DPS will not automatically restore Respondent's controlled substances registration even if Respondent prevails in these proceedings because the DPS will not reinstate a revoked registration sooner than one year from the date of the final revocation and upon filing of a new application for registration. According to the Government, these proceedings are therefore moot because, if Respondent's DEA registration is reinstated, the Government would have to immediately reinitiate proceedings by issuing an OSC on the ground that Respondent lacks authority to handle controlled substances in Texas.

The Government also asserts that Texas law does provide Respondent a mechanism to seek reinstatement of her DPS registration under Texas Health & Safety Code § 481.066(j) but Respondent has failed to seek a reinstatement under that authority. Under Texas Health & Safety Code § 481.066(j), the Governments contends that Respondent should be able to show good cause for reinstatement of her DPS registration based on the Texas Medical Board finding that ''rejected the Government's allegations serving as the basis of the suspension of Respondent's DEA registration.'' (ALJ Ex. 18.)

B. Respondent's Contentions

Respondent first contends that the allegations contained in the OSC/IS are untrue and, therefore, her DEA registration should not be ''permanently revoked.'' Respondent argues that 37 Tex. Admin. Code § 13.274(b)(1)(B) provides that within one year after a DPS revocation becomes final, the DPS will consider a request for reinstatement if Respondent demonstrates by a preponderance of the evidence that Respondent's DEA registration has not been permanently revoked. Respondent further contends, however, that it will be pointless to request a DPS hearing on the matter until after the DEA has issued a final order because the sole basis for the DPS revocation is the fact that the DEA suspended Respondent's DEA registration.

Respondent similarly contends that the DPS will not provide a hearing on the matter of reinstatement one year after revocation under 37 Tex. Admin. Code § 13.274(b)(2)(A) because there is no question of fact regarding whether DPS has taken adverse action against Respondent. Again, Respondent argues that such a hearing request will not be granted because the only issue pertains to the status of Respondent's DEA registration. Respondent contends that the restoration of her DEA registration is the only evidence necessary or sufficient to negate the basis of the revocation of her DPS registration and, therefore, only a DEA hearing can result in the resolution of the matter with Texas and with the DEA.

Respondent also argues that Respondent has exhausted her attempts at reinstatement of her DPS registration under a showing of good cause. (ALJ Ex. 19.)

C. Discussion and Conclusions

The parties' contentions and the Remand Order essentially concern two procedural issues: (1) whether Respondent has been afforded due process under federal law; and (2) whether the fact that Respondent does not possess state authority to handle controlled substances renders this proceeding moot.

(1) Federal Due Process and Mootness Doctrine

The Supreme Court of the United States has held that the ''Due Process Clause of the Fifth Amendment prohibits the United States, as the Due Process Clause of the Fourteenth Amendment prohibits the States, from depriving any person of property without 'due process of law.' '' *Dusenbery* v. *United States,* 534 U.S. 161, 167 (2002). ''The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.' '' *Mathews* v. *Eldridge,* 424 U.S 319, 333 (1976) (citations omitted).

In analyzing procedural due process issues, courts have generally engaged in a ''two-step inquiry: (1) Did the individual possess a protected interest to which due process protection was applicable? (2) Was the individual afforded an appropriate level of process?'' *Ward* v. *Anderson,* 494 F.3d 929, 934 (10th Cir. 2007) (citations omitted).

As to the first step, a license has consistently been held to be a property interest entitled to due process protection. *Barry* v. *Barchi,* 443 U.S. 55, 64 (1979).

The second step of the analysis in this case rests significantly on the interrelationship between the DEA-initiated OSC/IS and the relevant Texas statutes and regulations pertaining to the regulation of controlled substances by practitioners. The United States Court of Appeals for the Fifth Circuit has held that the DEA's revocation of a registration based on a state agency action ''would only be invalid if the alleged state agency errors rose to the level of a federal due process violation . . . .'' *Maynard* v. *DEA,* 117 Fed. App'x 941, 945 (5th Cir. 2004). The DEA's revocation of a COR amounts to the deprivation of a property interest and therefore must comport with the requirements of federal due process. *See Mathews,* 424 U.S. at 333. At a minimum,

[10] (ALJ Ex. 18 at 3.)

federal due process requires that a respondent be afforded adequate notice and opportunity to be heard ''at a meaningful time and in a meaningful manner.'' *Id.; see also Mullane* v. *Central Hanover Bank & Trust Co.,* 339 U.S. 306, 313 (1950).

Agency precedent has consistently held that where, for example, a state action precedes a DEA OSC or OSC/IS, the DEA need not inquire into the validity of a state licensing agency's decision. *George S. Heath, M.D.,* 51 FR 26,610 (DEA 1986). Similarly, where there is an independent basis for the state action, the DEA has relied on the state authority without further inquiry. *See Joseph Baumstarck, M.D.,* 74 FR 17,525 (DEA 2009); *Michael D. Lawton, M.D.,* 59 FR 17,792 (DEA 1994); *George S. Heath, M.D.,* 51 FR 26,610 (DEA 1986); *Hezekiah K. Heath, M.D.,* 51 FR 26,612 (DEA 1986). Summary disposition based on suspension of a respondent's state authority, of even a temporary nature, has been consistently upheld. *E.g., Roger A. Rodriquez, M.D.,* 70 FR 33,206 (DEA 2005). The Controlled Substances Act (CSA) requires that a practitioner be currently authorized to handle controlled substances in ''the jurisdiction in which he practices'' in order to maintain a DEA registration.[11] Therefore, because ''possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration,'' the DEA has repeatedly held that ''the CSA requires the revocation of a registration issued to a practitioner whose State license has been suspended or revoked.'' *See Scott Sandarg, D.M.D.,* 74 FR 17,528 (DEA 2009) (citing *David W. Wang, M.D.,* 72 FR 54,297 (DEA 2007); *Sheran Arden Yeates, M.D.,* 71 FR 39,130 (DEA 2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104 (DEA 1993); and *Bobby Watts M.D.,* 53 FR 11,919 (DEA 1988)).

A review of agency precedent, however, reveals no instance where a respondent's registration has been the subject of a final revocation by summary disposition where state action was triggered *solely* by the DEA suspension process, and the respondent was afforded no opportunity to be heard ''at a meaningful time and in a meaningful manner.'' *Mathews* v. *Eldridge,* 424 U.S 319, 333 (1976) (citations omitted). To the contrary, the DEA has recently rejected a due process argument by a respondent claiming the state action was based on the DEA's order immediately suspending his registration, stating: ''Respondent ignores, however, that the State's suspension order did not rely solely on my Order. Rather, the State Board also relied on Respondent's indictment by a federal grand jury . . . . [T]he board clearly conducted its own independent evaluation of the evidence against him and did not simply piggyback on my Order of Immediate Suspension.'' *Joseph Baumstarck,* 74 FR 17,525, 17,527 (DEA 2009) (internal citations omitted); *see also Oakland Medical Pharmacy,* 71 FR 50,100, 50,102 (DEA 2006) (rejecting the contention that it is circular for DEA to rely on a state suspension order to revoke a registration where the State did not rely solely on the DEA order in suspending a practitioner's state license).

The Texas authorities in the instant case did ''piggyback'' solely on the OSC/IS to suspend Respondent's state registration on August 4, 2009, and relied exclusively on the DEA action to suspend Respondent's state authority.[12]

The Government also argues in substance that the ultimate issue in this case is ''moot'' given Respondent's current lack of state authority.[13] Additionally, as of the hearing date, Respondent's registration was due to expire by its terms on August 31, 2010, and there is no evidence of record indicating that Respondent has submitted an application for renewal.[14] The Government's mootness argument with regard to Respondent's current application status is misplaced because this proceeding began as an immediate suspension. To find otherwise would be contrary to the applicable regulation and agency precedent.[15]

In *William R. Lockridge, M.D.,* 71 FR 77,791 (DEA 2006), the agency declined to apply the mootness doctrine to a case in which the respondent's registration had expired several months before the hearing and a renewal application had not been timely filed. In that decision, the Agency concluded that

> a case remains a live dispute when 'collateral consequences' attach to a proceeding which otherwise would be moot . . . . As several courts have noted in cases involving sanctions against licensed professionals such as attorneys, even a temporary suspension followed by a reinstatement does not moot a challenge to the initial suspension because the action 'is harmful to a [professional's] reputation, and 'the mere possibility of adverse collateral consequences is sufficient to preclude a finding of mootness.'

Id. at 77,797 (internal citations and formatting omitted). Additionally, ''the issuance of an immediate suspension creates collateral consequences beyond those that are present when the Government serves a Show Cause Order but allows the registrant to continue to handle controlled substances throughout the litigation.'' *Id.*

Consistent with the rationale set forth in *Lockridge,* I find that application of the mootness doctrine to Respondent's case is unwarranted and would deny both Parties an opportunity to resolve the evidentiary issues, as well as prejudice the public interest. Additionally, there is no indication that Respondent intends to suspend her medical practice or not seek restoration of her registration. *See Meetinghouse Community Pharmacy, Inc.,* 74 FR 10,073 (DEA 2009). Absent an opportunity to be heard ''at a meaningful time and in a meaningful manner'' under the Texas statutory scheme, reliance on agency precedent, including the mootness doctrine, to support summary disposition in this instance is entirely misplaced.

(2) The Texas Statutory and Regulatory Scheme

The Texas Controlled Substances Act (Texas CSA), Tex. Health & Safety Code § 481.001 et. seq., governs the registration of practitioners to dispense controlled substances in Texas. Pursuant to § 481.066(b), ''[t]he director may cancel, suspend, or revoke a registration, place on probation a person whose license has been suspended, or reprimand a registrant for cause described by Section 481.063(e).'' In addition, Section 481.063(e)(3) authorizes the denial of an application for a state registration ''to manufacture, distribute, analyze, [or] dispense . . . controlled substance[s]'' if the applicant's DEA registration has been ''suspended, denied, or revoked'' under the Federal Controlled Substances Act defined as 21 U.S.C. Section 801 *et seq.*[16]

The Texas regulatory structure for practitioners is further governed by the Texas Administrative Code, Title 37, Part 1, Ch 13. A ''registration terminates: . . . (3) when a regulatory board or DEA accepts a voluntary surrender, or denies, suspends, or revokes a license or a federal controlled substance registration. . . .'' [17] Of significance, the Texas Administrative Code states that the ''director will revoke a registration if the registrant: (1) violates a ground of denial described in the Act, § 481.063(e).'' [18] The Code further provides that upon revocation under this section, ''the registrant may request a hearing, *unless otherwise stated in the Act.''* [19] The state due process requirements for licenses, set forth at Tex. Gov't Code Ann. § 2001.054, do not apply to suspensions and revocations pursuant to Texas CSA §§ 481.063(e)(2)(A) or (B), (e)(3), (e)(4) or (e)(9). *Maynard* v. *DEA,* 117 Fed. App'x 941 (5th Cir. 2004); *see* Tex. Health & Safety Code Ann. § 481.063(h).

The applicable Texas statutes and regulations contemplate a right to a hearing pursuant to the Texas APA in certain enumerated circumstances, but not where the initial suspension or revocation was based solely on federal action.[20] Consistent with the foregoing, the Respondent has not been afforded a hearing in Texas nor is one contemplated. The procedural due process available to Respondent under Texas law

[11] *See* 21 U.S.C. 802(21).

[12] (*See* Gov't Ex. 5; Gov't Ex. 6; Gov't Ex. 7; Resp't Ex. 2.)

[13] (ALJ Ex. 18 at 3.)

[14] At hearing, the Government represented that ''there's no indication in the DEA system that an attempt was even made to submit a renewal application.'' The Respondent questioned the requirement ''to do meaningless acts if it's going to be kicked back,'' but indicated she would file a DEA application immediately. (Tr. 10–12.)

[15] 21 CFR 1301.36(h) states that ''[a]ny suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction.'' This section is distinguishable from the extension requirements for an ''applicant . . . who is doing business under a registration . . . not revoked or suspended . . . .'' 21 CFR 1301.36(i).

[16] *See* Tex. Health & Safety Code Ann. § 481.002(18) (identifying the federal Controlled Substances Act).

[17] 37 Tex. Admin. Code § 13.30 (2010).

[18] *Id.* § 13.274.

[19] *Id.* § 13.274(d) (emphasis added).

[20] I have also carefully considered the ''informal hearing'' provisions pursuant to § 13.301, but do not find that provision adequate to afford Respondent a meaningful right to a hearing, consistent with due process.

simply cannot support summary disposition on the facts of this case. Accordingly, I find that Respondent is entitled to a federal administrative hearing on the substantive issues alleged in the OSC/IS.

II. Substantive Issue

Whether the record establishes that Respondent's DEA COR BC0181999 as a practitioner should be revoked and any pending applications for renewal or modification of that registration should be denied because her continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f).

III. Findings of Fact

I find, by a preponderance of the evidence, the following facts:

A. Stipulated Facts

Respondent is registered as a practitioner in Schedules II–V under DEA registration number BC0181999.

B. General Overview

Respondent's State Medical License and Controlled Substance License

The Texas Medical Board issued an Order of Temporary Suspension (without Notice of Hearing) on August 19, 2008, thereby rendering Respondent's Texas medical license temporarily suspended. (Gov't Ex. 6; Tr. 33.) On October 16, 2009, the Texas Medical Board issued an Order Denying Temporary Suspension or Restriction of Texas Medical License, thereby reinstating Respondent's Texas medical license. (Gov't Ex. 7; Tr. 33.) The Texas Department of Public Safety revoked Respondent's Controlled Substances Registration on August 4, 2009, based solely on the Drug Enforcement Administration's immediate suspension of Respondent's Controlled Substance Registration.[21] (Resp't Ex. 2.). Respondent was previously disciplined by the Texas Medical Board on three separate occasions between December 2000 and April 2009; each action resulted in a monetary fine.[22]

Dr. Odette Louise Campbell (Respondent)

Respondent attended the College of William & Mary in Williamsburg, Virginia. She received a master's degree in psychology from Virginia Commonwealth University and attended medical school in Virginia. Respondent completed internal medicine and oncology residency programs in Philadelphia and remained at the hospital as an attending physician. She relocated to Galveston, Texas, and then to Dallas, Texas, where she has practiced medicine since approximately 1991. (Tr. 110.) Between 1999 and 2002, Respondent built four cancer centers. She built a fifth cancer center in 2005 at 4851 South I–35 East, Corinth, Texas. (Tr. 112.) She has been involved in multiple research projects regarding lymphoma, central nervous system lymphoma and the method of delivery of fentanyl to cancer patients. (Tr. 114.)

Dr. Robert James Babuji (Dr. Babuji)

Dr. Babuji is a practicing physician. He completed his basic medical degree at Stanley Medical College in Madras, India in 1986; he completed general internal medicine training in the United Kingdom from 1987 until 1991; from 1991 until 1992, Dr. Babuji conducted basic research in cardiology; in 1994, he relocated to the United States and completed residency training at the University of Utah in Salt Lake City, Utah; he completed an advanced heart failure and transplantation fellowship in Salt Lake City, a cardiology fellowship at the University of Virginia in Charlottesville and Salem, Virginia, and then a cardiology fellowship in San Francisco, California; in 1999, Dr. Babuji returned to the United Kingdom where he practiced cardiology and internal medicine; in 2002, he returned to the U.S. to start in private practice in Florida and then later in Dallas, Texas, where he has practiced in cardiology, internal medicine, and primary care for the last three years. (Tr. 265.) Dr. Babuji is not certified in pain management but based on his training and experience is familiar with the procedures involved in pain management, based in part on his treatment of patients with numerous pain conditions. Dr. Babuji further testified that he is familiar with the standard of care required to treat patients with chronic pain syndrome. (Tr. 266.)

C. DEA Investigations

(a) DEA Diversion Investigator Joel Lynn Dunn (DI Dunn)

DI Dunn has been a DEA Diversion Investigator for six years. He is assigned to the Dallas Field Division. DI Dunn received training as a diversion investigator at the DEA training academy. (Tr. 15.)

(b) DEA Diversion Investigator Anita Chalmers (DI Chalmers)

DI Chalmers has been a DEA Diversion Investigator for ten years. She is assigned to the Dallas Field Division, where she has been employed for twenty years. (Tr. 91.)

(c) DEA Diversion Investigator Richard Leakey (DI Leakey)

DI Leakey has been a DEA Diversion Investigator for approximately seven years. He is assigned to the Dallas Field Division. (Tr. 98.)

(d) Respondent's Registered Location

Respondent's DEA-registered location is the Corinth Medical Group, 4851 I–35 East, Denton, Texas. Respondent was evicted from that location in late 2008 and moved to a temporary location (Collier Street) for an unknown length of time and then to a permanent location at 431 Mesa Drive on or about February 1, 2009. (Tr. 160.) Respondent did not move any controlled substances from the Denton location and the medications were destroyed prior to Respondent's eviction. (Tr. 197–98.) DI Dunn testified that Respondent was practicing at 431 Mesa Drive in April 2009, when the FBI executed a search warrant of that location; that Respondent was not authorized to possess controlled substances at that location; and that controlled substances were found there. (Tr. 52, 53.) DI Dunn further testified he was unaware of any requests from or attempts made by Respondent to modify the address of her registered location but that Respondent has updated her registered location in the past and Respondent did not have a practice at 4851 I–35 East. (Tr. 85, 87.)

Respondent did update her new Mesa Drive registered address with the Texas Department of Public Safety and the Texas Medical Board. (Tr. 85, 160.) Respondent testified that she contacted the DEA seeking copies of records and provided her new address at that time. Respondent further stated that she believed she had fulfilled her requirement to change her registered address because she received documents from the DEA at 431 Mesa Drive. (Tr. 160.)

Respondent stated in a written request for hearing dated August 27, 2009, that

> [m]y office administrator notified the Dallas office of the DEA in the third week of February 2009 informing them of my new office address. At the time of the notification, my office had requested a copy of a prior report of a theft which occurred in January 2009 be sent to our new office address. In addition, my new office address had been sent to the Texas Medical Board and the Texas DPS office in Austin, Texas. My Duplicate prescriptions reflected my new office address which led me to believe that I had fulfilled the Federal law requirements. I did not also send my new address to the Arlington, Virginia office. I did not know that this additional notification was required until August 4, 2009. I have been unable to complete my change of address successfully on the DEA internet site after multiple attempts prior hereto . . . .

(ALJ Ex. 2.)

(e) Respondent's Issuance of Methadone to Opioid-Addicted Patients

(i) [JF]

DI Dunn testified that a physician must be registered with the DEA as a narcotic treatment program to prescribe methadone; Respondent is not registered with the DEA as a narcotic treatment program. (Tr. 21.) DI Dunn further testified that he did not consult with a physician regarding the standard of care applied when a physician treats a methadone patient with Suboxone but that he does consult the Code of Federal Regulations (CFR) which allows a physician to prescribe Suboxone. (Tr. 70.)

DI Dunn further explained that he was contacted by Lori Price, Director of the Denton Treatment Program, a narcotic treatment program that is registered by the DEA to administer methadone to narcotic addicts; that Ms. Price was concerned because she was aware of a number of

[21] *See* Tex. Health & Safety Code §§ 481.066(b), 481.063(e)(3); 37 Tex. Admin. Code § 13.274(a).

[22] In December 2000, Respondent was cited for substandard chart documentation resulting in a monetary fine, chart monitoring and eight hours of continuing education in medical recordkeeping; Respondent received a monetary fine for failure to timely notify the Texas Medical Board of the relocation of her practice from Corinth to Denton (date not reflected in record but assumed to be prior to April 2009); and in March or April 2009, Respondent received a monetary fine in relation to missing fentanyl. (Tr. 185.)

patients who left the clinic to be treated by Respondent; and that he asked Ms. Price to speak with the patients to ask them to contact him to discuss their treatment. (Tr. 21.)

DI Dunn related that [JF] contacted him and they spoke on several occasions; that [JF] went to Respondent for only one reason: to get off methadone and start taking Suboxone, a Schedule III controlled substance (Tr. 22); and that Respondent never prescribed Suboxone to [JF]. DI Dunn stated that he had not seen [JF]'s medical chart as of the time of Respondent's suspension. (Tr. 67.)

The Government introduced at hearing an unsworn but witnessed statement signed ''[JF],'' [23] indicating that [JF] received from Respondent prescriptions for Valium and methadone and that ''[a]s a result of taking these prescription [sic] I ended up on life sapport [sic] for 30 days. I could not walk or move any part of my body.'' (Gov't Ex. 12.)

Respondent testified that the Denton Treatment Center provides methadone treatment for patients that have methadone addiction issues and that she spoke with Lori Price when she contacted the Center to request [JF]'s records. (Tr. 130.) Respondent further testified that she did prescribe to [JF] 10 mg methadone quantity 120 with instructions to take two tablets two times per day, a thirty-day supply, pursuant to Respondent's instructions, and 10 mg diazepam quantity 90 with instructions to take one tablet every eight hours. (Gov't Ex. 13 & 14.) The medical record for [JF] indicates that [JF] initially began taking methadone to treat chronic pain from ''chronic arthritics pain in [the] neck, lumbar spine and left knee.'' (Resp't Ex. 6, at 8.)

Respondent testified that [JF] was self-referred to Respondent, whose name she said she received from Lori Price, and that [JF] wanted to stop taking methadone and start taking Suboxone in order to save money because she did not have a lot of money to receive treatment from the methadone clinic. (Tr. 132, 141, & 220.) Respondent explained that in order to change a patient's medication from methadone to Suboxone, the physician must first counsel the patient regarding potential side effects and then the patient must detoxify from methadone before taking Suboxone. (Tr. 141.) Respondent further explained that Suboxone was a superior medication for [JF] because it has less of a respiratory depressant effect and [JF] was on oxygen twenty four-hours per day; the Suboxone for [JF] would be used for pain management and [JF] signed a pain management agreement; [JF] had to first detoxify from the methadone and then Respondent would prescribe Suboxone; and [JF] did detoxify from methadone. (Tr. 141; Resp't Ex. 6; Tr. 143.)

Respondent also testified that, during an office visit, she did not prescribe Suboxone because [JF] determined that she was unable to afford the Suboxone; Respondent could not send [JF] back to the treatment center to resume methadone because the center had stopped seeing patients for the day; Respondent provided [JF] with a very low pain management dose of methadone: 20 mg with instructions to take one two times per day; Respondent previously took 120 mg of methadone per day; and if the methadone clinic had been open that day, Respondent would have sent [JF] back. (Tr. 143, 220.) Respondent agreed to place [JF] on a list to receive free Suboxone because Respondent can sponsor two Suboxone patients per year and agreed that Respondent would maintain [JF] on methadone in the interim. (Tr. 144.)

Respondent testified that [JF] was hospitalized four days after [JF]'s visit with Respondent because [JF] had aspiration pneumonia and an upper GI bleed; that no drug screen was performed at the hospital; and it was impossible for [JF] to overdose from Respondent's prescriptions as written. (Tr. 145.)

Dr. Babuji testified the normal course of treatment when starting a patient on Suboxone is to wean the patient off methadone first and then start prescribing Suboxone. (Tr. 267.) Dr. Babuji explained that Suboxone is used to treat opioid addiction and as a pain management tool and that Suboxone would be an appropriate treatment for [JF]. (Tr. 291.) Dr. Babuji further testified that, because [JF] was unable to afford the Suboxone, [JF] was maintained on a smaller dose of methadone to stop further withdrawal and allow a slow withdrawal of the methadone, which would be helpful for chronic pain syndrome, and that there was no reason for [JF] to return to the Denton Treatment Center because [JF] was already on methadone and being weaned off with the intent of starting on Suboxone. (Tr. 268.)

Based on his review of [JF]'s medical records, Dr. Babuji found that [JF] presented to Respondent with pain in the right foot, left knee, the lumbar region and the neck area. (Tr. 267.) Dr. Babuji testified that he reviewed the discharge summary from [JF]'s hospital visit; that the visit was the result of the exacerbation of chronic obstructive pulmonary disease which led to pneumonia; and that there was no evidence of a drug overdose. (Tr. 269, 290.)

(ii) [MM]

DI Dunn testified that he received [MM]'s patient file pursuant to a search warrant executed on the premises of Respondent's practice. (Tr. 43.) A review of the patient file indicated that [MM] was receiving methadone and that [MM]'s previous physician was a narcotic treatment program. (Tr. 41.)

DI Dunn further testified that he spoke with [MM], who told him that [MM] was a lifelong heroin addict; [MM] was seeing Respondent for narcotic treatment because the methadone from Respondent was less expensive than what [MM] received through the narcotic treatment program; and that although [MM] did sign a pain management agreement with Respondent, [MM] was not seeing Respondent for pain management. (Tr. 41.)

[MM] signed an unsworn, but witnessed statement indicating that [MM] was a recovering alcoholic and used heroin; [MM] relapsed and went to the methadone clinic ten years ago; in or around April 2009, after [MM] started receiving Medicaid and Social Security disability, [MM] heard that Respondent would accept Medicaid and prescribe methadone; and [MM] saw Respondent for addiction treatment, not pain treatment. (Gov't Ex. 18.)

[MM]'s patient file indicates [MM] signed a pain management agreement on April 15, 2009; [MM] wrote that [MM]'s reason for visiting Respondent's office was ''methadone, osteoporosis, ativane, and smoking patch''; that [MM]'s previous physician was the Brentwood clinic where [MM] received methadone; and [MM] had complaints and history of back pain and leg pain. [MM]'s patient file also reflects that Respondent noted that [MM] suffered from shoulder and leg pain, opioid addiction, anxiety, depression, chronic back pain and arthritis. (Gov't Ex. 16.)

Respondent testified that [MM] told her that she had been diagnosed with osteoporosis; that she explained to [MM] that she helps patients get off methadone and that she doesn't do methadone maintenance for patients with only addiction problems but she may use methadone to treat chronic pain; that [MM] said [MM] did have chronic pain; that Respondent reviewed the pain management contract with [MM]; and that [MM] presented as a dual-diagnosis patient suffering from both chronic pain and addiction. (Tr. 172.)

(iii) [TR]

DI Dunn testified that [TR]'s patient file was seized pursuant to a search warrant executed at Respondent's practice. DI Dunn has not spoken with [TR]. (Tr. 46.)

Respondent testified that [TR] described [TR]'s condition as back pain, sciatica and severe pain; that [TR] had been on methadone for pain; and that Respondent reviewed the pain management agreement with [TR] and subsequently placed [TR] on methadone with good results. (Tr. 171.)

The patient file for [TR] indicates that [TR] signed a pain management agreement on June 10, 2009; that [TR] stated the reason for [TR]'s visits to Respondent was a need for a new doctor, to resolve ''a lot of female problems and back problems'' and for pain management of severe back and leg pain; that [TR] had a history of or complaints of back pain and arthritis; and that [TR] had received 120 mg of methadone daily from a clinic. (Gov't Ex. 17.)

(f) Respondent's Possession of a Prescription Written in the Name of an Employee

DI Dunn testified that [HM] was an employee of Respondent; that diazepam, written in [HM]'s name, was recovered when a search warrant was executed at Respondent's home. (Tr. 29.) DI Dunn related that he spoke with [HM] regarding the diazepam found in Respondent's home and that [HM] stated that Respondent asked if she could write a prescription in [HM]'s name and then take the medication back from [HM] because Respondent could not write prescriptions in her own name. (Tr. 29.)

DI Dunn conceded that the sole basis for his conclusion that Respondent received a prescription written in [HM]'s name is [HM]'s statement and the recovery of the medication from Respondent's home. (Tr. 83.)

[23] [JF] was not called by either party, nor is there any evidence of record to indicate that [JF] was not otherwise available as a witness.

DI Leakey testified to assisting in the execution of the search warrant at Respondent's residence; that a bottle containing approximately fifty tablets of diazepam was found in the master bedroom's bathroom medicine cabinet; and that DI Leakey participated in DI Dunn's interview of [HM]. (Tr. 99, 100, 105–06.) [HM] signed an unsworn, but witnessed statement indicating that [HM] became a patient of Respondent in November 2008; that [HM]worked for Respondent until April 2009; that in early March Respondent asked [HM] to fill a prescription for her for diazepam and for hormones because Respondent did not have time to see her own doctor; that [HM] filled at CVS the prescription written by Respondent and then provided the medication to Respondent. [HM]'s statement said ''I have *never* taken Valium *ever* . . . .'' (Gov't Ex. 11) (emphasis in original). [HM] concluded by stating, ''[a]fter the FBI did the search of [Respondent's] house she called me to tell me they found the Valium RX in my name & she told them that I kept it at work & it must have fallen in a box of files she brought home. She asked me to tell everyone that story.'' (Gov't Ex. 11 at 2.)

A CVS pharmacy patient prescription record introduced in evidence by Respondent for [HM] indicates that [HM] received 10 mg diazepam quantity 10 on February 27, 2001, from Dr. [VS]. (Resp't Ex. 13.)

Respondent testified that [HM] was initially a patient who had depression, generalized anxiety disorder, morbid obesity, severe rheumatoid arthritis and multiple back surgeries; and that [HM] was taking Xanax and Effexor for anxiety disorder. (Tr. 149; Resp't Ex. 8.) Respondent also testified that [HM] was scheduled for back surgery, in preparation for which Respondent was transitioning [HM] from Xanax to Valium, which she considered to be a safer medication and which was the reason Respondent wrote [HM] the prescription for Valium. (Tr. 150.)

Respondent further testified that [HM] brought into the office the Valium written to [HM] by Respondent and left the bottle sitting on a desk in a room that was being painted; that Respondent, upon seeing a painter in the room with the unsecured medication, feared the medication would be stolen and placed the bottle in her lab coat pocket; Respondent then took her lab coat home and likely placed it in the laundry, as she typically does; Respondent has no further recollection regarding the whereabouts of the medication. (Tr. 153.)

Respondent explained that her relationship with [HM] deteriorated because [HM] intended to sue Respondent over a medical procedure performed by another doctor in Respondent's office. (Tr. 154.)

Debra Allinger testified that she worked in Respondent's office from March until August 2009; that on her second day of work she was asked to clean out [HM]'s belongings from an office that was to be painted; and that upon seeing a prescription bottle in the office, she told Respondent, who then put the bottle in her lab coat. (Tr. 297.)

Shelley Franks-Chapa testified that she was employed by Respondent from February 2009 to about June 2009, and began employment before February 14, 2009. (Tr. 310, 319.) Ms. Franks-Chapa further testified that she was familiar with an employee named [HM], also known as [GM]. (Tr. 312.) Ms. Franks-Chapa recalled being present in Respondent's office on an unknown date but during her period of employment, and overheard [HM] ask that her prescription of Valium be faxed out. (Tr. 312.) Ms. Franks-Chapa further recalled on cross-examination that the conversation took place in an end office which was about to be painted within a few days and that [HM] was present in the office working. (Tr. 316–17.)

(g) The DEA's Accountability Audit of Respondent's Practice and Respondent's Handling of Controlled Substances

DI Dunn testified that in May 2008, he launched an investigation of Respondent based on theft and loss reports related to the theft or loss of experimental fentanyl; the investigation revealed reports had not been completed properly, DI Dunn instructed Respondent as to the proper filing of the report form and no further action was taken and that investigation was unrelated to the instant matter. (Tr. 17, 55.) DI Dunn has been trained in how to conduct an audit at a registered location. (Tr. 16.) DI Dunn testified that he obtained Respondent's Demerol log from the FBI, who seized the log pursuant to an April 2009 search warrant. (Tr. 48.)

Respondent testified she believed that an employee, Marie Lopez, was stealing or forging prescriptions so she eventually fired Ms. Lopez. (Tr. 115, 116.) Respondent further testified that she believes that Ms. Lopez stole the fentanyl that was reported to the DEA as lost. (Tr. 196.)

Respondent described how, after the first theft from her office, she acquired two safes for the Mesa Drive location and placed one under the sink in the triage room and one in Respondent's office. (Tr. 119.) Respondent explained that some Schedule IV controlled substances were stored in cabinets in the triage room and that Suboxone, Demerol, probably Ambien, and sometimes Provigil, were stored in a safe under the sink, but that some Provigil was in the cabinet. (Tr. 192.) Respondent further testified that she believed that the safe in the triage room was opened with both a combination and a key and that Respondent did not have a key to the safe but a member of her clinical staff would keep the key during the day, and lock the key in the triage room at night. Respondent maintained the key to the triage room and was always the last person out of the office at night. (Tr. 193.) Respondent further explained that in late 2008, her office was broken into and a safe containing triplicate prescriptions and possibly two bottles of Suboxone was stolen; and Respondent reported the theft to the local police and the DEA. (Tr. 119, 196 & 199.)

Respondent testified her office procedure for documenting the receipt of controlled substances was as follows: certain employees were authorized to receive delivery of medications or office supplies; all medications were taken to the triage room, where there was a safe for storing controlled substances, and the delivery receipt was placed in the appropriate manual for the particular medication. (Tr. 120, 205.) Respondent further testified that because fentanyl was part of an investigational study, the medication was signed into a book upon receipt; each pill was counted by an independent person who was part of the investigational study. (Tr. 120.)

Respondent further testified that when her safe was stolen in late 2008, the Suboxone manual was damaged and Respondent later requested that Dendrite (a pharmaceutical supply company), send copies of receipts of all deliveries of Suboxone to her office. (Tr. 121, 123; Resp't Ex. 11.) Respondent then obtained from Community Pharmacy copies of receipts of medical supplies ordered by her office. (Resp't Ex. 9.)

Respondent testified that she typically purchased Demerol through Community Pharmacy and she requested copies of receipts from Community Pharmacy in an effort to account for the Demerol in her office. (Tr. 125.) Respondent testified that when she moved her practice from 7851 South I–35 East to 431 Mesa Drive, scheduled medications were destroyed, not moved. (Tr. 200.)

DI Dunn testified that an audit occurred after search warrants were executed on Respondent's registered and unregistered locations and home in April 2009, and that he did not participate in the execution of the search warrants. (Tr. 20, 33.) DI Dunn further testified that at a later time, he conducted an audit of Respondent's Suboxone 8 mg for the period beginning July 18, 2008, and ending April 9, 2009; the audit was conducted from materials located at DEA and FBI offices, based on Respondent's inventory records and dispensing logs that were seized pursuant to the execution of search warrants at Respondent's office; as well as from distributor records, ARCOS records, and a count of drugs that were identified during the execution of the search warrants; and approximately fifteen bottles of Suboxone were found to be missing. (Tr. 36; *see* Gov't Ex. 4.) DI Dunn testified that he had no recollection of seeing a report regarding, or being informed of, a break-in at Respondent's office. (Tr. 64.)

DI Dunn testified that Respondent had records indicating the dispensing of Demerol but not the receipt; because Demerol is a Schedule II controlled substance, it can only be transferred between registrants pursuant to a DEA Form 222, which Respondent did not have; and that DI Dunn did not request Respondent's DEA Form 222 because he was not present when the search warrant was executed. (Tr. 35, 65.)

DI Chalmers testified that she was present at the execution of the search warrant at Respondent's practice location; she conducted a search in the medication room and a location in the back of that room that may have been Respondent's office; DI Chalmers found controlled substances (Suboxone, Provigil, and possibly Ambien) in an unlocked cabinet; she inventoried but did not seize the controlled substances that she found; and that drug logs were among the documents seized from the medication room. (Tr. 92–93.)

Respondent further testified she did not recall having copies of DEA Form 222 for Demerol at the time of the April 2009 search,

stating ''I would guess that we did, but I'm not going to . . . .'' [24] (Tr. 126–27.) Respondent explained that during the relocation from the Corinth office to the temporary Denton office, medications were not transferred, so she ''didn't have those little DEA 222s, so I really didn't purchase any scheduled medications during that brief period of time.'' After moving to the permanent office ''on Mesa, we had to get those little 222s, because we . . . had to order them.'' (Tr. 197.)

IV. The Parties' Contentions

A. The Government

The Government first contends that there is ''no viable DEA registration to revoke in the matter'' because Respondent failed to file a renewal application and her registration expired by its terms on August 31, 2010. The Government argues that any discussion regarding revocation of Respondent's DEA registration is moot because Respondent does not currently possess a valid DEA registration. In the alternative, the Government argues that if the Deputy Administrator finds that collateral consequences require the issuance of a Final Order, then the Deputy Administrator should affirm the immediate suspension order on the grounds that Respondent's continued registration is inconsistent with the public interest.

The Government argues, in substance, that Respondent's ''experience in dispensing controlled substances and record of compliance with applicable controlled substances laws is abysmal.'' (ALJ Ex. 16, 10.) The Government supports its position with allegations that Respondent dispensed a controlled substance prescription for other than a legitimate medical purpose; Respondent prescribed a Schedule II controlled substance for the purpose of opioid addiction treatment; Respondent acted as a reverse distributor without proper authorization by accepting from patients and destroying controlled substances; Respondent illegally possessed controlled substances at an unregistered location; an accountability audit revealed that approximately fifteen bottles of Suboxone were missing from Respondent's office; and Respondent's substandard record-keeping prevented the DEA from performing audits of additional controlled substances.

B. Respondent

Respondent argues, in substance, that she has never previously been the subject of ''an allegation related to the manufacture, distribution or dispensing of controlled substances'' and Respondent has no conviction record under State or Federal law. Respondent further contends that although the DEA has suggested that Respondent's arrest in Denton County, Texas, should be considered in determining whether Respondent's DEA COR should be revoked, this fact should not be considered because it did not result in an indictment or conviction and because 21 U.S.C. 824(a) was never meant to apply to physicians in this circumstance.[25] (ALJ Ex. 17, 12.)

Respondent next contends that Respondent did notify the local DEA of her change of address and was unable to complete an attempt to ''change the national registration database,'' and Respondent reasonably believed that she had complied with the DEA regulations regarding address changes. (ALJ Ex. 17, 14.)

With regard to the unauthorized prescribing of a Schedule II controlled substance for the purpose of treating opioid addiction, Respondent contends that the allegation applies to only one prescription and that Respondent was within the standard of care for prescribing such medication and did not violate any laws because Respondent provided the methadone prescription for pain management, which Respondent documented.

Respondent also contends that she did not take a patient or employee's Valium for her own use. Respondent asserts that she came into possession of the medication because she found the medication in the open and attempted to secure it; and that she subsequently forgot about the medication, which eventually ended up in her home, in her laundry pile.

Respondent argues that although the DEA contends that Respondent failed to properly maintain logs and receipts for controlled substances, the DEA never asked to review her controlled substances logs and never asked Respondent to provide receipts.

Respondent finally contends that a finding that Respondent's continued registration would be inconsistent with the public interest, would not be consistent with the finding of the state licensing authority, which refused to suspend or revoke Respondent's medical license, and that Respondent has at all times ''remained compliant with State and Federal law in her practice of medicine and prescribing controlled substances.'' (ALJ Ex. 17, 16.)

V. Discussion and Conclusions

A. The Applicable Statutory and Regulatory Provisions

The Controlled Substances Act provides that any person who dispenses (including prescribing) a controlled substance must obtain a registration issued by the DEA in accordance with applicable rules and regulations.[26] ''A separate registration shall be required at each principal place of business or professional practice where the applicant . . . dispenses controlled substances.'' [27] DEA regulations provide that any registrant may apply to modify his registration to change his address but such modification shall be handled in the same manner as an application for registration.[28]

It is unlawful for any person to possess a controlled substance unless that substance was obtained pursuant to a valid prescription from a practitioner acting in the course of his professional practice.[29] A registered individual practitioner is required to maintain records of controlled substances in Schedules II through V that are dispensed and received, including the number of dosage units, the date of receipt or disposal, and the name, address and registration number of the distributor.[30]

B. Statement of Law and Discussion

The Controlled Substances Act, at 21 U.S.C. 824(a)(4), provides, insofar as pertinent to this proceeding, that the Deputy Administrator may revoke a COR if she finds that the continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).[31]

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for a DEA COR if she determines that such registration would be inconsistent with the public interest. In determining the public interest, the Deputy Administrator is required to consider the following factors:

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research, with respect to controlled substances.

(3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution or dispensing of controlled substances.

(4) Compliance with applicable state, federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

As a threshold matter, the factors specified in Section 823 (f) are to be considered in the disjunctive: the Deputy Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *See David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (DEA 1993); *see also D & S Sales,* 71 FR 37,607, 37,610 (DEA 2006); *Joy's Ideas,* 70 FR 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (DEA 1989).

Additionally, in an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied.[32] The burden of proof shifts to Respondent once the Government has made its *prima facie* case. *Medicine Shoppe—Jonesborough,* 73 FR 364 (DEA 2008); *see also Thomas Johnston,* 45 FR 72,311 (DEA 1980).

C. The Factors To Be Considered

Factor 1: The Recommendation of the Appropriate State Licensing Board

As described in the Procedural Section of these Recommended Rulings, Respondent does hold a valid state medical license but Respondent's state controlled substances

[24] Respondent's answer on direct examination was interrupted by Respondent's counsel, with a question on a different topic.

[25] I have specifically given no weight and find no relevance to any references or suggestions about ''arrests,'' ''criminal search warrants'' or similar statements appearing in this record.

[26] 21 U.S.C. 822(a)(2).

[27] 21 U.S.C. 822(e).

[28] 21 CFR 1301.51.

[29] 21 U.S.C. 844(a).

[30] 21 CFR 1304.03(b), 1304.22(a)(2)(ix), 1304.21(a), 1304.22(c) & 1304.22(a)(2)(iv).

[31] 21 U.S.C. 824(a)(4).

[32] 21 CFR 1301.44(e) (2010).

registration has been suspended. Respondent, therefore, does not possess valid authority to handle controlled substances in the jurisdiction in which she is registered. Given that the Texas authorities relied exclusively on the DEA action to suspend Respondent's state authority, however, Respondent's lack of such authority is not dispositive and has no relevance in determining whether Respondent's continued registration would be inconsistent with the public interest.

There is evidence, however, that the Texas Medical Board has taken prior action against Respondent's medical license. Although the Government presented no evidence regarding the matter, Respondent did testify that she has been disciplined by the Texas Medical Board on three prior occasions: 1) in December 2000, Respondent was cited for substandard chart documentation resulting in a monetary fine, chart monitoring, and eight hours of continuing education in medical recordkeeping; 2) Respondent received a monetary fine for failure to timely notify the Texas Medical Board of the relocation of her practice from the City of Corinth to the City of Denton; and 3) in March or April 2009, Respondent received a monetary fine in relation to missing fentanyl. (Tr. 186–87.)

Although no additional detail is available, the Texas Medical Board action taken against Respondent with regard to Respondent's failure to timely notify the Texas Medical Board of the relocation of her practice appears to be similar to Respondent's failure to notify the DEA of a subsequent change of practice location. Accordingly, the fact that Respondent was previously disciplined by the Texas Medical Board does weigh in favor of revocation.

It is important to also note that the Texas Medical Board did temporarily suspend Respondent's medical license on August 19, 2009, and reinstate Respondent's medical license on October 16, 2009; the evidence indicates that Respondent's Texas medical license is currently active. The August 19, 2009, suspension order referenced the suspension action taken by the DEA; however, the order also referenced numerous other grounds which were apparently unrelated to the grounds upon which the DEA issued the OSC/IS; specifically, the Texas order addressed issues related to the issuance of prescriptions to Respondent's patients by another physician. (Gov't Ex. 6, 7.)

These issues were not raised in the OSC/IS but were addressed in the Government's Prehearing Statement. At hearing, however, the Government did not elicit testimony regarding the issues related to prescriptions written by another physician but did submit some limited documentary evidence on the matter. (*See* Gov't Ex. 3, 6 & 7.) The documentary evidence provided is not sufficient to warrant a review of an issue which the Government has failed to adequately pursue in the proceeding and the issue, therefore, will not be considered further.

The Texas Medical Board's October 16, 2009 Order reinstating Respondent's Texas medical license offers little substantive insight with regard to its own factual findings, which were found to be inconclusive. ''The Panel is unable to determine from the evidence presented that Respondent is a continuing threat to the health of Respondent's patients or a continuing threat to the public. . . .'' (Gov't Ex. 7.) Accordingly, the action and findings of the Texas Medical Board do not significantly weigh for or against Respondent with regard to the temporary suspension and later reinstatement. The current active status of Respondent's Texas medical license does, on balance, weigh against a finding that Respondent's continued registration would be inconsistent with the public interest.

Factor 3: Respondent's Conviction Record

There is no evidence that Respondent has ever been convicted under any federal or state laws relating to the manufacture, distribution or dispensing of controlled substances. I therefore find that this factor, although not dispositive, weighs against a finding that Respondent's continued registration would be inconsistent with the public interest.

Factors 2 and 4: Respondent's Experience in Handling Controlled Substances; and Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

In this case, there is no evidence that, prior to any action related to this matter, Respondent has failed to remain in compliance with applicable federal laws relating to controlled substances. The testimony and evidence does reveal, however, that Respondent failed to properly notify the DEA that she relocated her practice from her registered location to a new unregistered location, in violation of both state and federal law.[33] There is no evidence that, prior to the current circumstances, Respondent has failed to comply with the Controlled Substances Act. The Respondent has admitted to a March or April 2009, Texas Medical Board monetary fine in relation to missing fentanyl. There is no other independent evidence of record relating to the circumstances surrounding that issue.

(a) Respondent's Registered Location

It is undisputed that Respondent relocated her practice from her registered location, 4851 I–35 East, Suite 101, Denton, Texas 76210 (I–35 office), to a new location, 4310 Mesa Drive, Denton, Texas 76207 (Mesa office), on or around February 1, 2009. Respondent testified that she relocated her practice to the Mesa office because she was evicted from the I–35 office in late 2008.[34] Respondent maintains that she did not move controlled substances or acquire controlled substances for use at her temporary Collier street location. (Tr. 197–98.) The evidence does indicate, however, that Respondent did possess and distribute controlled substances from the unregistered Mesa office during the period beginning approximately February 1, 2009, and ending with the issuance of the OSC/IS on August 4, 2009.

Federal law requires every person who dispenses any controlled substance to obtain a registration from the Attorney General.[35] Additionally, a separate registration must be obtained for each principal place of practice where an applicant dispenses controlled substances and a registrant must report any change of address by applying to modify his or her registration to change his/her address, which shall be treated as an application for registration.[36] The CFR clearly states the procedures a registrant must follow to request a change in the registered address.[37]

In this case, the evidence indicates that Respondent failed to modify her registration to update her Mesa office practice address. Respondent testified she believed that she properly notified the DEA of her new address when she requested certain documents be sent to her new location. The evidence of record reflects that Respondent has previously successfully modified the address of her registered location at least three times [38] and therefore Respondent was fully aware of the proper procedure for requesting an address change. (Gov't Ex. 2.) Additionally, there was no evidence presented at hearing confirming that Respondent has even yet successfully updated the address of her practice location.

The search warrant executed by the FBI and the DEA in April 2009 reflected the presence of controlled substances from Respondent's unregistered Mesa Drive location. I therefore find that Respondent failed to properly notify the DEA of the change in address of her registered location and Respondent possessed and dispensed controlled substances from an unregistered location, in violation of 21 U.S.C. 822(e) and 827(g) and 21 CFR 1301.51.

In mitigation, the Respondent's actions with regard to notifying DEA do not appear to be intentionally deceitful, because the Respondent credibly testified that she notified the Texas DPS of her new Mesa office address, and no other evidence of record was offered by either party at hearing to the contrary. (Tr. 161–64.) Respondent also introduced as evidence prescription pads which reflected the address of 4310 Mesa Drive, Denton, Texas. (Resp't Ex. 5.) Clearly the evidence as a whole is consistent with Respondent's testimony that the failure to update her new address was due to an omission, notwithstanding the evidence of neglect by Respondent to ensure it had been properly done.

(b) Respondent's Issuance of Methadone to Opioid-Addicted Patients

The Government provided evidence, which Respondent corroborated, that Respondent

[33] Any registrant may apply to modify his or her registration to change his or her name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. *Cf.* 21 CFR 1301.14 (2010). The request for modification shall be handled in the same manner as an application for registration. 21 CFR 1301.12 *et. seq.; see also* 37 Tex. Admin. Code § 13.23 (2010).

[34] Respondent testified that all controlled substances that remained at the I–35 location were destroyed, not relocated.

[35] 21 U.S.C. 822(a)(2).

[36] 21 U.S.C. 822(e), 827(g); 21 CFR 1301.51 (2010).

[37] *See* 21 CFR 1301.51 (2010).

[38] August 21, 2001; March 11, 2003; and September 16, 2004.

prescribed methadone to three (3) opioid-addicted patients [39] who were previously treated at an addiction treatment center. The Government, however, further alleged that Respondent's treatment of these patients amounted to the unauthorized treatment of narcotic-dependent patients by prescribing Schedule II controlled substances for the purpose of treating opioid addiction, which is inconsistent with 21 U.S.C. 823(g)(1) and 21 CFR 1306.04(c).

Federal law requires a separate registration for ''[p]ractitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment . . . .'' [40] A practitioner may, however, ''lawfully prescribe methadone to a patient for pain management purposes under his practitioner's registration.'' *Tony T. Bui, M.D.,* 75 FR 49,979 (DEA 2010) (citing 21 U.S.C. 823(f)). The Government presented evidence indicating that Respondent prescribed methadone to three patients who were previously treated with methadone at an addiction treatment center. (Gov't Exs. 12–14, 16–18.) The Government contends in part that Respondent was providing opioid addiction treatment because each of the three patients were already taking methadone when they first became patients of Respondent, and that each patient previously received methadone from a methadone clinic. This alone does not amount to substantial evidence indicating that Respondent was improperly prescribing a Schedule II controlled substance for the purpose of opioid addiction treatment.

Although the documentary evidence does indicate an opioid addiction in each of the three patients, this evidence consists of unsworn statements from patients [JF] and [MM], along with medical records relating to the three patients, which must be weighted accordingly. The allegation of improper prescribing of methadone is unsubstantiated by the documentary evidence and was, in fact, refuted by Respondent's expert witness; and, in each instance, Respondent has established an underlying purpose of pain management. ''While methadone is approved by the FDA, and has long been used, for the treatment of opioid addiction . . . the drug is also approved for the treatment of pain.'' *Bui,* 75 FR at 49,988. Moreover, the record contains no expert evidence showing that Respondent's prescribing of methadone was inconsistent with accepted medical practice for prescribing the drug for pain management.

The Government bears the burden on the issue of whether Respondent's prescribing of methadone ''was for the purpose of treating opioid addiction'' and not as part of an accepted medical practice for pain management. Similar to *Bui,* the Government has presented no expert evidence indicating such and relies solely on hearsay and unsworn statements. Respondent has testified that the treatment of the three patients in question was for pain management related to a number of underlying medical conditions, which are objectively documented in the medical records introduced at hearing by both parties. Additionally, the Respondent presented expert testimony from a medical doctor with experience treating chronic pain, even though not formally certified in pain management.

In *Calhoun* v. *Bailar,* 626 F.2d 145 (9th Cir. 1980), the court found that to constitute substantial evidence the probative value and reliability of hearsay evidence may be analyzed using many factors, such as: a consideration regarding the independence or possible bias of the declarant; the type of hearsay material presented; whether the statements are signed and sworn or anonymous, oral or unsworn; whether the statements are contradicted by direct testimony; whether the declarant is available to testify and, if so, whether the objecting party subpoenas the declarant or whether the declarant is unavailable and no other evidence is available; the credibility of the witness testifying to the hearsay; and whether or not the hearsay is corroborated. *Id.* at 149; *see also Richardson* v. *Perales,* 402 U.S. 389, 402–06 (1971).

DI Dunn credibly testified at hearing that his investigation revealed that Respondent treated several patients who previously had been treated for narcotic addiction at the Denton Treatment Center. DI Dunn obtained unsworn statements from two of those patients, [JF] and [MM], both indicating in substance that they did not consult Respondent for the purpose of pain management. That testimony and evidence, however, does not carry much weight based on the factors set forth in *Calhoun.*

The written patient statements presented by the Government were unsworn; there is no evidence that an attempt was made to subpoena the witnesses, and the Government provided no indication that the witnesses were unavailable to testify; no evidence was offered to explain why the statements were unsworn; there was no evidence presented to indicate whether the declarant witnesses are credible; and the statements provided are not corroborated by other record evidence.

For example, the patient files specifically refer to a number of objective medical findings and diagnoses that are inconsistent with the unsworn statements. In the case of [MM], the medical file reflects entries from April to August 2009, including patient complaints of osteoporosis left shoulder and leg; back, shoulder and leg pain at level seven, among other complaints; and diagnoses of chronic back pain; arthritis; opioid addiction; anxiety; depression; and weight management, among others; as well as positive physical findings on examination to include lumbosacral back pain. (Gov't Ex. 16.) In the case of [TR], the medical file reflects entries from June to August 2009, including patient complaints of back and left knee pain; ''lumbosacral back pain from scoliosis for several years. Pain 10/10 without meds.'' (Gov't Ex. 17, at 35.) The file reflects diagnoses of chronic back pain; left knee arthritis; anxiety; and depression, among others; as well as positive physical findings on examination to include positive lumbosacral back pain and bilateral hip pain, among other findings. (Gov't Ex. 17.) In the case of [JF], the medical file reflects entries from January to February 2009, including patient complaints of chronic pain complicated by history of opioid dependence resulting from chronic arthritic pain in the neck, back and left knee. Diagnoses included arthritis in the cervical and lumbar spine, chronic pain syndrome, and opioid dependence, among other findings.

In addition to the patient files, the unrebutted testimony and expert opinion of Dr. Babuji support a finding that the methadone was prescribed for pain management, not for opioid addiction. Although the Government did object to the testimony of Dr. Babuji at hearing on the grounds that he was not ''proffered as an expert,'' [41] that objection is misplaced.[42] The Government further argues in its post-hearing brief that Dr. Babuji's testimony be given no weight because he ''was not tendered and/or accepted as an expert witness . . . [and] [t]here is no indication from his testimony that [he] has any experience in pain management or addiction treatment.'' (ALJ Ex. 16, 6.) To the contrary, Respondent indicated in her Prehearing Statements that she was offering the witness as an expert, and I so find. Additionally, Dr. Babuji's testimony specifically included an admission that he was not certified in pain management, but he based his testimony in part on his experience treating his own patients with conditions of pain.

I find that Dr. Babuji was adequately proffered as an expert and I have evaluated his testimony as an expert witness with regard to the standard of care in treating patients with pain management conditions. Dr. Babuji is clearly qualified to testify regarding the general standard of care and treatment of patients with pain management issues, based on his education, training, and experience over twenty years, including practicing cardiology, internal medicine and primary care for the last three years in Dallas, Texas. (Tr. 265.)

Dr. Babuji's demeanor was serious and forthright throughout his testimony. The evidence reflected that Dr. Babuji has known the Respondent for between two and three years, having done cardiology consults in her Denton, Texas office approximately once per week. (Tr. 270.) Dr. Babuji's appearance and testimony at hearing was without benefit of financial compensation. On cross-examination the Government challenged the witness with regard to whether he had reviewed the entire [JF] file, suggesting that he had not, because the ''complete file . . . is approximately 700 to a thousand pages.'' [43]

[39] Referred to herein as [JF], [MM] and [TR].

[40] 21 U.S.C. 823(g) (2006).

[41] (Tr. 288.)

[42] The Government offers no authority in support this argument. While Respondent did offer Dr. Babuji as an expert witness, there is no formal requirement to either ''offer'' or ''accept'' an expert witness during hearing. *See United States* v. *Johnson,* 488 F.3d 690, 697–98 (6th Cir. 2007) (frowning on the practice of labeling the witness as an ''expert'' in the presence of the fact finder); *see also United States* v. *Rice,* No. ACM 30231, 1994 WL 164477 at *1 (AFCMR Apr. 22, 1994) (noting ''no requirement in either military or federal practice mandating that an expert witness be tendered (offered) and accepted before providing expert testimony.'')

[43] Government counsel asked the witness: ''Would it surprise you to learn that the complete

While there may be some doubt as to the exact number of pages reviewed by Dr. Babuji with regard to the [JF] medical file, he credibly maintained that he had sufficient information available to support his conclusion, noting his review of hundreds of pages of the medical file including the discharge summary. There is no other evidence to suggest the witness had a bias or interest in the outcome of the case.

I find that Dr. Babuji presented fully credible competent evidence within his stated area of expertise. The testimony is consistent with that presented by the Respondent, who credibly testified at hearing in detail as to the standard of care she used in treating the three patients at issue in this matter. The testimony of Dr. Babuji and the Respondent is also consistent with other documentary evidence of record including the relevant treatment records. Accordingly, I find that the Government has not established by a preponderance of the evidence that Respondent prescribed Schedule II controlled substances to patients for the purpose of treating opioid addiction in violation of 21 U.S.C. 823(a)(1) and 21 CFR 1306.04(c).

(c) Respondent's Possession of a Prescription Written in the Name of an Employee

The Government alleges that Respondent prescribed controlled substances for other than a legitimate medical purpose when she issued a prescription to a then-current employee and the controlled substance was later found in Respondent's home. Under DEA's regulations, a prescription for a controlled substance is unlawful unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' [44]

At the hearing in this matter, the Government presented evidence consisting of photographs of a prescription bottle for diazepam 10 mg, quantity 90, issued in the name of [HM], which DI Dunn testified was found in Respondent's bathroom medicine cabinet and which the DEA had tested; photographs of tablets; an unsworn statement by [HM]; and the testimony of DI Leakey, who assisted in the search of Respondent's residence and seizure of the [HM] prescription containing an estimated fifty (50) pills.[45] Respondent provided evidence consisting of Respondent's medical records for [HM] and CVS pharmacy records for [HM] along with the testimony of Respondent, Debra Allinger and Shelley Franks-Chapa.

DI Dunn testified that [HM] was a patient and employee of Respondent and that the DEA found, in Respondent's home, a prescription bottle for diazepam issued in the name [HM]. (Tr. 29.) DI Dunn's testimony is supported by photographs of the prescription bottle and several loose pills along with the testimony of DI Leakey, and an unsworn statement from [HM].

Respondent has not argued that the diazepam was not found in her home, although there may be some discrepancy regarding the last location where Respondent recalls seeing it; that the medication found was not actually diazepam; or that she did not authorize the prescription for [HM]. There is no dispute that the DEA did find in Respondent's home a prescription bottle containing diazepam issued in the name of [HM]. I therefore find no reason to provide less than full weight to the testimony of DI Dunn or DI Leakey that the prescription bottle of diazepam was found in a medicine cabinet in Respondent's home containing approximately fifty (50) pills. I do find reason, however, to provide less weight to the unsworn written statement of [HM] given the sworn testimony of Respondent, Debra Allinger and Shelley Franks-Chapa regarding the origin of the single Valium prescription at issue in this case.

DI Dunn testified that he spoke with [HM] and that the statement [HM] gave him was consistent with the written statement provided by the Government. (Tr. 29; Gov't Ex. 11.) DI Dunn testified that [HM] told him that Respondent asked if [HM] could write a prescription in [HM]'s name and then get the medication back from [HM] because Respondent could not write a prescription to herself. (Tr. 29–30.) I find no reason to doubt the testimony of DI Dunn with regard to his interaction with [HM]. I do, however, find that, consistent with the factors set forth in *Calhoun,* [HM]'s statements are not reliable.

Respondent's testimony indicated a possibility of bias of [HM] in that [HM] is a former patient and employee and the relationship between Respondent and [HM] ended badly. (Tr. 154.) Respondent testified that [HM] intended to initiate a lawsuit against her because of poor results from a medical procedure performed by another physician in Respondent's office. The accuracy of this testimony was uncontested and I find it otherwise credible. As a result of this prior dispute, [HM] would certainly have some interest or bias in the outcome of any proceeding related to Respondent's practice of medicine.

[HM]'s statement is contradicted by objective evidence of record. [HM]'s statement asserts that [HM] has ''*never* taken Valium *ever* . . . .'' (Gov't Ex. 11) (emphasis in original). Respondent, however, submitted CVS pharmacy records for [HM] indicating that [HM] did fill a prescription on February 27, 2001, for 10 diazepam 10 mg, written by Dr. [VS]. [HM] has, therefore, at least received a prescription for diazepam in the distant past thereby contradicting her statement that she has never taken Valium.[46] The Government also implied that the Valium prescription for [HM] was written ''before [Respondent] even had a patient consult with [GM].'' (Tr. 320.) While Respondent's medical records for [HM] appear to support that implication, (*see* Resp't Ex. 8), a review of the record as a whole indicates otherwise.

Respondent's medical records for [HM] include a report of a consultation on February 6, 2009, which indicates that Respondent prescribed diazepam (Resp't Ex. 8.); [HM]'s prescription records, as provided by Respondent, indicate that the diazepam prescription was filled on February 8, 2009. (Resp't Ex. 13, at 3.) The Government has provided no evidence indicating the actual date that the prescription was written and is presumably relying on Respondent's testimony that the prescription was written on February 3, 2009. (*See* Tr. 221.) I find no need to determine the precise date upon which the diazepam prescription was actually written because there is evidence that Respondent had written prescriptions for [HM] as early as September 26, 2008, as evidenced by [HM]'s prescription records. (Resp't Ex. 13.) Given the fact that [HM] worked in Respondent's office and presumably had a patient-physician relationship with Respondent, the actual date upon which the prescription was written provides little or no value to the evidence regarding whether Respondent prescribed controlled substances for other than a legitimate medical purpose.

[HM]'s statement is also contradicted by the testimony of Respondent, Debra Allinger and Shelley Franks-Chapa. [HM] stated that Respondent called her after the FBI searched her home and asked her to tell people that Respondent came into possession of the diazepam because [HM] kept the medication at work (presumably at Respondent's practice) and ''it must have fallen in a box of files she brought home.'' (Gov't Ex. 11.) Respondent and Ms. Allinger both credibly testified that [HM] left the medication sitting on top of a desk in a room that was being painted and that Respondent, after seeing the medication, retrieved it from the desk and placed it in the pocket of her lab coat. (Tr. 153, 297.) Additionally, Ms. Franks-Chapa testified that she witnessed [HM] requesting prescriptions for Valium.[47] (Tr. 313.)

Respondent objected at hearing to the admission of [HM]'s statement on the grounds that the statement was unsworn, constituted hearsay, and was unduly prejudicial because Respondent was not able to cross-examine the declarant. (Tr. 31.) Neither party has shown that [HM] was unavailable to testify and the Government has provided no explanation as to why [HM] was not made available as a witness. Neither party attempted to subpoena the witness. As the court recognized in *Calhoun,* however, a respondent cannot complain of an inability to cross-examine a witness with regard to a written report when the respondent has failed to exercise her right to subpoena the witness. That said, the absence of sworn testimony by [HM] at hearing, weighed against other credible sworn testimony and credible documentary evidence, significantly discredits the reliability and probative value of [HM]'s statement.

file regarding [JF]'s hospital visit is approximately 700 to a thousand pages?'' (Tr. 287.) The factual basis for this question remains a mystery, since no other medical records relating to [JF] were received in evidence other than Respondent's exhibit six. Respondent's exhibit seven relating to [JF] was withdrawn and the Government presented no case in rebuttal.

[44] 21 CFR 1306.04 (2010).

[45] (Gov't Ex. 11, 15; Tr. 29–31, 37–38, 99 & 105.)

[46] I take official notice from the 2007 edition of the Physicians' Desk Reference that Valium is a brand name product containing the Schedule IV controlled substance diazepam, a benzodiazepine derivative.

[47] It is unclear whether [HM] requested the prescription from Respondent or her nurse but the incident apparently occurred in Respondent's office. (Tr. 317.)

I find [HM]'s unequivocal statements that [HM] had ''never'' taken Valium, ''ever,'' and that it was ''prescribed only this one time for her,'' were directly contradicted by objective uncontested evidence of a past prescription for Valium issued to [HM] and testimony by Ms. Franks-Chapa that she witnessed [HM] requesting a prescription for Valium. [HM]'s past adverse patient and employment history with Respondent also indicates [HM] had a reason to be biased against Respondent. In light of the foregoing, the unsworn statement of [HM], corroborated only by the prescription found at Respondent's home, is entirely discredited by the objective and sworn testimony to the contrary.

Accordingly, I find that the Government has not established by a preponderance of the evidence that Respondent prescribed controlled substances for other than a legitimate medical purpose to a then-current employee.

(d) The DEA's Accountability Audit of Respondent's Practice

The Government alleges in the OSC/IS that an accountability audit ''performed at your office in April 2009, revealed . . . an unexplained shortage of approximately 13 bottles of Suboxone, or 390 dosage units.'' The Government's Prehearing Statement filed on June 15, 2010, further states that an

''accountability audit was conducted on the Suboxone 8mg for the period of July 1, 2008, through April 9, 2009. Respondent's records show dispensation of 38 bottles (1,140 dosage units) of Suboxone. There were 11 bottles present on-hand on the day of the search warrant. Therefore, Respondent could only account for 49 bottles (1,470 dosage units) of Suboxone, leaving a shortage of 13 bottles (390 dosage units unaccounted for based on the records.''

The Government's Prehearing Statement further stated in part that DI Chalmers would testify about the ''accountability audit conducted on the Suboxone . . . .''

The Government's evidence at hearing with regard to the Suboxone audit consisted of a two page ARCOS [48] Transaction History Report and the testimony of DI Dunn, reflecting an audit period of July 18, 2008 to April 9, 2009. (Tr. 34–35.) DI Dunn's direct testimony regarding the audit is reflected in the following testimony:

Q: Now how did you conduct your audit of Suboxone?

A: With the Suboxone, she did have some records there that showed an inventory date. I used that date as a starting point from her own records. She had a log of dispensing of Suboxone, so I was able to utilize that as well. I then turned to ARCOS's subpoena and found out who the provider for the Suboxone was, the distributor, subpoenaed their records, used the ARCOS records, and then from account of the drugs that were on hand on the date of the search warrant, we were able to do an audit with those numbers on that one drug.

(Tr. 36.) DI Dunn testified that from the foregoing audit fifteen (15) bottles of Suboxone were missing, each containing thirty (30) pills, for a total loss of 450 pills. (Tr. 36.)

DI Chalmers testified on direct examination that she participated in the FBI search of Respondent's practice location on Mesa Drive in April 2009, as DI Dunn was out of town and could not participate. DI Chalmers further testified that her responsibilities during the search were to speak with the Respondent and assist with the search warrant. DI Chalmers searched the ''medication room at the clinic and another location at the back of the room believed to be Respondent's office setting.'' (Tr. 92.) DI Chalmers testified that she did not conduct an audit on the Suboxone or other drugs found in the specific location that she searched, nor did she seize any of the controlled substances at that time. (Tr. 93.) DI Chalmers also testified that rather than conduct an audit, she did an inventory of the controlled substances ''that she encountered'' and also seized documents from the medication room, to include a drug log. While the evidence is clear that DI Chalmers did not seize any drugs, there is no evidence of record reflecting whether any drugs were seized from the premises or if all drugs present were inventoried, since DI Chalmers's role in the search was limited to a narrow location and purpose.

The evidence of an audit in this case simply cannot support any credible findings of a shortage of Suboxone during the alleged time period. DI Dunn's testimony of a shortage of fifteen bottles of Suboxone as of the date of the April search appears to rest on the ''account of the drugs that were on hand on the date of the search warrant'' compared with the data obtained from the ''ARCOS records,'' and records from the distributor.[49] There was no documentary or testimonial evidence offered to indicate the search established an accurate count of the number of bottles of Suboxone present in Respondent's office, which is an essential component of the audit.[50] The testimony by DI Chalmers clearly indicates that she only inventoried the controlled substances that she encountered and there is no evidence whatsoever as to the number of other agents participating in the search, what other agents encountered, the scope of the search or the identity and total inventory of controlled substances found during the search.[51] There is no evidence of record to support the conclusions reached by DI Dunn regarding the audit, to include the details related to the search of Respondent's office, specific items seized or inventoried, the location of the items and related information as may be found in a search inventory.

Additionally, the reliability of the audit results is further undermined by the distributer records. (*See* Resp't Ex. 11.) As an example, the ARCOS data reflected in Government exhibit four reflects a transaction date of October 28, 2008, for the shipment of three (3) bottles of Suboxone, thirty (30) dosage units each, for a total of ninety (90) dosage units, from the supplier Dendrite. An invoice from Dendrite with a process date of October 28, 2008, reflects a shipment of ''6 SUBOXONE SUBLINGUAL 8MG CIII TABLETS–30 TABLETS PER BOTTLE.'' (Resp't Ex. 11, at 3 & 9.) While there may be an explanation for the discrepancy, none was offered at hearing nor is an explanation readily apparent from the limited evidence offered with regard to the audit. Evidence submitted by Respondent also indicates that some of the Suboxone shipments were returned during the relevant time period. (Resp't Ex. 11, at 4.)

Other discrepancies exist but it is unnecessary to elaborate further. While I find the testimony of DI Dunn and DI Chalmers generally credible, the limited evidence offered by the Government at hearing related to the audit of Respondent's handling of Suboxone for the time period of July 18, 2008 to April 9, 2009, is so lacking in specificity and reliability that it cannot support any credible findings or constitute substantial evidence.[52]

Accordingly, I find that the Government has not established by a preponderance of the evidence that Respondent cannot account for ''approximately 13 bottles of Suboxone or 390 dosage units.''

[48] While neither party offered background information regarding ARCOS during hearing, it is noted that ''Registrants are also required to report records of sales or acquisitions of controlled substances in Schedules I and II, of narcotic controlled substances listed in Schedules III, IV and V, and of psychotropic controlled substances listed in Schedules III and IV with the DEA's Automation of Reports and Consolidated Orders System (ARCOS). 21 CFR 1304.33(c); 21 U.S.C. 827(d). These reports must be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted. 21 CFR 1304.33(b).'' *Easy Returns Worldwide, Inc.* v. *United States,* 266 F. Supp. 2d 1014, 1016 (E.D. Mo. 2003).

[49] DI Dunn testified that he ''subpoenaed their records,'' meaning the distributor of the Suboxone. Government exhibit four indicates the source of the data is ARCOS rather than distributor records. DI Dunn was asked whether the subpoenaed distributor records ''matched up'' with the ARCOS report, and DI Dunn stated he ''believed so.'' (Tr. 36–37.) Remarkably, the Government submitted no audit report or any other supporting documentation with regard to distributor records, drug inventory reports compiled at the time of the April 2009 search of Respondent's office, or any other related documentation to factually support the audit results. The only distributor evidence with regard to the Suboxone shipments was offered by the Respondent. Additionally, no testimonial or other evidence was offered with regard to the definition, source, or reliability of ARCOS data.

[50] It is noteworthy that the OSC/IS and Government's Prehearing Statement recited specifically that thirteen bottles of Suboxone were missing for a total dosage count of 390, differing from the testimony at hearing that fifteen bottles of Suboxone were missing for a total dosage count of 450.

[51] The evidence at hearing suggested that the scope of the April 9, 2009 search warrant did not specifically relate to the search and seizure of controlled substances from any of the premises, but rather involved the search and seizure of records. (Tr. 93, 105.)

[52] The Government's post-hearing brief (ALJ Ex. 16) states ''DI Dunn's accountability audit of Suboxone is also uncontested.'' This ignores the fact that Respondent alleged in her Prehearing Statement discrepancies with the Suboxone audit. At hearing, Respondent further offered Respondent's exhibit eleven to rebut the audit results, which was admitted without objection. (Tr. 123.)

(e) DEA 222 Forms, Effective Controls and Disposal of Controlled Substances

The Government alleges in the OSC/IS that Respondent's ''dispensing log indicates that you dispensed other controlled substances, such as Demerol; however, you were unable to provide investigators with any records showing receipt of those controlled substances'' as required by 21 CFR 1304.21. The Government's Prehearing Statement further noticed: the absence of DEA 222 Official Order Forms accounting for Demerol purchases, and no receiving or distribution records for Provigil; and the ''Narcotic Logbook also showed receipt of controlled substances returned to Respondent by patients that did not want the medication. This activity is not specifically authorized by Respondent's registration.'' [53]

The DEA regulations require all applicants and registrants to provide ''effective controls and procedures to guard against theft and diversion of controlled substances.'' [54] In determining whether there has been substantial compliance with the required security standards, the Deputy Administrator may consider a number of factors, including, but not limited to: the type and form of activity conducted; the quantity of controlled substances handled; the type of storage system used; the adequacy of key control systems; the adequacy of supervision over employees with access to storage areas; and the adequacy of the registrant's system for monitoring the receipt, distribution and disposition of controlled substances.[55] A practitioner must store controlled substances listed in Schedules II–V in a ''securely locked, substantially constructed cabinet.'' [56] Additionally, a registrant must ''notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft'' and complete a DEA Form 106 regarding the theft or loss.[57]

DEA regulations require a registrant to dispose of controlled substances consistent with procedures outlined in 21 CFR § 1307.21. There are no provisions in the regulations to allow a non-registrant to return a controlled substance to a registrant. There is no factual dispute in this case, and the Respondent readily admitted in testimony, that on occasion controlled substances were returned and destroyed. An undated ''narcotic log'' introduced at hearing reflects the return of ''various'' medications during the month of December, although no year is indicated. (Gov't Ex. 10, at 1.)

The Respondent testified in substance that her office policy was that if a patient did not like the medication, or had a bad reaction to the medication, the patient could return it; ''we would count it, document it, destroy it'' and it ''didn't happen very often.'' (Tr. 248.) There is no indication that this practice as described by Respondent was a frequent occurrence, and there is no evidence of any diversion of the controlled substances returned. In fact, the un-rebutted testimony of the Respondent is that they were destroyed.

The testimony of Respondent and DI Chalmers provides evidence that Respondent did not properly secure all Schedule II–V controlled substances in a securely locked, substantially constructed cabinet. Although there is no evidence regarding the exact quantities of controlled substances maintained at Respondent's Mesa office, there is sufficient evidence in the form of Respondent's testimony, and that of DI Chalmers, to determine that Respondent did maintain possession of some controlled substances, including at least fentanyl and Suboxone. Additionally, given the credible testimony of both Respondent and DI Chalmers that some controlled substances were found in unlocked cabinets, it is apparent that Respondent did not store all Schedule II–V controlled substances in a securely locked, substantially constructed cabinet as required by applicable regulations. The fact that Respondent did not maintain control over the key to access her medication safe and was unfamiliar with the necessary procedure for opening the safe further indicates that Respondent also did not maintain an adequate key control system.

Although the evidence indicates that Respondent did not follow adequate security procedures, the question remains as to whether that information can be considered in determining if Respondent's continued registration is consistent with the public interest. In order to comport with due process requirements, the DEA must ''provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action.'' *CBS Wholesale Distributors,* 74 FR 36,746 (DEA 2009) (citing *NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc.,* v. *NLRB,* 920 F.2d 130, 134 (2d Cir. 1990)). The DEA has previously held that an issue cannot be the basis for a sanction when the Government has failed to ''disclose 'in its prehearing statements or indicate at any time prior to the hearing' that an issue will be litigated.'' *Id.* at 36,750 (citing *Darrell Risner, D.M.D.,* 61 FR 728 (DEA 1996)). The DEA has also previously found, however, that a respondent may waive his objection to admission of evidence not noticed by the Government prior to the hearing when a respondent does not timely object and when the respondent also raises the issue himself. *Gregory D. Owens, D.D.S.,* 74 FR 36,751, 36,755 (DEA 2009).

In the instant matter, the Government did not raise the issue of security controls in the OSC or in its Prehearing Statement. In fact, the Government first raised the issue of Respondent's security controls during the direct examination of DI Chalmers. The Government asked DI Chalmers whether Respondent's storage cabinets were locked and if they were capable of being locked. (Tr. 94.) While it is true that Respondent did not object to the line of questioning, and offered some testimony on direct examination with regard to controlled substances kept locked in safes, Respondent's primary testimony regarding the issue was raised during the Government's cross-examination of Respondent.

I therefore find that the Government did not provide Respondent with adequate notice regarding Respondent's security control measures and that the issue cannot serve as a basis for determining whether Respondent's continued registration would be inconsistent with the public interest.[58]

The Government also alleges that Respondent failed to effectively monitor the receipt and distribution of controlled substances because Respondent did not maintain an effective recordkeeping system in accordance with 21 CFR §§ 1304.03(b), 1304.04, 1304.11, 1304.21 and 1304.22(c). This substantive issue was noticed in the OSC/IS and in subsequent Prehearing Statements.

Pursuant to 21 CFR §§ 1304.03(b), 1304.22(a)(2)(ix), 1304.21(a), 1304.22(c) and 1304.22(a)(2)(iv), a registered individual practitioner is required to maintain records of controlled substances in Schedules II–V that are dispensed and received, including the number of dosage units, the date of receipt or disposal, and the name, address and registration number of the distributor. It is unlawful to fail to make, keep or furnish required records.[59]

One mandatory recordkeeping vehicle is DEA Form 222, the ''official triplicate order form[] used by physicians to order scheduled narcotics'' and other controlled substances.[60] A menu of federal regulations specifies procedures relating to DEA Form 222, such as obtaining, 21 CFR § 1305.11, executing, § 1305.12, filling § 1305.13, and endorsing DEA Form 222, § 1305.14, among other procedures.[61] In addition, 21 CFR § 1305.03 requires that a DEA Form 222 be used for each distribution of a controlled substance listed in Schedule I or II, and Section § 1305.13 provides that these order forms must be maintained separately from all other records and that they ''are required to be kept available for inspection for a period of 2 years.''

Failing to comply with recordkeeping laws and regulations relating to controlled substances can justify revocation. ''[A] blatant disregard for statutory provisions implemented to maintain a record of the flow of controlled substances and to prevent the diversion of controlled substances to unauthorized individuals[] would justify revocation'' of a certificate of registration.'' [62]

[53] Gov't PHS, at 4.

[54] 21 CFR 1301.71 (2010).

[55] *Id.* 1301.71(b).

[56] *Id.* 1301.75(b).

[57] *Id.* 1301.76(b).

[58] In this case, even assuming, *arguendo,* that I were to consider this additional evidence of security control measures with regard to an appropriate sanction, I would not find the additional facts to warrant revocation.

[59] 21 U.S.C. 842(a)(5).

[60] *Robert L. Dougherty, Jr., M.D.,* 60 FR 55,047, 55,048 (DEA 1995).

[61] *See, e.g.,* 21 CFR 1305.15–.19.

[62] *Robert L. Dougherty, Jr., M.D.,* 60 FR 55,047, 55,050 (DEA 1995) (citing *George D. Osafo, M.D.,* 58 Fed. Reg 37,508, 37,509 (1993) (revoking practitioner's registration where ''[r]espondent failed to comply with numerous recordkeeping requirements[, explaining that] . . . it is a registrant's responsibility to be familiar with the

Continued

DEA regulations state that a registered individual practitioner is required to keep records of controlled substances in Schedules II, III, IV and V which are dispensed.[63] As a general matter, records are required to be kept by the registrant and must be available for at least two years.[64]

The evidence at hearing on this issue included the testimony of DI Dunn and DI Chalmers. DI Dunn testified that he reviewed the records seized by the FBI during search warrants executed at the Respondent's registered and unregistered office locations, as well as her home. DI Chalmers testified that she was present at the search of Respondent's unregistered office on Mesa Drive in April 2009, participating in a search of the medication room and a location at the back of the medication room that may have been the Respondent's office. DI Chalmers further testified that drug logs were among the items seized. (Tr. 92.) DI Dunn explained that from his review of the records seized he found records for the dispensing of Demerol, but not the receipt of that drug. He further explained that because Demerol is a Schedule II controlled substance, it can only be transferred between registrants pursuant to a DEA Form 222. A review of the seized documents by DI Dunn revealed no copies of DEA Form 222.

DI Dunn further testified that ''there were other drugs there or an indication of other drugs there'' to include the controlled substances Demerol, Ambien, Balacet and Provigil. (Tr. 34, 36.) DI Dunn indicated that dispensing logs existed for Demerol but no invoices were found reflecting purchases of Demerol. DI Dunn also found no dispensing logs or inventories for Provigil and Ambien.

The evidence at hearing further included a narcotic log seized from Respondent during the April 2009 FBI search, reflecting the administration of Demerol on numerous occasions from August 26, 2008, to March 25, 2009. (Gov't Exs. 9, 10 at 2.)

The Respondent testified that she was never asked for any copies of DEA Form 222 and was unaware of any of the audits. With regard to whether she possessed copies of DEA Form 222, as required, her testimony was equivocal. The Respondent testified on direct examination that she ''did not recall having DEA Form 222's for Demerol at the time of the April 2009 search'' but ''guessed'' that ''we did.'' The Respondent was less equivocal in her testimony regarding having copies of DEA Form 222 at the Collier street temporary office, stating ''I didn't have those little DEA 222s, so I really didn't purchase any scheduled medications during that brief period of time.'' (Tr. 197.) Respondent also introduced records that Respondent obtained from a pharmacy supplier that include three references to Demerol purchases by Respondent. The shipping dates were August 26, September 24, and October 30, 2008. (Resp't Ex. 9, at 5–7.) None of the documents appear relevant to the presence of copies of DEA Form 222 at Respondent's unregistered Mesa office as of April 2009, because Respondent testified that no controlled substances were moved from her registered office in Denton, Texas to the temporary Collier Street office, as they were destroyed prior to Respondent's being evicted. (Tr. 197–98.)

The absence of any copies of DEA Form 222 found by DI Dunn during his review of the seized documents related to the search of Respondent's office, along with Respondent's lack of certainty that any were present, supports a finding that Respondent did not keep proper records for controlled substances that were ordered and maintained under her registration. DI Dunn's testimony is consistent with the testimony of DI Chalmers regarding the seizure of documents during the April 2009 search warrant, including the seizure of Government exhibits nine and ten. While the testimony offered with regard to the specifics of the FBI search was limited, the evidence as a whole reflects that a considerable quantity of documents was seized from Respondent's office. The fact that no copies of DEA Form 222 were found, independent of whether Respondent was asked to produce them, is persuasive proof of non-compliance.

The Respondent's testimony on the topic is equivocal at best, and is fully consistent with a finding that few if any copies of DEA Form 222 were maintained at the Respondent's unregistered Mesa office during 2009. ''Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against diversion of controlled substances.'' *Paul H. Volkman, M.D.,* 73 FR 30,630, 30,643 (DEA 2008). The evidence of record, including the Respondent's own testimony, reflects that at least during the time period from in or about November or December 2008 until April 2009, Respondent did not properly maintain copies of DEA Form 222 for Demerol, a Schedule II controlled substance. Similarly, the Respondent's acceptance and documentation of returned controlled substances was not in compliance with applicable regulations. Nor did the Respondent maintain other documentation related to the controlled substances Ambien Balacet and Provigil.

(f) Respondent's Testimony

In mitigation, the Respondent testified that she had never had a prior DEA complaint or investigation, and has been in medical practice for twenty-five years, practicing in Texas since 1991. (Tr. 110, 113 & 225.) Respondent further testified that in January 2008 she became aware of a theft of fentanyl and reported the theft to DEA and other law enforcement agencies. DI Dunn also testified that he investigated the reported theft issues in May 2008, and found Respondent's reporting of theft to be proper but the theft and loss reports submitted by Respondent were incomplete. (Tr. 55.) Respondent also testified at hearing to the theft of a safe from her office in late 2008, which possibly included Suboxone and other scheduled medications, as well as ''all my triplicates.'' (Tr. 119, 196.) The Respondent also testified that in late 2008 she was evicted from her then-registered location and had to move to a temporary office (Collier office) for a short period of time, before moving to her permanent office location (Mesa office). During late 2008 and 2009, Respondent also experienced employee issues, to include alleged misuse of prescription pads, theft and related financial matters. (Tr. 209–10.) At Respondent's Mesa office she has five active examination rooms, and relies on her staff to maintain logs and inventory. (Tr. 205.) Respondent has approximately thirty (30) patient visits per day and described herself as a ''workaholic'' working non-stop without a lunch break. (Tr. 116.)

I find the Respondent's testimony at hearing to be generally credible. The Respondent's manner throughout her testimony was serious and deliberate. Respondent's education, experience and training, which included regular continuing medical education in pain management, reasonably supported her opinion testimony with regard to patients [JF], [HM], [TR] and [MM]. This opinion testimony was also fully consistent with Dr. Babuji's testimony. The Respondent testified throughout a four hour period without reference to notes or other written material, unless specifically directed by counsel, and was accurately able to recall events with a reasonable level of certainty. The Respondent did not display hostility during testimony or other visible mannerisms that adversely impacted her credibility.

On balance, however, the Respondent's record-keeping violations, handling of returned controlled substances and failure to properly change her registered address weigh significantly in favor of revocation.

Factor 5: Such Other Conduct Which May Threaten the Public Health and Safety

As to factor five, there is no other substantial evidence of record demonstrating conduct by Respondent which may threaten the public health or safety, other than the risk of diversion inherent in the failure to maintain effective controls and procedures to guard against theft and diversion of controlled substances, which has been evaluated under factors two and four.

VI. CONCLUSION AND RECOMMENDATION

I find that a balancing of the foregoing public interest factors supports a finding that the Government has established a prima facie case in support of revocation of Respondent's registration, or denial of an application for registration. Once DEA has made its prima facie case for revocation, the burden then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall* v. *DEA,* 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *United States Dep't of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72, 311 (DEA 1980).

A ''Respondent's failure to maintain accurate records . . . is sufficient by itself. . .'' in some cases, to conclude that granting a registration would be inconsistent with the public interest. *Volkman,* 73 FR at 30644.

Federal regulations applicable to controlled substances''); *see also Hugh I. Schade, M.D.,* 60 FR 56,354, 56,356 (DEA 1995) (noting the inventory procedures required by Sections §§ 1304.11 to 1304.13, and 1305.06).

[63] 21 CFR 1304.03(b) (2010).

[64] *Id.* § 1304.04

The facts in *Volkman* pertaining to record keeping violations involved a doctor who ''rapidly became the largest practitioner-purchaser in the nation of oxycodone'' which included ordering ''hundreds of thousands of dosage units of these drugs'' over time periods as short as several months. *Id.* at 30,643. The facts in *Volkman* further reflected that no dispensing logs were maintained, at times exceeding an entire year. *Id.* at 30,645.

Additionally, where a registrant has committed acts inconsistent with the public interest, a registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct. *Patrick W. Stodola,* 74 FR 20,727 (DEA 2009). Also, ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest.'' *Joseph Gaudio,* 74 FR 10,083, 10,094 (DEA 2009).

The Respondent testified in substance that she updated her new registration address with Texas authorities, made various efforts to do so with DEA including receiving correspondence, and therefore thought she had satisfied her obligation. (Tr. 161–63; ALJ Ex. 2.) Respondent's explanation for record keeping violations is less specific. The Respondent's testimony as a whole demonstrated that she understood the seriousness and importance of record keeping requirements, and testified that while at the temporary Collier street location ''I didn't have those little DEA 222s, so I really didn't purchase any scheduled medications during that brief period of time.'' (Tr. 197.) The Respondent also testified that she believed she ''had very effective oversight'' of controlled substances.'' (Tr. 248.) This belief is contradicted by Respondent's own testimony. Respondent also testified that she relied heavily on her staff with regard to inventory and maintenance of controlled substances, and that Respondent did very little herself. (Tr. 205.) The evidence of record does demonstrate, however, that Respondent's errors were often due to lack of knowledge, omission or neglect, rather than a deliberate violation of the record keeping requirements.

The alleged conduct supported by substantial evidence in this case centers on Respondent's record keeping violations, which have been documented to be deficient over a relatively short period of time, as well as a failure to update her registered address, and improper acceptance and disposal of returned controlled substances from patients. The Government argues in its post-hearing brief that revocation is the appropriate remedy in this case. An agency's choice of sanction will be upheld unless unwarranted in law or without justification in fact. A sanction must be rationally related to the evidence of record and proportionate to the error committed. *See Morall* v. *DEA,* 412 F.3d 165, 181 (D.C. Cir. 2005) (sanction will be upheld unless unwarranted in law or without justification in fact).

In support of its recommendation for revocation, the Government cites *Paul H. Volkman,* 73 FR 30,630, 30,644 (DEA 2008), which is significantly distinguishable from the facts of this case. Respondent's conduct in this case occurred over a comparatively short period of time, with substantially fewer controlled substances, and with no evidence of actual diversion of any controlled substances. The Government cites no other precedent to support a revocation sanction on facts similar to Respondent's, nor does there appear to be any. The Respondent's errors and conduct clearly were neglectful and serious during the relevant time period, and likely due in part to ongoing issues including eviction from her registered office, employee problems, and an office break-in and theft, among other factors. That said, a revocation penalty is simply not rationally related to the evidence of record established by substantial evidence or proportionate to Respondent's misconduct.

I find that Respondent's testimony as a whole demonstrates that she has sufficiently accepted responsibility for her actions and omissions with regard to a revocation penalty, but Respondent's explanation of past errors and demonstrated plan to avoid future violations is insufficient to support an unconditional registration. Accordingly, I recommend that Respondent's COR BC0181999 as a practitioner not be revoked or a pending application denied, on the condition that Respondent: a) within a reasonable period of time as set forth in the agency's final order in this matter, satisfy the appropriate DEA designee that Respondent has state authority to handle controlled substances in Texas, the state in which she is registered with DEA;[65] b) submit to the nearest Field Division Office of DEA no later than one (1) year after issuance of a DEA COR, documentation reflecting successful completion of accredited training at Respondent's expense, in the proper maintenance, inventory, and record-keeping requirements for controlled substances, with such training to take place after the Agency issues a final order in this matter; and c) for one (1) year after the issuance of a COR, Respondent shall submit to the nearest Field Division Office of DEA, on a quarterly basis, a log of all controlled substances in Schedules II, III, IV and V received, maintained and dispensed by Respondent.

Dated: October 26, 2010

s/ Timothy D. Wing,
Administrative Law Judge

[FR Doc. 2015–17310 Filed 7–13–15; 8:45 am]

BILLING CODE 4410–09–P

[65] 21 U.S.C. 824(a)(3).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–24]

Trenton F. Horst, D.O.; Decision and Order

On March 25, 2014, Administrative Law Judge Gail A. Randall (ALJ) issued the attached Recommended Decision.[1] The Government filed Exceptions to the Recommended Decision.

Having reviewed the record in its entirety, I have decided to adopt the ALJ's findings of fact and conclusions of law.[2] However, for reasons explained below, I respectfully amend the ALJ's recommended sanction because it is contrary to precedent and, in my opinion, gives insufficient weight to the Agency's interest in deterring intentional diversion, both on the part of Respondent and the community of registrants. *See David A. Ruben,* 78 FR 38363, 38386 (2013). A discussion of the Government's Exceptions follows.

The Government's Exceptions

The Government raises two exceptions to the ALJ's recommended decision: First, it takes exception to the ALJ's finding that Respondent '' 'has sufficiently accepted responsibility for his actions and instituted remedial measures to ensure that the misconduct will not reoccur.' '' Exceptions, at 2 (quoting R.D. 36). Second, it argues that the ALJ's recommended sanction is inconsistent with agency precedent. Exceptions, at 5–6.

As for the first exception, the Government urges that I reject this finding, contending that Respondent ''continues to[] minimize the nature of his misconduct.'' *Id.* at 4–5. As support for its contention, the Government cites Respondent's testimony regarding his treatment at a rehabilitation center which it maintains was inconsistent with his conduct during his stay. More specifically, the Government notes Respondent's testimony that:

> it was a little bit difficult to acclimate myself for the first few weeks, probably six weeks. It took me a while to kind of get into the flow of things. Thereafter, I'd like to think I became a model participant. I spent seven months there.

Tr. 210. The Government then notes that Respondent was subject to a ''no female contract'' during the initial four months of his treatment, and that he breached the contract when he had contact with another patient and engaged in sexual relations with her

[1] All citations to the Recommended Decision (R.D.) are to the ALJ's slip opinion as originally issued.

[2] As ultimate factfinder, I am familiar with my obligations under the Administrative Procedure Act and the role of the ALJ's recommended decision. *See Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951) (''The 'substantial evidence' standard is not modified in any way when the Board and its examiner disagree . . . . The findings of the examiner are to be considered along *with the consistency and inherent probability of testimony.* The significance of his report, of course, depends largely on the importance of credibility in the particular case.'') (emphasis added). So too, the courts are quite familiar with the standard of review of an Agency decision. Accordingly, I decline to publish the ALJ's discussion of the substantial evidence test and the standard of review.

approximately two months into his stay. Exceptions, at 2. The Government implies that his testimony was disingenuous because the incident occurred two weeks later than Respondent claimed it did. *Id.* The Government does not, however, explain why it matters whether the incident occurred six weeks or two months into his stay.

The Government also maintains that Respondent engaged in a pattern of minimizing his misconduct, both during his time in treatment and in his testimony at the hearing. In support of this contention, it cites evidence showing that Respondent admitted his breach of the no-female contract to the treatment center staff only upon learning that he was going to be subject to a polygraph. As for his testimony, the Government argues that ''Respondent did not divulge that he broke [the] contract . . . on direct examination.'' *Id.* at 3. It then argues that even on cross-examination, Respondent failed to truthfully answer its questions because he did not admit to having sexual relations with the female patient until he was specifically asked if he had sex with female patients.[3] However, when the Government specifically asked the question, he did answer it truthfully.

Most significantly, to the extent the Government relies on this incident and Respondent's testimony regarding it to contend that he ''has consistently minimized his misconduct,'' Exceptions, at 5; its argument is misplaced. As the Government acknowledges, the incident and his testimony ''*ha[ve] little or nothing to do with controlled substances.*'' *Id.* at 2 (emphasis added). Nor does the Government cite to any case holding that an applicant's breach of the terms of a treatment contract, which does not involve a violation of the Controlled Substances Act or applicable state law (as would failing a drug test), constitutes conduct which may threaten public health or safety. *Cf. Mark G. Medinnus,* 78 FR 62683, 62684 (2013) (rejecting contention that violation of internal clinic operating policy, which did not otherwise violate CSA or state law, constituted conduct inconsistent with the public interest.).

Because Respondent's breach of his no-female contract does not constitute actionable misconduct under the public interest standard, his testimony regarding the incident is not relevant in assessing whether he has accepted responsibility for his misconduct. While this evidence is arguably relevant in assessing Respondent's claim that he has been rehabilitated, it is undisputed that he successfully completed inpatient treatment, that he has been in compliance with his Oklahoma Health Professionals Program contract, and that he passed all of his random drug tests. RX 2.

There is, however, evidence that supports the Government's contention that Respondent does not fully acknowledge his misconduct. As ultimate fact-finder, I am not bound by the Government's failure to cite this evidence which I conclude is properly considered in reviewing the Government's contention that the ALJ's recommended sanction is inconsistent with agency precedent.

The ALJ found that Respondent not only abused methamphetamine, but that he also wrote prescriptions for controlled substances for A.B., his then-girlfriend (and fellow methamphetamine abuser), as well as for S.M. and Z.M., who were two of her friends. With respect to A.B., the evidence showed that between July 29, 2010 and September 12, 2011, Respondent issued her 15 prescriptions for Lortab 7.5mg and 10mg (then a schedule III controlled substance[4] which combines hydrocodone and acetaminophen), as well as one prescription for both Xanax (alprazolam, a schedule IV drug) and promethazine with codeine cough syrup (schedule V). Moreover, the Lortab prescriptions, which ranged from 40 to 80 tablets, authorized 28 refills. In total, the prescriptions, with refills, provided A.B. with approximately 2,540 tablets of hydrocodone.

With respect to S.M., at a minimum, the evidence showed that Respondent issued him a prescription for 60 tablets of hydrocodone/apap with three refills.[5] *See* GX 13. As for Z.M., the evidence shows that Respondent issued him a prescription for 40 tablets of Lortab 7.5 with two refills. GX 14.

Respondent did not dispute that he failed to perform a physical exam on A.B., S. M., and Z.M., or that the prescriptions were improper. Indeed, he testified that: ''[i]mproper, I think, is a weak word. I think it was stupid. I think you used the word 'idiotic' earlier.'' Tr. 201 (testimony regarding prescriptions to A.B.); *see also id.* at 203 (admitting that the prescriptions to S.M. and Z.M. were ''very improper'').

While Respondent also asserts that he received no monetary gain from writing these prescriptions, *see* Tr. 204, this is irrelevant. What is relevant is that Respondent knowingly and improperly diverted controlled substances to three individuals, including his girlfriend A.B., whom he knew was a drug abuser.

Further, while Respondent acknowledged that the prescriptions were improper, he then maintained that he prescribed to A.B. ''out of compassion'' because ''[s]he was in pain.'' *Id.* at 252. And he further asserted that she did not ''use hydrocodone as a drug of choice, as far as recreational drugs'' because ''[s]he was a methamphetamine addict.'' *Id.* at 253.

The ALJ rejected the Government's contention that Respondent's testimony was an attempt to minimize his misconduct. According to the ALJ, ''[w]hile the reasons Respondent gave for prescribing hydrocodone to A.B. certainly do not justify his improper methods of prescribing, they also do not represent an attempt to minimize or rationalize his behavior.'' R.D. at 35. In the ALJ's view, this was so because Respondent prefaced this testimony with ''his statement that 'it was improper and I admit that.''' *Id.* (quoting Tr. 252).

Read more broadly, however, his testimony most certainly was an attempt to minimize his misconduct. Indeed, on further questioning, Respondent testified that:

[3] The Government initially asked Respondent: ''How did you break that contract?'' Tr. 263. Respondent answered that he was ''a friendly person, and they would approach me, and it's kind of hard when people talk to you, to not talk to them, to completely ignore them.'' *Id.* While this may not have been the answer the Government was seeking, there is no evidence that Respondent's answer was untruthful.

Following this, the Government asked Respondent: ''Did you do more than speaking with females?'' *Id.* Respondent answered:

I had basically what could be called a girlfriend. She was very attentive to me, which I was appreciative of. My marriage was likely in ruins, and it was something that was—it was nice to have someone to talk to. And once that was—basically once that was discovered, I was placed on my no-female contract, and—well, actually I was on my no-female contract when that was discovered, and basically I got reprimanded and eventually I got my act together.

Id. at 264. Here again, this may not have been the answer the Government was seeking, but there is no evidence that it was untruthful.

[4] Combination hydrocodone products have since been placed in schedule II of the Controlled Substances Act. *See Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II,* 79 FR 49661 (2014).

[5] The record includes three documents from Walgreens which have the caption: ''Audit/Board of Pharmacy Inspection Report.'' While each of the documents contains a copy of a prescription issued by Respondent on January 27, 2011, each document lists a different prescription number, a different store number, and a different sold date. GX 13. Thus, it is unclear whether two of the documents were simply refills of the original prescription or whether Respondent issued S.M. multiple prescriptions on the same date.

. . . . I'm exquisitely sorry that I ever prescribed these things, these medicines for these people. You know, I know that I did it improperly. *I know I didn't have proper documentation.* Deep down, when I was writing them, I knew better.

Id. at 258 (emphasis added). Continuing, Respondent testified that:

Deep down, whenever I was writing them, I knew better. *I let my heart and my empathy get the best of me,* more than my brain. I know better now. I've gone through extensive counseling, extensive instruction, boundaries course times two, to understand what my infractions were.

Id. (emphasis added).

Contrary to Respondent's assertion, this was not simply a matter of not having proper documentation to support the prescriptions. Notably, while the ALJ apparently credited his testimony that A.B. was in pain, noting that this testimony ''went unrebutted,'' *see* R.D. at 35, the evidence shows that while Respondent prescribed to A.B for more than one year, he made no claim that he ever conducted a physical exam on her or performed any diagnostic tests to determine whether she legitimately had pain or whether her pain warranted the prescribing of controlled substances. *See* Tr. 172–74 (testimony of Government's expert that the hydrocodone prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice).

As for his assertion that he prescribed ''out of compassion'' and ''empathy,'' this too is amply refuted by his failure—over the course of more than one year—to take appropriate steps to determine the source of her purported pain. And given his acknowledgement that he knew early in his relationship with A.B. that she was a meth addict, his claim that he prescribed to her ''out of compassion'' begs the question of why he did not usher her into treatment.[6]

Respondent also justified A.B.'s hydrocodone prescriptions on the ground that she did not ''use hydrocodone as a drug of choice, as far as recreational drugs'' because ''[s]he was a methamphetamine addict.'' *Id.* at 253. Apparently the possibility that A.B. could also have been abusing hydrocodone to bring her down from the meth she abused or was selling the drug to support her meth addiction never dawned on him.

Finally, Respondent attempted to rationalize his prescribing to A.B. on the ground that he did not understand the boundaries applicable to the practice of medicine. *Id.* However, this excuse does not explain his decision to prescribe controlled substances to both S.M. and Z.M. Indeed, it is unclear what his excuse is for prescribing to S.M. and Z.M.

Thus, this does not strike me as an ''unequivocal acceptance of responsibility for his misconduct.'' R.D. at 36. I need not, however, reject the ALJ's finding that ''Respondent has sufficiently accepted responsibility for his actions'' because as the ALJ properly noted, ''[e]ven when a respondent is genuinely remorseful and has instituted sufficient remedial measures,'' DEA has ''impose[d] sanctions to deter egregious violations of the CSA'' and ''has placed special emphasis on the need to deter intentional diversion of controlled substances.'' *Id.* at 36 (citing *David A. Ruben,* 78 FR 38363, 38386–87 (2013); *Joseph Gaudio,* 74 FR 10083, 10094–95 (2009)).

The ALJ noted that ''Respondent's improper prescriptions to A.B., S.M., and Z.M. clearly constitute intentional diversion.'' R.D. at 37. I agree. So too, she noted that while his ''improper prescribing practices were limited to A.B. and a few of her friends, under DEA precedent they clearly warrant sanctions to deter Respondent and others from repeating the practice.'' *Id.* Again, I agree.

The ALJ also noted ''[w]here the respondent intentionally diverted controlled substances, the Agency required the respondents to periodically submit logs of all controlled substances they prescribe and *suspended [their] registrations* for a period of time commensurate with the severity of the misconduct.'' *Id.* at 38 (citing *Ruben,* also citing *Michael S. Moore,* 76 FR 45867, 45868 (2011), and *Gregory D. Owens,* 74 FR 36751, 36757–58 (2009)) (emphasis added). Yet notwithstanding that she found Respondent's prescriptions ''troubling to say the least,'' *id.* at 37, the ALJ recommended no period of suspension.

The ALJ offered no explanation as for why she believed a period of outright suspension is unwarranted. To be sure, earlier in her decision, the ALJ opined that the Agency ''has granted registrations with restrictions to respondents whose misconduct was more egregious and/or lasted longer than the misconduct of Respondent here.'' *Id.* (citing *Ruben, Owens, Moore,* and *Roger D. McAlpin,* 62 FR 8038, 8040 (1997)).

Yet in both *Ruben* and *Moore,* the Agency suspended each respondent's registration for a period of one year. As for the ALJ's assertion that the respective registrant's misconduct in each of these cases was more egregious than Respondent's, that is certainly true with respect to *Ruben.* But Respondent's misconduct in knowingly diverting controlled substances to three persons, including his girlfriend to whom he provided some 2,540 dosage units of hydrocodone and did so knowing that she was meth addict, is itself, sufficiently egregious to warrant a suspension for a period of one year. As for *Moore,* while the physician's misconduct in growing marijuana for his own and his wife's use was certainly egregious, there was inconclusive evidence as to whether he knowingly distributed it to others; thus, it is debatable whether his misconduct was more egregious than Respondent's.

As for *Owens,* the ALJ asserted that the Agency ''grant[ed] a registration to a respondent who prescribed controlled substances for seven years based on an expired registration.'' R.D. at 37. However, the actual decision to grant a registration to Dr. Owens notwithstanding the above-described misconduct had been made in a proceeding which was resolved seven years earlier and there was no evidence that he was diverting controlled substances. *See Gregory D. Owens,* 67 FR 50461 (2002). So too, the misconduct which gave rise to the second *Owens* decision did not involve the diversion of controlled substances and was comparatively minor.[7]

Moreover, the 2002 *Owens* order predates the Agency's decision in *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007), which held for the first time that notwithstanding the remedial nature of proceedings under 21 U.S.C. 823 and 824, the Agency can consider the need to deter similar acts on the part of both the individual registrant/applicant and the community of registrants. Indeed, this Agency recently denied a physician's application for a new registration based, in substantial part, on his issuance of prescriptions after his registration had expired. *See Anthony E. Wicks,* 78 FR

[6] Even assuming that the ALJ credited Respondent's testimony that A.B. was in pain, *see* R.D. at 33, because it was undisputed that he lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing the prescriptions to her, I decline to give this testimony any weight. Indeed, the ALJ later found that the prescriptions ''clearly constitute intentional diversion.'' *Id.* at 35.

[7] As for the conduct which gave rise to the second *Owens* proceeding, Dr. Owens was found to have not complied with the 2002 order because he failed to file a quarterly drug activity log during a four-month period between September 3 and December 31, 2002, and failed to report a 2005 state board action. 74 FR at 36756–58. While Dr. Owens' misconduct was considerably less egregious than that involving the intentional diversion of controlled substances, the Agency nonetheless suspended his registration outright for a period of three months. *Id.* at 36758.

62676, 62678 (2013); *see also Linda Sue Cheek,* 76 FR 66972 (2011) (denying application based, in part, on physician's issuance of prescriptions without being registered). For the same reason, I respectfully disagree with the ALJ's reliance on *McAlpin.*

Accordingly, notwithstanding that I do not reject the ALJ's finding that Respondent has ''sufficiently accepted responsibility for his actions'' and has produced evidence of his remedial efforts, R.D. at 36, I conclude that the ALJ's recommended order fails to give appropriate weight to the Agency's substantial interest in deterring the intentional diversion of controlled substances. While I will grant Respondent's application, consistent with similar cases, I will order that his registration be suspended outright for a period of one year. *See Ruben,* 78 FR at 38386 (imposing one-year suspension based on acts of intentional diversion notwithstanding ALJ's finding that registrant accepted responsibility for his misconduct and undertook remedial training); *Gaudio,* 74 FR at 10095 (imposing one-year suspension based on acts of intentional diversion and holding renewal application in abeyance pending registrant's acknowledgement of his misconduct); *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (imposing one-year suspension based on acts of intentional diversion where registrant acknowledged her misconduct).[8]

Moreover, upon the completion of the suspension, Respondent's registration shall be subject to the following conditions for a period of two years:

Respondent shall keep a log of all controlled substances he prescribes on a monthly basis for each calendar month. The log shall list each prescription in chronological order; the patient's name and address; the name, quantity, strength and dosing instructions for each drug prescribed; and the number of refills authorized. Respondent shall submit a copy of the log to the local DEA Field Office no later than five business days following the last day of each month.

In the event Respondent opens his own practice, he shall consent to unannounced inspections of his registered location and waive his right to require DEA personnel to obtain an administrative inspection warrant prior to conducting an inspection.

Respondent shall not prescribe any controlled substances to himself, a family member, or any person with whom he has or had a personal or romantic relationship.

Respondent shall have no intentional contact with A.B., S.M., or Z.M.

Respondent shall notify the local DEA Field Office of the results of any drug test he fails, no later than three business days after receiving notification of having failed any such test. This condition shall apply whether the test in conducted by the Oklahoma Board of Osteopathic Examiners, the Oklahoma Health Professions Program, any other licensing authority, any hospital at which he seeks or obtains privileges, or any other employer.

Respondent shall further notify the local DEA Field Office in the event that the Oklahoma Board of Osteopathic Examiners or the Oklahoma Bureau of Narcotics and Dangerous Drug Control (or any other licensing authority) initiates any proceeding, or imposes sanctions against his medical license or state controlled substance registration respectively. Respondent shall make such notification no later than three business days upon being notified of any such action, regardless of whether he has been formally served with either a complaint or order issued by any such agency.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Trenton F. Horst, D.O., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, granted subject to the conditions set forth above. I further order that Respondent's Certificate of Registration be, and it hereby is, suspended for a period of one year. This Order is effective immediately.

Dated: July 6, 2015.

Chuck Rosenberg,

Acting Administrator.

Dedra S. Curteman, Esq., for the Government.

Spencer B. Housley, Esq., for the Respondent.

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

I. INTRODUCTION

Gail A. Randall, Administrative Law Judge. This proceeding is an adjudication pursuant to the Administrative Procedure Act, 5 U.S.C. 551 *et seq.,* to determine whether the Drug Enforcement Administration (''DEA'' or ''Government'') should deny [1] a physician's application for a DEA Certificate of Registration pursuant to 21 U.S.C. 823(f) (2006). Without his registration, the physician, Trenton F. Horst, D.O. (''Respondent'' or ''Dr. Horst''), would be unable to lawfully prescribe, dispense or otherwise handle controlled substances in the course of his medical practice.

II. PROCEDURAL HISTORY

The Deputy Assistant Administrator, Drug Enforcement Administration (''DEA'' or ''Government''), issued an Order to Show Cause (''Order'') dated February 27, 2013, proposing to revoke [2] the DEA Certificate of Registration, No. BH9311604, of Respondent, as a practitioner, pursuant to 21 U.S.C. 824(a)(3)–(4), and deny any pending applications for renewal or modification of such registration because Respondent does not ''have authority to handle controlled substances in the State of Oklahoma'' and because the Respondent's continued registration would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). [Administrative Law Judge Exhibit (''ALJ Exh.'') 1 at 1].

Specifically, the Order alleged that Respondent was ''registered with the DEA as a practitioner in Schedules II–V under DEA registration BH9311604 at St. Mary's Physician Associates, LLC, 330 South Fifth Street, Suite 103, Enid, Oklahoma 73701.'' [*Id.*]. The Order further alleged that Respondent was without authority to handle controlled substances in the state of Oklahoma, which is the state that listed on his DEA

[8] The scope of Respondent's unlawful prescribings far exceeds those of Dr. Krishna-Iyer, who wrote unlawful prescriptions during three undercover visits. *See Jayam Krishna-Iyer,* 71 FR 52148, 52158 (2006). Moreover, this Agency has held that proof of a single act of intentional diversion can support the denial of an application or the revocation of an existing registration. *See Dewey C. MacKay,* 75 FR 49956, 49977 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011).

[1] DEA regulations and precedent clearly establish that ''a registrant, who has been served with an Order to Show Cause, [must] file his renewal application at least 45 days before the expiration of his registration, in order for it to continue in effect past its expiration date and pending the issuance of a final order by the Agency.'' *Paul Weir Battershell, N.P.,* 76 FR 44359, 44361 (DEA 2011) (citing *Paul Volkman,* 73 FR 30,630, 30,641 (DEA 2008)); 21 CFR 1301.36(i). Respondent's Certificate of Registration, Number BH9311604, expired by its own terms on October 31, 2013, about eight months after the Order to Show Cause was served, and Respondent did not apply for renewal until October 31, 2013. [ALJ Exh. 14]. Thus, Respondent's application for renewal will be considered an application for registration. *See Battershell,* 76 FR at 44,361 (holding that although the registration had expired, the renewal application may be considered). Accordingly, the issue in this case is whether DEA should grant Respondent's application, not whether DEA should revoke his registration.

[2] As explained *supra* note 1, the issue is whether the DEA should grant Respondent's application, not whether his registration should be revoked, as the Order to Show Cause suggests.

Certificate Of Registration (''COR''), since his Oklahoma Bureau of Narcotics (''OBN'') registration expired on October 31, 2011. [*Id.*]. The Order further alleged that Respondent's state osteopathic license was suspended [3] on June 21, 2012, for a period of five years, by the Oklahoma State Board of Osteopathic Examiners (''Oklahoma State Board''). [*Id.* at 2]. Thus, the Order stated that the DEA must revoke Respondent's DEA registration because he lacks authority to handle controlled substances in the state of Oklahoma. [*Id.* at 1].

On March 27, 2013, the Respondent, through counsel, timely filed a request for a hearing. [ALJ Exh. 2].

On April 3, 2013, the Government filed its Motion for Summary Disposition [ALJ Exh. 3]. On April 18, 2013, the Respondent, through his attorney, filed a timely Response to Motion for Summary Disposition. [ALJ Exh. 4]. On April 29, 2013, the Government filed a reply to the Respondent's Response to Motion for Summary Disposition, [ALJ Exh. 5], and on May 7, 2013, the Government filed a Renewed Motion for Summary Disposition, [ALJ Exh. 6].

On May 10, 2013, I issued my Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (''Summary Disposition''), recommending that the Administrator summarily revoke Respondent's DEA registration because Respondent was without state authority to dispense controlled substances and thus was ineligible for a DEA registration as a practitioner. [ALJ Exh. 7 at 9–12].

On July 30, 2013, after my Summary Disposition was delivered to the Administrator, but before a final decision was rendered by the Administrator, Respondent filed a Notice to Court and Amended Motion to Reconsider. [*See* ALJ Exh. 8 at 1]. Therein, Respondent informed DEA that he had obtained an Oklahoma Board of Narcotics license which gave Respondent authority to handle controlled substances, so ''the fundamental facts of the case have now changed.'' [*Id.*]. Consequently, the Deputy Administrator ruled that ''the finding necessary to support the revocation of Respondent's registration under section 824(a)(3) can no longer be made.'' [*Id.*]. Noting that the Order to Show Cause also alleged that Respondent's continued DEA registration would be ''inconsistent with the public interest,'' the Deputy Administrator ordered the Government to notify his office as to whether the Government will seek a remand of the case to adjudicate that matter. [ALJ Exh. 10 at 2]. The Government requested a remand on August 6, 2013, [ALJ Exh. 9], which the Deputy Administrator granted on August 23, 2013, [ALJ Exh. 8].

The hearing in this case took place on December 17 through December 18, 2013, at the U.S. Tax Court in Oklahoma City, Oklahoma. [ALJ Exh. 13]. Respondent and the Government were each represented by counsel. At the hearing, the Government introduced documentary evidence and called six witnesses and Respondent introduced documentary evidence and called five witnesses, including himself.

After the hearing, the Government and the Respondent submitted proposed findings of fact, conclusions of law and argument.

III. ISSUE

The issue in this proceeding is whether the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration (''DEA'' or ''Government'') should deny the application [4] of Trenton F. Horst, D.O. (''Respondent''), as a practitioner, pursuant to 21 U.S.C. 824(a)(4), and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f), because his continued registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).

IV. FINDINGS OF FACT

A. Stipulated Facts

The parties have stipulated to the following facts:

1. Respondent's DEA registration BH9311604, which authorized Respondent to handle controlled substances in Schedules II–V at St. Mary's Physician Associates, LLC, 330 South Fifth Street, Suite 103, Enid, Oklahoma 73701, expired by its terms on October 31, 2013.
2. Respondent submitted a renewal application for a DEA registration on October 31, 2013.
3. Respondent has an active and valid license to practice medicine in the State of Oklahoma.
4. Respondent has an active and valid license to handle controlled dangerous substances from the Oklahoma Bureau of Narcotics.
5. Respondent has not been charged with or convicted of any federal or state crimes relating to the manufacture, distribution, or dispensing of controlled substances.

[ALJ Exh. 14].

B. Respondent's Background, Employment, Registration, and Licensure

Respondent testified credibly regarding his medical background, employment, and training, facts which were undisputed at the hearing. [Tr. 182–192]. Respondent graduated from Oklahoma State University College of Osteopathic Medicine with honors in 1999. [Tr. 183]. Shortly thereafter, Respondent completed both an internship and residency at the Tulsa Regional Medical Center. [Tr. 184–85]. Upon completion of his internship and residency, Respondent was awarded a fellowship at the Scott & White Clinic and Memorial Hospital in Temple, Texas, where he learned the specialty of gastroenterology from 2002 to 2005. [Tr. 185–86]. In 2005, Respondent began working in a private ''single-specialty group'' called Digestive Disease Specialists, Incorporated. [Tr. 187].

By 2007, Respondent was board-certified in both internal medicine and gastroenterology. [Tr. 186–87]. He began working for St. Mary's Hospital in Enid, Oklahoma ''on or about June 1, 2010'' in a hospital-owned clinic named Red Carpet Gastroenterology.[5] [Gov't Exh. 6 at 2; Tr. 192]. As explained in further detail below, during his employment at St. Mary's, Respondent abused controlled substances, resulting in St. Mary's terminating his employment and the DEA issuing the Order to Show Cause. After completing therapy at an in-patient substance abuse rehabilitation facility, Respondent obtained employment as a delivery driver for Pizza Hut while he searched for employment as a physician. [Tr. 229; *see also* Tr. 33, 60–61]. Respondent later worked as a ''patient liaison'' at New Beginning Women's Healthcare from the fall of 2012 until April 2013, and then as a ''chart reviewer'' for Prairie View Hospice. [Tr. 230–31]. Since May 2013, Respondent has been employed as a

[3] I note here that the Oklahoma State Board of Osteopathic Examiners did not, in fact, suspend Respondent's license; rather, it placed the license on probation for five years. [Gov't Exh. 6 at 4].

[4] As explained *supra* note 1, the issue is whether the DEA should grant Respondent's application, not whether his registration should be revoked, as the Order to Show Cause suggests.

[5] While Respondent was technically an employee of St. Mary's, he principally worked at Red Carpet, a clinic across the street from the hospital that at least one witness described as ''a private practice.'' [Tr. 78, 100, 130, 131, 150]. Respondent was the only physician working at Red Carpet, and he designed the clinic's name and logo. [Tr. 78, 130, 135–136, 150].

physician at Accident Care and Treatment Center (''ACTC''). [Tr. 231].

On June 29, 2005, Respondent was issued DEA Certificate of Registration (''COR'') Number BH9311604, which is the COR at issue in this case. [Gov't Exh. 22 at 3]. That COR expired by its terms on October 31, 2013. [Tr. 27, ALJ Exh. 14]. Respondent also holds an active, valid license to practice medicine in the State of Oklahoma and an active, valid license from the Oklahoma Bureau of Narcotics to handle controlled substances. [ALJ Exh. 14].

C. Respondent's Substance Abuse

In 2009, while Respondent was employed at Digestive Disease Specialists, Respondent met and began an extra-marital relationship [6] with A.B.,[7] a medical assistant employed at the same location. [Tr. 78–79, 194–95, 250]. Respondent first became aware that A.B. was abusing controlled substances in November of 2010, when she called him and asked him to bail her out of jail after she was charged with possession of marijuana, a controlled substance. [Tr. 195–96]. Soon after that, in December 2010, Respondent began using illegal substances with A.B. and eventually moved in with A.B. on July 4th or 5th, 2011. [Tr. 195, 196, 198, 199].

Respondent credibly testified, and the Government did not refute, that before moving in with A.B., Respondent had never taken amphetamines or methamphetamine. [Tr. 194–95]. Also, Respondent credibly testified, and the Government did not refute, that he has never been charged with or convicted of any crimes involving illegal substances. [Tr. 195; ALJ Exh. 14].

Several St. Mary's employees testified that they noticed ''red spots,'' ''boils,'' or ''lesions'' on Respondent's neck and elbow on at least two occasions. [Tr. 86; 119–122]. Although the reason for the Government soliciting testimony about the red spots is unclear, the insinuation seemed to be that the red spots were an indication of drug use. [Tr. 119. 121–22 (Government witness describing marks on the fleshy area of the elbow)]; 199 (Respondent counsel stating that ''[t]here's been insinuations at least by the Government that [Respondent was] IV drug-using'')]. Respondent denied ever using IV drugs, [Tr. 199], and, other than the red spots, the Government offered no evidence to the contrary. Indeed, a drug screen taken by Respondent in July of 2011 did not indicate any such use, and the witnesses who testified about the spots never explicitly linked the spots to drug use. In fact, the witness the Government used as an expert linked the spots to a bacteria, not to drug use. [Tr. 120–21]. While cross examining this expert, Respondent's attorney suggested that the explanation for the red spots was Respondent's cycstic acne. [Tr. 124–25]. At that time, the Government's witness admitted that it was beyond the scope of her expertise to testify about such conditions. [Tr. 125]. The Government's witness also testified that the red spots ''appeared to be a boil, a bite,'' [Tr. 121], which is consistent with what Respondent told his receptionist when she inquired about the spots, [Tr. 86]. Given the thin evidence offered by the Government regarding the source of the red spots on Respondent's skin and Respondent's several explanations for the spots, I find that the Government failed to meet its burden of proof to show that Respondent used IV drugs or that the red spots on Respondent's elbow and neck were related to illicit drug use.

Respondent's receptionist at Red Carpet, Brenda Martin, testified that Respondent told her that he had been present on at least one occasion while A.B. made a ''drug run.'' [Tr. 81–82; *see also* Gov't Exh. 19]. Ms. Martin noted, however, that Respondent pointed out he did not participate in the drug transactions; he stayed in the back seat of the car while the transaction was completed. [Tr. 81–82]. Ms. Martin also testified that in conversations she had with Respondent, he admitted to being present while A.B. and her associates were ''in the garage making meth,'' although Respondent also told Martin that he ''didn't have anything to do with it.'' [Tr. 85].

Several witnesses testified that at some point during his employment at St. Mary's, Respondent began coming to work tired and tardy on a regular basis.[8] [Tr. 85, 94 (testimony of Brenda Martin); 104 (testimony of Michelle Lee Bays); 139 (testimony of Krista Ann Roberts); 241–44 (testimony of Respondent)]. Ms. Martin testified that Respondent's fatigue got so bad that he would take ''catnap[s]'' in his office between patient visits and had to reschedule several appointments after being late to work. [Tr. 83–84]. Staff members took special notice of Respondent's fatigue when they saw an incoherent notation written by Respondent on a patient's progress note that referenced the patient ''still having pain from right pink chair.'' [Tr. 85–86, 139; Gov't Exh. 17]. Respondent corrected the error by creating a new note from memory of the patient visit, and he admitted that he had trouble focusing the day he wrote the original note. [Tr. 136–140; Gov't Exh. 17].

Respondent's staff at Red Carpet expressed their concerns about Respondent's tardiness, fatigue, and personal life to Michelle Bays, the practice administrator at St. Mary's. [Tr. 100, 104–105]. As a result of these reports, St. Mary's solicited a signed statement from Ms. Martin about her conversations with and observations of Respondent while at work. [Tr. 102–05; Gov't Exh. 19]. Respondent voluntarily submitted to a drug test, apparently requested by St. Mary's,[9] on July 18, 2011. [Tr. 115–116, 205; Gov't Exh. 8]. The drug test came back positive for marijuana, methamphetamine, and amphetamines, and resulted in Respondent's termination from St. Mary's in August, 2011. [Tr. 118, 120, 131, 206, 245; Gov't Exh. 8]. Respondent admits to using methamphetamine, but at the hearing he offered explanations

[6] Despite the Government's argument that Respondent speaking with co-workers about his relationship with A.B. is probative of Factor Five, I ruled at the hearing that the details of Respondent's romantic relationship with A.B. are not relevant to these proceedings. [Tr. 81, 86–87]. I now reaffirm that ruling, and only mention Respondent's relationship to give factual context to the events that led to Respondent's drug abuse and improper prescribing, which are, of course, relevant. In making my determinations about whether Respondent's registration is in the public interest, I assign no weight to Respondent's marital indiscretions.

[7] Before the hearing, I issued a Protective Order which protects the identities of third parties in these proceedings. [ALJ Exh. 12].

[8] The witnesses at the hearing did not all agree on the longevity of Respondent's fatigue and tardiness. Ms. Martin testified that for the first few months she worked for Respondent, Respondent was ''very efficient and punctual'' and that Respondent's fatigue began approximately one month before his termination. [Tr. 91, 93; Gov't Exh. 9]. Respondent himself also testified that ''[m]ost of my, quote, tiredness came during the month of July.'' [Tr. 243]. Michelle Bays, the St. Mary's employee in charge of overseeing day-to-day operations at hospital clinics, is the only witness who testified that Respondent's fatigue and tardiness lasted longer than a month. She testified that the fatigue and tardiness occurred for ''more than a month and a half'' and that ''[i]t was an issue for the time I—my whole time when I worked with him.'' [Tr. 100, 106]. Ms. Bays's recollection of the chronology of events, however, is not reliable for several reasons. First, as noted above, her testimony regarding the timing of Respondent's fatigue and tardiness conflicts with the testimony of two other witnesses. Second, she testified that she began overseeing Red Carpet in September 2009 and that Respondent ''was already there'' at that time, [Tr. 100], but it is clear from the record that Respondent did not begin working at Red Carpet until June 2010 [Gov't Exh. 6 at 2; Tr. 131]. Thus, while I find Ms. Bays to be generally credible, I find that her testimony regarding the timing of events in this case not credible. I also find that Respondent's tiredness and tardiness at work occurred approximately during the month immediately preceding his termination from St. Mary's.

[9] The Government's witnesses did not explain who requested the drug test, but Respondent, when asked who initiated the test, testified that Michelle Bays ''escorted me to the facility where [the drug test] was done.'' [Tr. 205].

for why marijuana and amphetamines were in his system. [Tr. 245].

Regarding Respondent's methamphetamine use, Respondent credibly testified that he began using it in December 2010 and stopped around August of 2011. [Tr. 196–97]. Respondent testified that he used methamphetamine ''maybe twice a month'' before moving in with A.B. in July of 2011, and ''maybe once or twice a week at most'' after moving in with A.B. [Tr. 197]. Respondent also credibly testified that before becoming involved with A.B., he had never used methamphetamine or any other illicit drug. [Tr. 196]. The Government offered no evidence rebutting this testimony.

With respect to the positive result for marijuana on the drug test, Respondent credibly testified that marijuana was in his system at the time of the drug screen because he was ''exposed'' to it while living with A.B., who regularly smoked marijuana with her associates. [Tr. 245]. Dr. Westcott, whom I certified at the hearing as an expert in addiction management, testified that second-hand marijuana smoke could cause a positive result on a drug screen if the subject were exposed to a concentrated amount, but also testified that positive results for marijuana on a drug screen normally mean the subject used the drug. [Tr. 379–82]. The Government, on the other hand, presented no evidence to rebut Respondent's explanation for the drug test's positive result for marijuana, opting instead to simply argue that Respondent's explanation was an ''attempt[] to minimize the significance of his failed drug screen.'' [Government Brief (''Gov't Br.'') at 33].

To be sure, Respondent has used marijuana in the past. At the Board hearing, Respondent testified that he had used marijuana with friends on a ''sporadic, recreational'' basis. [Gov't Exh. 21 at 11]. Furthermore, Respondent's discharge summary from Santé, appended to the Board hearing transcript, notes that Respondent had ''secondary'' issues with ''cannabis abuse.'' [Gov't Exh. 21, Attach. 1]. But none of this evidence contradicts Respondent's testimony at the hearing in these proceedings regarding his marijuana use. In these proceedings, Respondent never testified that he had never used marijuana; Respondent merely testified that the particular drug screen he failed was the result of exposure to marijuana rather than his personal use. [Tr. 245]. Indeed, the Government never asked Respondent generally whether he had ever used marijuana; it only asked whether the failed drug screen was the result of marijuana use. [Tr. 245]. In context, this testimony cannot be construed as a general denial by Respondent of any and all allegations of marijuana use. Thus, Respondent's testimony is not inconsistent with other evidence that proves Respondent has used marijuana in the past.

I therefore find that Respondent's explanation for the positive marijuana result on the drug screen, which was corroborated by Dr. Westcott's testimony on cross examination and unrebutted by the Government, is credible. I also find that Respondent has used marijuana in the past, but that the frequency of such use is unclear from the record. In the absence of any evidence to rebut Respondent's credible testimony regarding the drug test, however, I find that the Government failed to establish that the positive result for marijuana on the drug test was the result of Respondent's personal use.

With respect to the drug screen's positive result for amphetamines, Respondent testified that amphetamines were in his system due to a prescription drug he was taking called Vyvanse. Respondent and Dr. Westcott both testified that Vyvanse is a medication used to treat Attention Deficit Disorder (''ADD''), and that it is ''in the amphetamine class.'' [Tr. 246–48, 382–83]. Respondent testified that he was issued a valid prescription for Vyvanse in 2009, and began taking pills leftover from that prescription every day when ADD symptoms began to reoccur about a week and a half before he failed the drug screen at St. Mary's. [Tr. 246, 248–49]. This explanation is corroborated by two exhibits the Government itself introduced. First, the Board Order found that Respondent ''contacted the Board and confirmed that he had tested positive for . . . Vyvanse.'' [Gov't Exh. 6 at 2]. Second, at the Board hearing, Respondent testified to the same facts regarding his Vyvanse use as he did at the hearing in these proceedings. [Gov't Exh. 21 at 14–15]. Respondent and Dr. Westcott also testified that Vyvanse stays in the system for at least two days, and that in a drug test it would likely result in a positive result for amphetamines. [Tr. 248, 383]. Similar to its approach to the marijuana issue, the Government opted to not offer any evidence to rebut Respondent's explanation of the positive amphetamine result, instead arguing that ''Respondent would have the Court believe [his] less than plausible explanation in the face of unrefuted evidence that he tested positive at a time when he was dating a methamphetamine addict and living at her house where methamphetamine was manufactured.'' [10] [Gov't Br. at 33]. This circumstantial evidence is not convincing in light of the credible testimony Respondent gave at the hearing in these proceedings, which was nearly identical to the testimony he gave at the Board hearing. I therefore find that the Government has failed to establish that Respondent improperly used amphetamines.

Respondent further testified that he never possessed or used illicit drugs while at work, and St. Mary's employees testified that they never concluded otherwise. [Tr. 123, 149, 200–01]. The Government refutes Respondent's assertion, arguing that Respondent's use of illicit drugs at work is evidenced by the fact that ''he tested positive for these drugs while on the job and commuted a great distance to his job.'' [Gov't Br. at 29–30]. Yet, Respondent's expert witness testified on cross examination that methamphetamine and amphetamines stay in the system for two to four days, and Respondent testified that it was ''widely known'' that marijuana can stay in your system for up to thirty days. [Tr. at 254, 382]. The Government failed to introduce any evidence to rebut this testimony, making considerably less plausible the suggestion that Respondent's drug use at home would wear off during his long commute. I therefore find that the Government failed to establish that Respondent used or possessed illicit drugs while at work.

Within hours of his termination, which immediately followed his failed drug test, Respondent voluntarily reported himself to the State Board of Osteopathic Examiners (''State Board'' or ''Board'') and the Oklahoma Health Professional Program (''OHPP''). [Tr. 206–07; Gov't Exh. 6 at 2]. However, Respondent did not report himself to the DEA. [Tr. 273]. In fact, Respondent did not communicate with the DEA about his drug abuse until about a year later. [Tr. 274].

As a result of Respondent contacting the Board, the Board conducted an investigation and held a hearing on June 21, 2012, after Respondent returned

[10] The Government also suggested, without overtly accusing, that Respondent acted improperly by taking ''a *two year-old* prescription for which he did not seek the care of a doctor in a recent visit.'' [Gov't Br. at 33 (emphasis in original); Tr. at 246 (Government counsel asking Respondent, ''So you took it outside the usual course of professional practice[?]'')]. The Government, however, cites no regulation, and I can find none, that forbids the use of ''leftover'' prescription drugs. Further, the Government has offered no evidence to establish that the Respondent's prescription for Vyvanse restricted his use of the drug two years after the issuance of the prescription. I therefore find that the Government failed to establish any wrongdoing by Respondent regarding his consumption of Vyvanse.

home from in-patient therapy.[11] [Gov't Exh. 6 at 1; Tr. 207–208]. The same day as the hearing, the Board issued a Findings of Fact, Conclusions of Law, and Agreed Order of Probation (''Board Order''), which is pertinent to these proceedings and binding on this Court under the principles of collateral estoppel. [Gov't Exh. 6; Tr. 30]; *David A. Ruben,* 78 FR 38,363, 38,365 (DEA 2013); *Robert L. Dougherty, M.D.,* 76 FR 16,823, 16,830 (DEA 2011). Specifically, in relation to Respondent's drug abuse, the Board found the following:

3. On or about August 2, 2011, St. Mary's Regional Medical Center (''Hospital'') in Enid, Oklahoma terminated Dr. Horst's employment at the Hospital. Dr. Horst had failed a drug screen and tested positive for marijuana, methamphetamine and another drug.

4. Dr. Horst contacted the Board and confirmed that he had tested positive for marijuana and a C–II medication Vyvanse for ADHD. Dr. Horst also confirmed that the Hospital had terminated his employment.

[Gov't Exh. 6 at 2]. Respondent stipulated to and ''[did] not contest any of the factual allegations raised by the Board.'' [Gov't Exh. 6 at 2]. Respondent also testified at the hearing in the present proceedings that he agreed with the Board's findings. [Tr. 217].

D. Improper Prescriptions

In addition to Respondent's illicit drug use, the Government proved, and Respondent admitted, that Respondent issued illegitimate prescriptions for purposes other than legitimate medical purposes. [Tr. 170–172, 201–04; Gov't Exhs. 9–14, 16]. Respondent wrote the prescriptions in question for three patients: A.B., Z.M., and S.M. [Tr. 170–172, 201–04; Gov't Exhs. 9–14, 16]. Patient A.B. was the same A.B. with which Respondent was romantically involved, and the other two were A.B.'s friends. [Tr. 201, 203]. Respondent admitted that he knew A.B. abused controlled substances when he issued her the improper prescriptions. [Tr. 196–97, 251–52].

To prove Respondent illegitimately issued the prescriptions in question, the Government offered Dr. Arthur Douglas Beacham, III as an expert witness in the area of osteopathic medicine with an emphasis in pain management. [Tr. 164; Gov't Exh. 15]. Dr. Beacham reviewed patient files and prescriptions written by Respondent for A.B., Z.M., and S.M., and testified that he could ''find no documentation that would support the legitimate medical purpose of controlled medications.'' [Tr. 170–172; Gov't Exhs. 9–14, 16]. Specifically, Dr. Beacham testified that there was ''no documentation to support history or present illness or a physical exam or an assessment nor a plan.'' [Tr. 172–73]. Thus, Dr. Beacham concluded that, in his expert opinion, ''the prescriptions were written for a matter outside medical necessity.'' [Tr. 173–74]. Dr. Beacham also prepared a report containing these same conclusions, which was also admitted into evidence without objection. [Tr. 171; Gov't Exh. 16]. Respondent admitted to issuing the improper prescriptions and did not refute the testimony of the Government's expert witness. [Tr. 201–04].

Respondent filed the patients' records of A.B., S.M., and Z.M. in his own desk rather than with Red Carpet's other patient files. The records were found by a St. Mary's employee[12] in Respondent's desk drawer after Respondent's termination from St. Mary's, and Respondent admits that he should have filed those files with the rest of the clinic's records. [Tr. 131–36, 203; Gov't Exhs. 9–11].

The Board Order included factual findings regarding Respondent's illegitimate prescriptions. These findings, as noted above, are binding on this court. *Ruben,* 78 FR at, 38,365; *Dougherty,* 76 FR at 16,830. Specifically, the Board found the following:

6. Upon Dr. Horst's termination of employment by [St. Mary's], staff at the [Red Carpet] Clinic discovered patient charts in Dr. Horst's office that were kept separate and apart from the Clinic's patient records. These separate charts represented patients never scheduled or seen by Clinic staff. They represent patients AB, SM, and ZM.

7. Patient AB's chart includes a patient registration and medical history, but no physical examination. Chart is on the Clinic's patient record forms. There are no prescribed medications or exam notes recorded. Beginning July 29, 2010 Dr. Horst issued to patient AB sixteen (16) prescriptions of controlled dangerous substances (CDS) with seventeen refills up until his termination by the Hospital. None of these prescriptions are charted. They include Hydrocodone, Promethazine with Codeine syrup, and Alprazolam. Dr. Horst admitted that he had an extramarital affair with patient AB.

8. Patient SM's chart includes a patient registration and medical history, but no physical examination. Chart is on the Clinic's patient record forms. There are no prescribed medications or exam notes recorded. Beginning January 27, 2011 Dr. Horst issued patient SM two (2) CDS prescriptions of Hydrocodone with one (1) refill. None of these prescriptions are charted.

9. Patient ZM's chart includes a medical history, but no patient registration and no physical examination. Chart is on the Clinic's patient record forms. There are no prescribed medications or exam notes. On November 29, 2010 Dr. Horst issued patient ZM one (1) CDS prescription of Hydrocodone with two (2) refills. This prescription is not charted.

[Gov't Exh. 6 at 2–3]. As noted above, Respondent stipulated to all of these facts at the Board hearing and testified at the hearing in the present proceedings that he agreed with the Board's findings. [Gov't Exh. 6 at 2; Tr. 217]. Additionally, the Board concluded that Respondent's actions constituted ''a violation of the Oklahoma Osteopathic Medicine Act, 59 O.S. §§ 620 *et seq.,* and specifically . . . § 637(A)(2)(f)(g)(12) and (13).'' [Gov't Exh. 6 at 4].

E. Respondent's Remedial Actions and Oversight of Respondent

Upon suggestion by the former OHPP president, Respondent checked himself into an in-patient rehabilitation facility in Argyle, Texas, called Santé Center for Healing (''Santé'') on October 12, 2011. [Tr. 208–09]. Respondent testified that he paid for his time at Santé by ''cash[ing] in everything we had as far as IRAs, 401(k)s, profit-sharing, anything that we'd saved up over the years.'' [Tr. 210]. Half of the money Respondent gathered went to Santé, and the other half ''went to sustaining [his] family while [he] was gone.'' [Tr. 210]. Respondent also testified that even after ''cashing out'' many of his assets, Respondent still owes Santé $87,000. [Tr. 210].

Respondent described his experience at Santé as ''intensive,'' especially in the beginning. [Tr. 209–210]. The staff there did various tests and evaluations on Respondent when he arrived, and the daily therapy regimen started early in the morning and lasted until 7:00 p.m., utilizing several different techniques such as group and one-on-one therapy. [Tr. 209–210]. While at Santé, Respondent was required to isolate

[11] As explained below, the hearing took place so long after Respondent's termination from St. Mary's because Respondent had checked into an in-patient rehabilitation center and his hearing was continued. [*See* Gov't Exh. 5].

[12] There are no allegations of privacy invasions regarding the St. Mary's employee finding the files in Respondent's desk drawer. The St. Mary's employee who found the patient files in Respondent's desk, Krista Roberts, testified that she found the files after she offered to help Respondent clean out his desk and that Respondent consented to her help. [Tr. 132–33].

himself from those outside the treatment facility, and was not even permitted to discuss medical issues with other patients. [Tr. 214–15]. Respondent candidly admitted during direct examination that ''it was a little bit difficult to acclimate myself for the first few weeks, probably six weeks,'' but after the initial acclamation phase, he ''became a model participant.'' [Tr. 210; *see also* Tr. 258–260; *but see* Tr. 408; Gov't Exh. 21, Attach. 1]. On cross examination, Respondent also admitted that he broke a ''no female contract'' at Santé by having a sexual relationship with a female patient.[13] [Tr. 260–64].

In addition to his drug abuse therapy, Respondent completed a program at Santé entitled ''Maintaining Proper Boundaries,'' which, according to a letter from the medical director at Santé, is a comprehensive educational and experiential course designed to address the factors that lead to boundary violations, result from boundary violations and are required in the reparation and prevention of any further boundary issues. The course focuses particularly on sexual boundary issues: including sexual boundary transgressions and interpersonal sexual boundary violations, however also recognizes verbal, ethical, moral and legal boundary violations.

[Resp't Exh.. 3; Tr. 212–13].

Respondent completed his time at Santé on May 25, 2012, whereupon he received a ''certificate of sobriety.'' [Resp't Exh. 2; Tr. 213–14, 224]. Respondent testified that his ''sobriety date'' is October 12, 2011. [Tr. 208–09].

Respondent testified that in June 2012, after returning from seven months of therapy at Santé, he met with State Board members and investigators to discuss how he can ''make things right and get on with my life, and hopefully piece my career and life back together.'' [Tr. 217–18]. On June 21, 2012, the Board held a hearing for Respondent's case, which was attended by Respondent without counsel, and issued the Board Order the same day. [Gov't Exh. 6]. The Board Order, to which Respondent had previously agreed in his meeting with the Board members, placed Respondent's medical license on five years' probation and required that Respondent (1) enter into and comply with a contract with OHPP; (2) regularly attend counseling sessions with ''A Chance to Change'' and report to the Board on his progress in counseling; (3) have no contact with A.B.; (4) appear at the next regularly scheduled Board meeting and, when requested, at subsequent Board meetings; and (5) reimburse the Board for the costs it incurred in conducting its proceedings. [Gov't 6 at 4; Tr. 217–20].

Respondent's agreement with the OHPP required Respondent to submit to random bimonthly drug tests and attend at least 75 percent of the weekly ''Caduceus meetings'' conducted by OHPP. [Tr. 218–19; Resp't Exh. 1]. Caduceus meetings are similar to Alcoholics Anonymous meetings, but tailored specifically for physicians. [Tr. 351–52]. Dr. Robert Westcott, the president of the OHPP, testified that Caduceus meetings are a place where physicians can ''discuss issues about being in recovery and being a physician that you really can't talk about in just a regular open AA meeting.'' [Tr. 352]. Respondent testified that since entering into an agreement with OHPP, he has not failed any of his required drug tests and has 100 percent attendance at the weekly Caduceus meetings.[14] [Tr. 219–21]. Respondent testified that the OHPP has also asked him to ''attend other 12-step type meetings,'' and that he normally attends those meetings two or three times per week. [Tr. 219]. Respondent also offered into evidence an attendance log which showed that between June 16, 2012, and September 12, 2013, Respondent attended Alcoholics Anonymous meetings almost every week, usually attending more than one meeting per week.[15] [Resp't Exh. 4; Tr. 221–23].

Dr. Westcott, the president of the OHPP, testified that Respondent has fully cooperated with his OHPP contract, that Respondent has ''done very well'' in his recovery, and that he has ''every reason to believe that [Respondent will] continue to do so.'' [Tr. 372, 377]. He also testified that under OHPP supervision, ''it would (be) very, very unusual for a person to be able to use and continue to use without being caught.'' [Tr. 369]. In fact, Dr. Westcott testified that the OHPP has a 90% success rate of helping physicians stay sober. [Tr. 367–68]. The Government offered no evidence to refute that Respondent has been diligent in abiding by the terms of his probation.

In addition to the conditions of Respondent's probation, the Board itself conducts a certain amount of oversight over physicians who have been disciplined. Most notably, at least every quarter, the Board uses the Prescription Monitoring Program (''PMP'')[16] to review the prescriptions issued by disciplined physicians. [Tr. 370–71]. DEA investigators also have access to the PMP, and use it to monitor registrants suspected of misconduct. [*See* Tr. 39–40].

Respondent is also subject to oversight at his current place of employment, ACTC. [Tr. 422]. Dr. Richard Swenson, the medical director in charge of supervising the physicians at ACTC, testified that the ''locked cabinet or closet'' in which the controlled substances are stored at ACTC is ''under constant video surveillance'' and the drugs themselves are not dispensed by the physicians. [Tr. 418, 438]. Respondent is not permitted to issue prescriptions for controlled substances; he must obtain approval from a doctor with an unfettered license who personally meets and examines the patient before issuing the prescription. [Tr. 419, 437–38].

Although no formal procedures are in place for licensed physicians to review Respondent's charts, Dr. Swenson testified that almost all of the clinic's patients come in for multiple visits and see multiple doctors throughout the course of their treatment. As such, the charts for each patient are normally reviewed by multiple doctors. [Tr. 423–24, 433]. Dr. Swenson also testified that ACTC has a ''no tolerance'' policy regarding diversion of controlled substances, meaning he would immediately report any concerns of diversion. [Tr. 424–25]. On cross examination, Dr. Swenson testified that ACTC does not conduct drug screens or enter into pain contracts before prescribing controlled substances known to be abused. [Tr. 433–36]. However, Dr. Swenson explained that such precautions are normally used only at ''chronic pain management clinics.'' [Tr. 434]. Even Group Supervisor John Kushnir, the Government's representative at counsel table at the hearing, testified that while ACTC had some minor bookkeeping

[13] I admitted evidence of this relationship for impeachment purposes only. [Tr. 292–93].

[14] Although the letter from OHPP offered into evidence by Respondent reports slightly less than 100 percent attendance, [Resp't Exh. 1], Respondent credibly testified on direct examination that the reason for the discrepancy is that he was not aware of the sign-in procedures during the first few weeks he attended the meetings. [Tr. 219]. In any case, both the letter from the OHPP and Respondent's testimony verify that Respondent has been faithful to his contract with the OHPP regarding meeting attendance.

[15] The attendance logs indicated that Respondent did not attend OHPP meetings for the weeks of July 8–14, 2012, September 16–22, 2012, October 21–27, 2012, October 28–November 3, 2012, January 13–19, 2013, and April 7–13, 2013. [Resp't Exh. 4]. However, the logs do not indicate whether meetings were scheduled during those weeks; they only list the meetings Respondent actually attended. Thus, it is impossible to tell from the logs alone what percentage of scheduled meetings Respondent attended.

[16] DI Survovec described the PMP as ''a real-time recording of controlled substance prescriptions that are issued.'' [Tr. 40]

issues, the oversight ACTC conducts over controlled substances dispensing is ''good.'' [Tr. 335].

Notably, ACTC has experience with disciplined physicians because it works with the State Board to employ disciplined physicians. [Tr. 420–21]. This practice began under the clinic's former medical director, who had himself experienced substance abuse problems and was ''interested in seeing what he could do to help other providers that found themselves in that same circumstance.'' [Tr. 421]. Other than Respondent, ACTC currently employs one other physician and one medical assistant with restricted licenses. [Tr. 420, 421]. Dr. Swenson testified that ACTC has a good track record of helping physicians remain sober and reestablish their professional careers. [Tr. 421–22].

F. DEA Investigations of Respondent

DEA first interviewed Respondent in August of 2012, after learning that Dr. Horst's medical license had been put on probation by the State Board. [Tr. 26, 32]. In attendance at that interview were Diversion Investigator Mary Surovec, Group Supervisor John Kushnir, Respondent, and Dr. Robert Westcott. [Tr. 32]. Dr. Westcott attended the meeting at the request of Respondent. [Tr. 32, 275, 387]. Notably, DI Surovec testified that when asked about the allegations in the Board Order, Respondent ''didn't really deny anything.'' [Tr. 33]. DI Surovec and GS Kushnir also asked Respondent to surrender his DEA registration. [Tr. 32, 55, 226, 318]. Respondent asked what his options were, and he was told that he could either surrender his license or be served with an order to show cause. [Tr. 56, 227, 320]. Respondent told DI Surovec and GS Kushnir that ''he was going to think about surrendering.'' [Tr. 33; 227]. Respondent testified that he was hesitant to surrender his COR because other physicians had told him that after surrendering a DEA registration, ''you never get it back.'' [Tr. 276].[17] Indeed, both DI Surovec and GS Kushnir testified that they did not recall making any indications to Respondent that he would be able to regain a surrendered COR through demonstrated compliance and rehabilitation. [Tr. 61–62].

[17] The Government sought testimony from Dr. Westcott that, in fact, he was the one who advised Respondent to not surrender his registration, but Dr. Westcott credibly denied doing such. [Tr. 391–392].

V. STATEMENT OF LAW AND DISCUSSION

A. Positions of the Parties

1. Government's Position

The Government timely filed Government's Proposed Findings of Fact and Conclusions of Law (''Government's Brief'') with this Court on January 31, 2014. In its brief, the Government set forth proposed findings of fact, conclusions of law, and arguments in favor of denying Respondent's COR. The Government argues that it met its burden of proving a prima facie case, primarily focusing on factors two, four, and five of the public interest analysis set forth in 21 U.S.C. 823(f). [Gov't Br. at 24, 28].

With respect to factors two and four, the Government points out that Respondent stipulated to the factual allegations in the Board Order regarding his positive drug test and improper issuing of prescriptions. [*Id.* at 25]. Moreover, the Government relies on its expert witness, who testified that Respondent's prescribing of controlled substances to A.B., S.M., and Z.M. were without a legitimate medical purpose. [*Id.* at 25–27].

Regarding factor five, the Government argues that Respondent's actions of prescribing controlled substances to A.B., someone he knew to be a drug abuser, were particularly harmful to the public health and safety given Respondent's ''practic[e] as a solo gastroenterologist in a small community.'' [Gov't Br. at 28–29]. The Government also argues that Respondent's admitted abuse of illicit and controlled substances also posed a threat to public health and safety. [*Id.* at 29]. Although Respondent insists that he never used or possessed illicit drugs at work, the Government argues that ''the sheer fact that he tested positive for these drugs while on the job and commuted a great distance to his job demonstrates that Respondent's behavior while he was employed as a physician caused a threat to the public health and safety.'' [*Id.* at 29–30].

The Government also argues that Respondent's remedial actions are not sufficient to entrust him with a DEA COR because Respondent has demonstrated a lack of candor with the DEA. The Government points out that (1) Respondent did not report to DEA the positive results of the drug test he took while working for St. Mary's, (2) Respondent ''could not admit that his self-abuse . . . contributed to his inability to perform as a doctor,'' (3) Respondent's testimony was ''rife with inconsistencies,'' and (4) Respondent was not forthright in his testimony about his experience at Santé. [Gov't Br. at 32–33].

Finally, the Government argues that even if Respondent has shown sufficient remorse and instituted remedial measures, his actions were too egregious to warrant his registration. [Gov't Br. at 34–36]. Further, the Government argues that in light of the current prescription drug abuse epidemic, the need to deter improper prescribing weighs in favor of denying Respondent's registration. [*Id.* at 36].

2. Respondent's Position

Respondent timely filed Respondent's Proposed Findings of Fact, Conclusions of Law, and Argument (''Respondent's Brief'') on January 30, 2014. Therein, Respondent ''fully admits to writing improper prescriptions to three individuals'' and ''further admits to using methamphetamine, sometimes as often as twice a week.'' [Resp't Br. at 7]. Respondent also notes that the entirety of his impropriety was during a six month time period, but does not dispute that the Government has proved its prima facie case. [*Id.*].

Rather, Respondent argues that it has rebutted the case against him with evidence that he takes responsibility for his actions and has instituted sufficient remedial actions to justify his registration. Respondent argues that he has made ''significant, dramatic, and substantial efforts at rehabilitation and [has] demonstrated commitment to fully comply with any and all regulations placed upon him by state licensure boards.'' [*Id.* at 7]. In particular, he argues that his participation in (1) a seven-month inpatient substance abuse program, (2) boundaries training, (3) OHPP programs, (4) random drug testing, and (5) support groups demonstrate his commitment both to recovery from substance abuse and compliance with the Board's conditions of licensure. [*Id.*]. Respondent also argues that his substance abuse was short-lived, and that he has now been sober for over two years. [*Id.*]. Moreover, Respondent argues that his circumstances have ''changed drastically since the time of his misconduct''; he has reconciled with his wife, attended family counseling, ended his relationship with A.B., and even shortened his commute to work. [*Id.* at 9].

B. Statement of Law and Analysis

Pursuant to 21 U.S.C. 823(f) (2011), the Deputy Administrator may deny an application for a DEA COR if he determines that such registration would be inconsistent with the public

interest.[18] Similarly, pursuant to 21 U.S.C. 824(a)(4), the Deputy Administrator may revoke a DEA COR, if he determines that such registration would be inconsistent with the public interest. In determining the public interest, the following factors are considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f) (2011).

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration be denied. *See Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (DEA 2003) (citing *Henry J. Schwartz, Jr. M.D.,* 54 FR 16,422, 16,424 (DEA 1989)). Moreover, the Deputy Administrator is ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Thus, ''this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor'' each party. *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (DEA 2009). ''Rather, it is an inquiry which focuses on protecting the public interest[.]'' *Id.*

The Government bears the ultimate burden of proving that the requirements for registration are not satisfied. 21 CFR 1301.44(d) (2014). Specifically, the Government must show that Respondent has committed acts that are inconsistent with the public interest. 21 U.S.C. 823(f); *Jeri Hassman, M.D.,* 75 FR 8,194, 8,227 (DEA 2010). However, where the Government has made out a *prima facie* case that Respondent's application would be ''inconsistent with the public interest,'' the burden of production shifts to the applicant to ''present[ ] sufficient mitigating evidence'' to show why he can be trusted with a new registration. *See Medicine Shoppe—Jonesborough,* 73 FR 364, 387 (DEA 2008). To this point, the Agency has repeatedly held that the ''registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Id.; see also Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (DEA 2007). The Respondent must produce sufficient evidence that he can be trusted with the authority that a registration provides by demonstrating that he accepts responsibility for his misconduct and that the misconduct will not reoccur. *See id.; see also Samuel S. Jackson, D.D.S.,* 72 FR at 23,853. The DEA has consistently held the view that ''past performance is the best predictor of future performance.'' *Alra Laboratories,* 59 FR 50,620 (DEA 1994), *aff'd Alra Laboratories, Inc.* v. *DEA,* 54 F.3d 450, 451 (7th Cir 1995).

Factor One: Recommendation of Appropriate State Licensing Board

Recommendations of state licensing boards are relevant, but not dispositive, in determining whether a respondent should be permitted to maintain a registration. *See Gregory D. Owens, D.D.S.,* 74 FR 36,751, 36,755 (DEA 2009); *see also Martha Hernandez, M.D.,* 62 FR 61,145, 61,147 (DEA 1997). According to clear agency precedent, a ''state license is a necessary, but not a sufficient condition for registration.'' *Robert A. Leslie, M.D.,* 68 FR at 15,230; *John H. Kennedy, M.D.,* 71 FR 35,705, 35,708 (DEA 2006).

DEA possesses ''a separate oversight responsibility with respect to the handling of controlled substances,'' which requires the Agency to make an ''independent determination as to whether the granting of [a registration] would be in the public interest.'' *Mortimer B. Levin D.O.,* 55 FR 8,209, 8,210 (DEA 1990); *see also Jayam Krishna-Iyer, M.D.,* 74 FR at 461. Even the reinstatement of a state medical license does not affect this Agency's independent responsibility to determine whether a DEA registration is in the public interest. *Levin,* 55 FR at 8,210. The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within a state government. *Edmund Chein, M.D.,* 72 FR 6,580, 6,590 (DEA 2007), *aff'd Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008).

Here, it is undisputed that Respondent holds a valid license to practice medicine in the state of Oklahoma. [Gov't Br. at 21; ALJ Exh. 14]. Because his licensure does not constitute a recommendation from the Board, however, I find that factor one weighs neither for nor against Respondent's registration.

Factors Two and Four: Registrant's Experience with Controlled Substances and Registrant's Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

Respondent's experiences with handling controlled substances, as well as his compliance with laws related to controlled substances, are relevant considerations under the public interest analysis. Pursuant to the Controlled Substances Act, ''[p]ersons registered by the Attorney General under this subchapter to . . . dispense controlled substances . . . are authorized to possess . . . or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.'' 21 U.S.C. 822(b); *Leonard E. Reaves, III, M.D.,* 63 FR 44,471, 44,473 (DEA 1998); *see also* 21 CFR 1301.13(a) (providing that ''[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.''). As such, the DEA properly considers practitioners' past compliance with CSA requirements and DEA regulations in determining whether registering such a practitioner would be in the public interest.

The regulation applicable here is DEA's long-standing requirement that a prescription be issued for ''a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' *Ralph J. Chambers, M.D.,* 79 FR 4,962, 4,970 (DEA 2014) (quoting 21 CFR 1306.04(a)). DEA precedent further establishes that ''a practitioner must establish and maintain a bona-fide doctor-patient relationship in order to be acting 'in the usual course of . . . professional practice' and to issue a prescription for a 'legitimate medical purpose.' '' *Paul H. Volkman,* 73 FR 30,630, 30,642 (DEA 2008). Whether a valid doctor-patient relationship was established is determined by looking to state law. *Id.*

Here, Respondent issued prescriptions to A.B., S.M., and A.M. outside the usual course of his professional practice. The Government's expert credibly testified at the hearing that after reviewing the prescriptions and the patient files, he could ''find no documentation that would support the legitimate medical purpose of controlled

[18] The Deputy Administrator has the authority to make such a determination pursuant to 28 CFR 0.100(b), 0.104 (2013).

medications'' because there was ''no documentation to support history or present illness or a physical exam or an assessment nor a plan.'' [Tr. 170–173; Gov't Exhs. 9–14, 16]. Dr. Beacham's written report credibly reached these same conclusions. [Tr. 171; Gov't Exh. 16]. Respondent admitted to issuing the prescriptions improperly and did not refute the testimony of the Government's expert witness. [Tr. 201–04].[19]

In addition to his issuing of improper prescriptions, Respondent's possession[20] of methamphetamine violated federal law. Under the CSA, it is ''unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice.'' 21 U.S.C. 844(a). It is undisputed that Respondent possessed methamphetamine, which is a Schedule III controlled substance under 21 U.S.C. 812, without a prescription. [*See* Tr. 200; Resp't Br. at 3].

I find that Respondent's possession of a controlled substance without a prescription, combined with his improper issuing of prescriptions to A.B., S.M., and Z.M., clearly weigh against Respondent's registration under factors two and four of the public interest analysis.

Factor Three: Registrant's Conviction Record Relating to Controlled Substances

Pursuant to 21 U.S.C. § 823(f)(3), the Deputy Administrator may deny a pending application for a certificate of registration upon a finding that the applicant has been convicted[21] of a felony related to controlled substances under state or federal law. *See Thomas G. Easter II, M.D.,* 69 FR 5,579, 5,580 (DEA 2004); *Barry H. Brooks, M.D.,* 66 FR 18,305, 18,307 (DEA 2001); *John S. Noell, M.D.,* 56 FR 12,038, 12,039 (DEA 1991).

Here, the Government concedes that it ''did not introduce any evidence during this proceeding regarding a Federal or State conviction for Respondent relating to controlled substances.'' [Gov't Br. at 23]. Indeed, the parties stipulated that ''Respondent has not been charged with or convicted of any federal or state crimes relating to the manufacture, distribution, or dispensing of controlled substances.'' [ALJ Exh. 14]. However, the Government also correctly points out that under DEA precedent, factor three is not dispositive and ''is of considerably less consequence in the public interest inquiry.'' [Gov't Br. at 23 (quoting *Ruben,* 78 FR at 38,379 n.35]. I therefore find that this factor weighs neither for nor against Respondent's registration.

Factor Five: Such Other Conduct Which May Threaten the Public Health and Safety

Under the fifth public interest factor, the Agency considers ''[s]uch other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5). The Administrator has clarified this language by reasoning that since Congress used the word ''may,'' factor five includes consideration of conduct ''which creates a probable or possible threat (and not an actual) threat [sic] to public health and safety.'' *Roni Dreszer, M.D.,* 76 FR at 19,434; *Michael J. Aruta,* 76 FR 19,420, 19,420 (DEA 2011); *Beau Boshers, M.D.,* 76 FR 19,401, 19,402 n.4 (DEA 2011); *Jacobo Dreszer, M.D.,* 76 FR 19,386, 19,386 n.3 (DEA 2011).

Taking into consideration Congress's clear statutory language and legislative intent under the CSA, misconduct considered under factor five also ''must be related to controlled substances.'' *Terese, Inc. D/B/A Peach Orchard Drugs,* 76 FR 46,843, 46,848 n.11 (DEA 2011); *Tony T. Bui, M.D.,* 75 FR at 49,989 (''In short, DEA has never held that a practitioner's prescribing practices with respect to non-controlled substances provide an independent basis for concluding that the practitioner has engaged in conduct which may threaten public health and safety and has thus committed acts inconsistent with the public interest.'').

Long-standing agency precedent indicates that a ''practitioner's self-abuse of a controlled substance is a relevant consideration under factor five.'' *Tony T. Bui, M.D.,* 75 FR at 49,989; *Allan L. Gant, D.O.,* 59 FR 10,826, 10,827 (DEA 1994); *David E. Trawick, D.D.S,* 53 FR 5,326 (DEA 1988). This Agency has upheld such a position, ''even when there [was] no evidence that the registrant abused his prescription writing authority'' or when there was ''no evidence that the practitioner committed acts involving unlawful distribution to others.'' *Tony T. Bui, M.D.,* 75 FR at 49,989. In determining the likelihood that a respondent's self-abuse would impair the public interest, the DEA may look to the duration of the drug abuse. *See Roger D. McAlpin, D.M.D.,* 62 FR 8,038, 8,040 (DEA 1997) (finding ''serious questions regarding Respondent's fitness to possess a DEA registration'' because of ''his self-abuse of controlled substances from at least 1974 to 1990'').

Here, it is undisputed that Respondent self-abused controlled substances. Respondent admitted at the hearing that he used methamphetamine with A.B. for about eight months and admitted at the Board hearing that he has sporadically used marijuana in the past. Under factor five of the public interest analysis, this self-abuse weighs against Respondent's registration.

In addition to his self-abuse of drugs, other aspects of Respondent's behavior are also troubling under factor five. For example, Respondent continued prescribing hydrocodone, a highly abused drug, to A.B. despite knowing that A.B. regularly abused controlled substances such as methamphetamine and marijuana. Also, while Respondent did not personally take part in the sale or manufacturing of any illegal drugs, he was present or nearby while an illegal transaction took place and while methamphetamine was being manufactured. Taking into consideration these facts, combined with Respondent's self-abuse of controlled substances, I find that factor five weighs against Respondent's registration.

Having found that factors two, four, and five weigh against Respondent, I find that the Government has met its burden to prove a *prima facie* case that Respondent's registration would not be in the public interest. I now turn to whether remedial measures instituted by Respondent show that he can be trusted with a DEA registration.

Remedial Measures

Where the Government has made out a *prima facie* case that Respondent's registration would be inconsistent with the public interest, the burden of production shifts to the applicant to ''present[ ] sufficient mitigating evidence'' to show why he can be trusted with a new registration. *See*

[19] The Government also produced evidence, and Respondent admitted, that Respondent stored A.B.'s, S.M.'s, and Z.M.'s patient files in his own desk rather than with Red Carpet's other patient files. [Tr. 132–36, 203; Gov't Exhs. 9–11]. While this was certainly suspicious and Respondent admitted it was improper, I can find no regulation Respondent violated by storing the files in his desk, and the Government cites none. Indeed, the Government's argument section in its brief makes no mention of the location of the files.

[20] In order to follow agency precedent, I will take into consideration evidence of Respondent's self-abuse of illicit drugs under the fifth public interest factor. *Tony T. Bui, M.D.,* 75 FR 49,979, 49,989 (DEA 2010). Thus, under factor four I only consider Respondent's possession of methamphetamine and not his use.

[21] The Administrator interprets the term ''conviction'' by affording it the ''broadest possible meaning.'' *Donald Patsy Rocco, D.D.S.,* 50 FR 34,210, 34,211 (DEA 1985). Thus, evidence of a guilty plea is probative under the third factor of the public interest analysis. *See e.g., Farmacia Ortiz,* 61 FR 726, 728 (DEA 1996); *Roger Pharmacy,* 61 FR 65,079, 65,080 (DEA 1996).

Medicine Shoppe—Jonesborough, 73 FR at 387. To this point, the Agency has repeatedly held that the registrant must ''accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct. *Id.; see also Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (DEA 2007). Specifically, to rebut the Government's *prima facie* case, the respondent is required ''to accept responsibility for [the established] misconduct, [and] also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR 8,194, 8,236 (DEA 2010) (citing *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 464 n.8 (DEA 2009)).

In determining whether a respondent has accepted responsibility and whether misconduct will reoccur, the Agency has historically looked to a number of considerations, including genuine remorse and admission of wrongdoing, *Lawrence C. Hill, M.D.,* 64 FR 30,060, 30,062 (DEA 1999), lapse of time since the wrongdoing, *Norman Alpert, M.D.,* 58 FR 67,420, 67,421 (DEA 1993), candor with the court and DEA investigators, *Jeri Hassman, M.D.,* 75 FR 8,194, 8,236 (DEA 2010), and attempts to minimize misconduct, *Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (DEA 2010). In self-abuse cases, the Agency has acknowledged that successful rehabilitation efforts are an important consideration in determining whether a respondent can be trusted with a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10,077, 10,082 (DEA 2009); *Tony T. Bui, M.D.,* 75 FR 49,979, 49,990 (DEA 2010).

At the hearing, Respondent stated several times that '' 'regret' is not even a strong enough word. I'm very remorseful for my ever going down that pathway.'' [Tr. 197, 238]. He unequivocally stated that he accepts ''full responsibility'' for his misconduct and that he is ''appalled at [his] behavior.'' [Tr. 196, 238, 256, 257]. Respondent also testified, and the Government did not rebut, that he has been sober since October of 2011, confirming the effectiveness of his treatment and his commitment to remaining sober. [Tr. 259]. Most importantly, Respondent provided unrebutted evidence of his successful rehabilitation at an inpatient facility, where he received intensive therapy for about seven months. [Tr. 210 ; Resp't Exh. 2;]. Notably, Respondent displayed his genuine intent to become and remain sober by spending his own money—including retirement investments—to pay for his rehabilitation. [Tr. 210]. Moreover, Respondent provided evidence, largely unrebutted by the Government, that he faithfully attended support group meetings, passed random drug tests, and was otherwise successful in abiding by the terms of his probation.

The Government argues that Respondent cannot be trusted with a COR because he was not candid with DEA investigators or this Court and that his testimony was ''rife with inconsistencies.'' [Gov't Br. at 33]. I disagree. The Government's first argument to this effect is that Respondent failed to self-report his failed drug screen to DEA, and that when Respondent first met with DEA investigators, he ''failed to admit . . . the fact that he issued illegal prescriptions to A.B., S.M., or Z.M., and did not admit his self-abuse of marijuana.'' [Gov't Br. at 32]. DI Surovec, however, testified that in her first meeting with Respondent, ''[w]e asked him about the allegation in the board order, and he really didn't deny anything.'' [Tr. 33]. The Board Order mentioned Respondent's improper prescribing and the positive result for marijuana on the drug screen. [Gov't Exh. 6 at 2, 3]. In that context, it can hardly be said that Respondent was attempting to conceal facts from the DEA that were contained in the very document about which the DEA was questioning him. Furthermore, Respondent's failure to self-report to the DEA does not show a lack of candor, given that he had already self-reported to the Board. [Tr. at 273–74]. Rather, Respondent's explanation that he did not know he needed to self-report is the more plausible explanation. [Tr. 273–74].

The Government also argues that Respondent was not candid because he ''could not admit that his self-abuse . . . contributed to his inability to perform as a doctor.'' [Gov't Br. at 32]. Respondent testified that he was tired at work because of his commute, heavy workload, and lack of sleep at A.B.'s house and that using methamphetamine, which is a stimulant, did not contribute to his fatigue. [Tr. 243–44, 249]. While this may seem like Respondent was trying to minimize the effects of his drug use, I find that this was merely Respondent's honest assessment of his situation at the time. Indeed, the Government elicited this testimony itself. [Tr. 243–44].

The Government similarly argues that Respondent minimized his misconduct by testifying that he prescribed hydrocodone to A.B., a known drug abuser, ''out of compassion [because] [s]he was in pain,'' and that ''hydrocodone was not her drug of choice.'' [Gov't Br. at 33]. Again, this testimony was specifically elicited by Government counsel and went unrebutted. While the reasons Respondent gave for prescribing hydrocodone to A.B. certainly do not justify his improper methods of prescribing, they also do not represent an attempt to minimize or rationalize his behavior. Indeed, Respondent's explanation for prescribing to A.B. was preceded by his statement that ''it was improper and I admit that.'' [Tr. 252]

Additionally, the Government argues that Respondent's testimony was ''rife with inconsistencies.'' [Gov't Br. at 33]. For example, the Government points to Respondent's explanations as to why he tested positive for marijuana and amphetamine. As explained above, however, Respondent's explanation about these drug test results were credible and went unrebutted by the Government.

The Government also argues that Respondent was not ''forthright regarding his treatment at Santé'' because he failed on direct examination to disclose that he broke his ''no female contract'' at the treatment center. [Gov't Br. at 33]. The Government points out that on direct examination Respondent testified that he was a ''model patient,'' but that his breaking of the no-female contract contradicts that statement. [Gov't Br. at 33].[22] The Government, however, ignores Respondent's testimony that directly precedes his ''model patient'' statement: ''[I]t was a little bit difficult to acclimate myself for the first few weeks, probably six weeks. It took me a while to kind of get into the flow of things. Thereafter, I'd like to think I became a model participant.'' [Tr. 210]. While Respondent did not divulge on direct examination every detail about his struggles in rehabilitation, his statement that he became a ''model participant'' was not an attempt to conceal anything.

I therefore find that Respondent has sufficiently accepted responsibility for his actions and instituted remedial measures to ensure that the misconduct will not reoccur. At the hearing, Respondent was consistent, sincere, and unequivocal in his acceptance of responsibility for his misconduct. The success of Respondent's rehabilitation is evidenced by his more than two years of sobriety and his faithful attendance at support group meetings since being discharged from therapy. His separation from A.B., the epicenter of most of his

[22] Over Respondent counsel's vehement objection at the hearing, I allowed the Government to introduce evidence of Respondent's relationship with a woman at Santé. [Tr. 261–263]. However, because this subject was not disclosed prior to the hearing, I admitted the evidence for impeachment purposes only. [Tr. 293].

problems, displays his commitment to avoiding influences that could lead to a relapse into abusing controlled substances or improperly issuing prescriptions.

Even when a respondent is genuinely remorseful and has instituted sufficient remedial measures, however, the Agency sometimes imposes sanctions to deter egregious violations of the CSA. *David A. Ruben, M.D.,* 78 FR 38,363, 38,386 (DEA 2013); *Joseph Gaudio, M.D.,* 74 FR 10,083, 10,094–95 (DEA 2009). In light of the prescription drug epidemic, the Agency has placed special emphasis on the need to deter intentional diversion of controlled substances, which includes issuing prescriptions ''outside of the usual course of professional practice and [without] a legitimate medical purpose.'' *David A. Ruben, M.D.,* 78 FR at 38,386–87; *but see Tyson D. Quy, M.D.,* 78 FR 47,412, 47,412 n.2 (DEA 2013) (''Because there is no evidence that Respondent diverted controlled substances to others and this is a first offense, I conclude that consideration of the Agency's deterrence interests is not warranted.''). ''Indeed, this Agency has revoked a practitioner's registration upon proof of as few as two acts of intentional diversion and has further explained that proof of a single act of intentional diversion is sufficient to support the revocation of a registration.'' *David A. Ruben, M.D.,* 78 FR at 38,386 (citing *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,977 (DEA 2010)).

Respondent's improper prescriptions to A.B., S.M., and Z.M. clearly constitute intentional diversion. He admits to improperly prescribing a highly abused drug, hydrocodone, to a known drug addict, A.B., and two of her friends, S.M. and Z.M.. While he only wrote one prescription each to S.M. and Z.M., he continued to prescribe controlled substances to A.B. for over a year, totaling fifty-four distributions of controlled substances, including refills. [Gov't Exhs. 12–14]. Thus, although Respondent's improper prescribing practices were limited to A.B. and a few of her friends, under DEA precedent they clearly warrant sanctions to deter Respondent and others from repeating the practice.

I will not recommend, however, that the Agency deny Respondent's registration altogether. While Respondent's improper prescriptions are troubling to say the least, the DEA has granted registrations with restrictions to respondents whose misconduct was more egregious and/or lasted longer than the misconduct of Respondent here. *David A. Ruben, M.D.,* 78 FR at 38,386 (granting a registration to a respondent who improperly prescribed drugs after being placed on probation by state board); *Gregory D. Owens, D.D.S.,* 74 FR 36,751, 36,755, 36,757–58 (DEA 2009) (granting a registration to a respondent who prescribed controlled substances for seven years based on an expired registration); *Michael S. Moore, M.D.,* 76 FR 45,867, 45,868 (DEA 2011) (granting a registration to a respondent who was convicted of growing and distributing marijuana); *Roger D. McAlpin, D.M.D.,* 62 FR 8,038, 8,040 (DEA 1997) (granting a registration to a respondent who self-abused controlled substances for sixteen years and forged a prescription to obtain controlled substances).

In each of these cases, the DEA granted the respondents' registrations but also imposed restrictions, suspensions, or conditions. Where the respondent intentionally diverted controlled substances, the Agency required the respondents to periodically submit logs of all controlled substances they prescribe and suspended the respondents' registrations for periods of time commensurate with the severity of the misconduct. *See Ruben, M.D.,* 78 FR at 38,387–88; *Gregory D. Owens, D.D.S.,* 74 FR at 36,757–58; *Moore,* 76 FR at 45,869. Where the respondent self-abused controlled substances, the Agency required the respondent to submit to random drug tests. *See Moore,* 76 FR at 45,869; *McAlpin,* 62 FR at 8,040–41. Given that Respondent has a history of self-abuse and improper prescriptions, similar conditions are appropriate here.

I also note that some of the oversight currently placed over Respondent may not be present if he is granted a DEA registration. Specifically, it is not clear from the record how much of the oversight of Respondent by ACTC would be conducted if Respondent had an unfettered DEA registration. Indeed, some of the oversight conducted by ACTC, such as approval from other doctors for prescriptions of controlled substances, is done precisely because Respondent has no DEA registration and thus is not authorized to dispense controlled substances. This part of oversight would presumably—though not necessarily—be lifted if Respondent were granted a DEA registration. Moreover, Respondent expressed at the hearing his desire to work as a gastroenterologist, so he may not be under ACTC supervision much longer. [Tr. 233]. Given Respondent's history of improper prescribing, DEA is justified in placing certain restrictions on Respondent's COR to ensure precise compliance with the CSA and DEA regulations in the event that ACTC no longer supervises Respondent's prescribing practices.

VI. CONCLUSION AND RECOMMENDATION

Therefore, given that Respondent has a history of both self-abuse and intentional diversion but has demonstrated genuine remorse and instituted significant remedial measures, I recommend that Respondent's registration be granted with the following conditions:

(1) For six months following the publication of the Deputy Administrator's final order in this case, Respondent shall keep a log of all controlled substance prescriptions he issues. Said log shall be maintained in chronological order, and shall list each patient by name, and include the name of the drug prescribed, the number of refills authorized, the strength of the dosage unit, the quantity, and the dosing instruction. Not later than ten days following the end of each calendar month, Respondent shall provide the local DEA field office with a complete copy of the log for the preceding month. If during any month Respondent is required to maintain said logs he prescribes no controlled substances, he shall submit a letter declaring such to the local DEA field office no later than ten days following the end of that month.

(2) Respondent shall agree to have no intentional contact with A.B., S.M., Z.M., or any other person with whom Respondent abused controlled substances.

(3) Respondent shall comply with the terms of his probation instituted by the Board and shall comply with any other conditions the Board shall see fit to impose on his license or registration.

(4) Respondent shall notify the local DEA field office if he fails any drug screen administered by any entity.

I further recommend that Respondent's registration be suspended for six months following the effective date of his registration.

Dated: March 25, 2014.

Gail A. Randall,

Administrative Law Judge.

[FR Doc. 2015–17309 Filed 7–13–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

ZRIN 1290–ZA02

Guidance for Executive Order 13673: ''Fair Pay and Safe Workplaces''

AGENCY: Department of Labor.

ACTION: Proposed guidance; extension of comment period.

SUMMARY: On May 28, 2015, the Department of Labor (DOL) published proposed guidance to assist federal agencies and the contracting community in implementing Executive Order 13673, ''Fair Pay and Safe Workplaces,'' which is designed to improve contractor compliance with labor laws and increase efficiency and cost savings in Federal contracting. The deadline for submitting comments is being extended from July 27, 2015, to August 11, 2015, to provide additional time for interested parties to provide comments on the DOL guidance. The Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA), which on May 28, 2015, jointly published a proposed rule implementing Executive Order 13673, are similarly extending the comment period for their proposed rule by 15 days to August 11, 2015.

If you have already commented on the proposed guidance you do not need to resubmit your comment. Should you choose to do so, you can submit additional or supplemental comments. DOL will consider all comments received from the date of publication of the proposed guidance through the close of the extended comment period.

DATES: The comment period for the Proposed Guidance published on May 28, 2015, at 80 FR 30573, scheduled to close on July 27, 2015, is extended until August 11, 2015.

ADDRESSES: You may submit comments, identified by ZRIN 1290–ZA02, by either of the following methods:

Electronic comments: Comments may be sent via *http://www.regulations.gov*, a Federal E-Government Web site that allows the public to find, review, and submit comments on documents that agencies have published in the **Federal Register** and that are open for comment. Simply type in ''guidance on fair pay and safe workplaces'' (in quotes) in the Comment or Submission search box, click Go, and follow the instructions for submitting comments.

Mail: Address written submissions to Tiffany Jones, U.S. Department of Labor, Room S–2312, 200 Constitution Avenue NW., Washington, DC 20210.

Instructions: Please submit only one copy of your comments by only one method. All submissions must include the agency name and ZRIN, identified above, for this document. Please be advised that comments received will become a matter of public record and will be posted without change to *http://www.regulations.gov*, including any personal information provided. Comments that are mailed must be received by the date indicated for consideration.

FOR FURTHER INFORMATION CONTACT: Kathleen E. Franks, Director, Office of Regulatory and Programmatic Policy, U.S. Department of Labor, Room S–2312, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–5959. Copies of the proposed guidance may be obtained in alternative formats (large print, Braille, audio tape or disc), upon request, by calling (202) 693–5959. TTY/TDD callers may dial toll-free [1–877–889–5627] to obtain information or request materials in alternative formats.

SUPPLEMENTARY INFORMATION: On May 28, 2015, DOL published proposed guidance in the **Federal Register** at 80 FR 30573. DOL was to receive comments on this guidance on or before July 27, 2015.

DOL has determined that it is appropriate to provide an additional 15-day period for comment on the guidance, after considering requests to extend the comment period.

To allow the public sufficient time to review and comment on the proposed guidance, DOL is extending the comment period until August 11, 2015.

Mary Beth Maxwell,

Principal Deputy Assistant Secretary, Office of the Assistant Secretary for Policy, U.S. Department of Labor.

[FR Doc. 2015–17281 Filed 7–13–15; 8:45 am]

BILLING CODE 4510–HX–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 proposed extension of the ''Consumer Price Index Housing Survey.'' 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 September 14, 2015.

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, telephone 202–691–7628 (this is not a toll free number). (See Addresses Section.)

SUPPLEMENTARY INFORMATION:

I. Background

The Consumer Price Index (CPI) is the timeliest instrument compiled by the U.S. Government that is designed to measure changes in the purchasing power of the urban consumer's dollar. The CPI is used most widely as a measure of inflation, and is used in the formulation of economic policy. It also is used as a deflator of other economic series, that is, to adjust other series for price changes and to translate these series into inflation-free dollars.

II. Current Action

Office of Management and Budget clearance is being sought for the CPI Housing Survey. The continuation of the collection of housing rents for the CPI is essential since the CPI is the nation's chief source of information on retail price changes. If the information on rents were not collected, Federal fiscal and monetary policies would be hampered due to the lack of information on price changes in a major sector of the U.S. economy, and estimates of the real value of the Gross Domestic Product could not be made. The consequences to both the Federal and private sectors would be far reaching and would have

serious repercussions on Federal government policy and institutions.

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: Extension.

Agency: Bureau of Labor Statistics.

Title: CPI Housing Survey.

OMB Number: 1220–0163.

Affected Public: Individuals or households; business or other for-profit.

Total Respondents: 168,600.

Frequency: Semi-annually.

Total Responses: 168,600.

Average Time per Response: 5.0807829 minutes.

Estimated Total Burden Hours: 14,277 hours.

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 8th day of July 2015.

Kimberly D. Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2015–17074 Filed 7–13–15; 8:45 am]

BILLING CODE 4510–24–P

OFFICE OF MANAGEMENT AND BUDGET

Audits of States, Local Governments, and Non-Profit Organizations; OMB Circular A–133 Compliance Supplement

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice of availability of the 2015 OMB Circular A–133 Compliance Supplement.

SUMMARY: This notice announces the availability of the 2015 OMB Circular A–133 Compliance Supplement (Supplement). The notice also offers interested parties an opportunity to comment on the 2015 Supplement.

DATES: The 2015 Supplement supersedes the 2014 Supplement and will apply to audits of fiscal years beginning after June 30, 2014. All comments on the 2015 Supplement must be in writing and received by October 31, 2015. Late comments will be considered to the extent practicable. We received no comments on the 2014 Supplement.

See the *Comments* section of **SUPPLEMENTARY INFORMATION** for further information on submitting comments.

ADDRESSES: The 2015 Supplement is available online on the OMB home page at *https://www.whitehouse.gov/omb/circulars/a133_compliance_supplement_2015*.

FOR FURTHER INFORMATION CONTACT: Recipients and auditors should contact their cognizant or oversight agency for audit, or Federal awarding agency, as appropriate under the circumstances. The Federal agency contacts are listed in Appendix III of the Supplement. Subrecipients should contact their pass-through entity. Federal agencies should contact Gilbert Tran, Office of Management and Budget, Office of Federal Financial Management, at (202) 395–3052.

SUPPLEMENTARY INFORMATION:

Synopsis of 2015 Supplement

The 2015 Supplement adds five new programs and deletes 11 programs (including nine completed under the American Recovery and Reinvestment Act). It has also updated for program changes and technical corrections. In addition, it removed two compliance requirements from the standard list of such requirements: Davis Bacon (formerly compliance requirement D) and Real Property Acquisition and Relocation Assistance (formerly compliance requirement K). Part 3—Compliance Requirements is divided into two subparts. Subpart 3.1 is applicable to awards issued prior to December 26, 2014 and Subpart 3.2 is applicable to awards issued on or after December 26, 2014.

The five added programs are:

- CFDA 14.267—Continuum of Care (CoC) Program
- CFDA 14.269—Hurricane Sandy Community Development Block Grant Disaster Recovery Grants (CDBG–DR)
- CFDA 20.616—National Priority Safety Programs (as part of existing cluster 20.001—Wage Rate Requirements Cross Cutting Section)
- CFDA 21.015—Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies of the Gulf Coast States
- CFDA 93.545 –Consumer Operated and Oriented Plan (CO–OP) Program

The eleven deleted programs are:

- CFDA 93.991—Preventive Health and Services Block Grant
- CFDA 84.037—Student Financial Assistance Cluster– Perkins Loan Cancellations (part of Student Financial Aid Cluster)
- CFDA 14.253—Community Development Block Grant ARRA Entitlement Grants (CDBG–R) (Recovery Act Funded)
- CFDA 14.254—Community Development Block Grants/Special Purpose Grants/Insular Areas—(Recovery Act Funded)
- CFDA 14.255—Community Development Block Grants/State's Program and Non-Entitlement Grants in Hawaii—(Recovery Act Funded)
- CFDA 14.884—Public Housing Capital Fund Competitive (Recovery Act Funded)
- CFDA 14.885—Public Housing Capital Fund Stimulus (Formula) (Recovery Act Funded)
- CFDA 16.803—Recovery Act—Edward Byrne Memorial Justice Assistance Grant (JAG) Program/Grants to States and Territories
- CFDA 16.804—Recovery Act—Edward Byrne Memorial Justice Assistance Grant (JAG) Program/Grants to Units of Local Government
- CFDA 93.719—State Grants to Promote Health Information Technology
- CFDA 93.408—Nurse Faculty Loan Program (ARRA–NFLP)

A list of changes to the 2015 Supplement can be found at Appendix V. Appendix VII provides an audit alert concerning deletion of American Recovery and Reinvestment Act programs from clusters (which accounts for many of the deleted programs), an updated coverage treatment of National Institutes of Health awards and low-risk auditee criteria.

Due to its length, the 2015 Supplement is not included in this notice. See **ADDRESSES** for information about how to obtain a copy online.

Comments

Electronic mail comments may be submitted to: *Hai_M._Tran@omb.eop.gov*. Please include ''A–133 Compliance Supplement—2015'' in the subject line and the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and email address in the text of the message. Comments may also be submitted via facsimile at 202–395–3952.

Comments may be mailed to Gilbert Tran, Office of Federal Financial Management, Office of Management and Budget, 725 17th Street NW., Room 6025, New Executive Office Building, Washington, DC 20503.

Due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date.

Comments may also be sent through *http://www.regulations.gov*—a Federal E-Government Web site that allows the public to find, review, and submit comments on documents that agencies have published in the **Federal Register** and that are open for comment. Simply type ''A–133 Compliance Supplement—2015'' (in quotes) in the Comment or Submission search box, click Go, and follow the instructions for submitting comments. Comments received through the Web site by the date specified above will be included as part of the official record.

Mark Reger,

Deputy Controller.

[FR Doc. 2015–17236 Filed 7–13–15; 8:45 am]

BILLING CODE P

NATIONAL SCIENCE FOUNDATION

Committee Management Renewal

The NSF management officials having responsibility for the Proposal Review Panel for International and Integrative Activities, #2469 has determined that renewing this committee for another two years and amending the committee name to the Proposal Review Panel for Integrative Activities due to a recent NSF reorganization is necessary and in the public interest in connection with the performance of duties imposed upon the Director, National Science Foundation (NSF), by 42 U.S.C. 1861 *et seq.* This determination follows consultation with the Committee Management Secretariat, General Services Administration.

Effective date for renewal and amendment of the committee name is July 10, 2015. For more information, please contact Crystal Robinson, NSF, at (703) 292–8687.

Dated: July 9, 2015.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2015–17189 Filed 7–13–15; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

AGENDA

TIME AND DATE: 9:30 a.m., Tuesday, July 28, 2015

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

STATUS: The one item is open to the public.

MATTER TO BE CONSIDERED:

8614A Commercial Space Accident Report—In-Flight Breakup During Test Flight, Scaled Composites SpaceShipTwo, N339SS, Near Koehn Dry Lake, California, October 31, 2014.

NEWS MEDIA CONTACT: Telephone: (202) 314–6100. The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle Hall at (202) 314–6305 or by email at *Rochelle.Hall@ntsb.gov* by Wednesday, July 22, 2015.

The public may view the meeting via a live or archived webcast by accessing a link under ''News & Events'' on the NTSB home page at *www.ntsb.gov*.

Schedule updates, including weather-related cancellations, are also available at *www.ntsb.gov*.

FOR MORE INFORMATION CONTACT: Candi Bing at (202) 314–6403 or by email at *bingc@ntsb.gov*.

FOR MEDIA INFORMATION CONTACT: Eric Weiss, (202) 314–6100 or by email at *eric.weiss@ntsb.gov*.

Dated: Friday, July 10, 2015.

Candi R. Bing,

Federal Register Liaison Officer.

[FR Doc. 2015–17377 Filed 7–10–15; 4:15 pm]

BILLING CODE 7533–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–325 and 50–324; License Nos. DPR–71 and DPR–62; NRC–2015–0100]

In the Matter of Duke Energy Progress, Inc., and North Carolina Eastern Municipal Power Agency; Brunswick Steam Electric Plant, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct transfer of licenses, order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an Order to Duke Energy Progress, Inc. (Duke Energy) and North Carolina Eastern Municipal Power Agency (NCEMPA), approving the direct transfer of control of the Renewed Facility Operating License Nos. DPR–71 and DPR–62, and ownership interest for the Brunswick Steam Electric Plant (Brunswick), Units 1 and 2, to the extent currently held by NCEMPA. As a result of the transaction, Duke Energy will become the sole owner of the Brunswick facility and will hold 100 percent ownership of the facility. The conforming license amendments will remove references to NCEMPA. No physical changes to the facility or operational changes were proposed in the application and Duke Energy will remain as the licensed operator of the facility. This Order is effective upon issuance.

DATES: The Order was issued on July 6, 2015, and is effective for one year.

ADDRESSES: Please refer to Docket ID NRC–2015–0100 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0100. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public

Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced (if document is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Martha Barillas, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2760, email: *Martha.Barillas@nrc.gov*.

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated at Rockville, Maryland, this 6th day of July 2015.

For the Nuclear Regulatory Commission.

Martha Barillas,

Project Manager, Plant Licensing Branch II–2, Division of Operator Reactor Licensing, Office of Nuclear Reactor Regulation.

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

In the Matter of DUKE ENERGY PROGRESS, INC., NORTH CAROLINA EASTERN MUNICIPAL POWER AGENCY, Brunswick Steam Electric Plant Units 1 and 2

Docket Nos. 50–325 and 50–324

License Nos. DPR–71 and DPR–62

ORDER APPROVING DIRECT TRANSFER OF LICENSES AND APPROVING CONFORMING AMENDMENTS

I

Duke Energy Progress, Inc. (Duke Energy), and North Carolina Eastern Municipal Power Agency (NCEMPA), are the owners of Brunswick Steam Electric Plant (Brunswick), Unit Nos. 1 and 2. With respect to their ownership, they are co-holders of Renewed Facility Operating License Nos. DPR–71 and DPR–62. The Brunswick facility consists of two General Electric boiling-water reactors and an independent spent fuel storage installation (ISFSI), located in Brunswick County, North Carolina. The ISFSI is licensed under a general license pursuant to Title 10 of the Code of Federal Regulations (10 CFR) Part 50. The facility operating licenses authorize Duke Energy to possess, use, and operate the Brunswick facility.

II

By application dated December 22, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14358A253), as supplemented by letters dated March 4, 2015 (ADAMS Accession No. ML15075A102); June 1, 2015 (ADAMS Accession No. ML15152A205); June 10, 2015 (ADAMS Accession No. ML15161A289); and June 24, 2015 (ADAMS Accession No. ML15175A036), Duke Energy and NCEMPA requested, pursuant to 10 CFR, Section 50.80 (10 CFR 50.80), that the U.S. Nuclear Regulatory Commission (NRC) consent to the direct transfer of Operating License Nos. DPR–71 and DPR–62 for the Brunswick facility, to the extent currently held by NCEMPA, to co-owner Duke Energy.

The interest in Brunswick held by Duke Energy is 81.67 percent undivided ownership interest and that held by NCEMPA is 18.33 percent undivided ownership interest. Duke Energy is the licensed operator for the facility. Following approval of the proposed direct transfer of control of the licenses, Duke Energy will acquire NCEMPA's ownership interest in the facility and would hold 100 percent of the facility.

The applicant also requested approval of the conforming license amendments that would remove references to NCEMPA in the licenses. The proposed direct transfer of control of the Brunswick operating licenses will not result in any change in the role of Duke Energy as the licensed operator and owner of the licensed facility and will not result in any changes to its financial qualifications, decommissioning funding assurance, or technical qualifications.

Approval of the direct transfer of the facility operating licenses was requested by Duke Energy and NCEMPA pursuant to 10 CFR 50.80 and 50.90. A notice entitled, ''Notice of Consideration of Approval of Transfer of Licenses and Conforming Amendment,'' was published in the **Federal Register** on April 21, 2015 (80 FR 22228). No comments or hearing requests were received.

Under 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. Upon review of the information in the licensee's application, and other information before the Commission, the NRC staff has determined that Duke Energy is qualified to hold 100 percent of the license as proposed by the transfer of NCEMPA's 18.33 percent ownership interests, and that the transfer of the licenses is otherwise consistent with the applicable provisions of law, regulations, and orders issued by the NRC, and subject to the conditions set forth below. The NRC staff has further found that the application for the proposed license amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I; the facility will operate in conformity with the application, the provisions of the Act and the rules and regulations of the Commission; there is reasonable assurance that the activities authorized by the proposed license amendments can be conducted without endangering the health and safety of the public and that such activities will be conducted in compliance with the Commission's regulations; the issuance of the proposed license amendments will not be inimical to the common defense and security or to the health and safety of the public; and the issuance of the proposed amendments will be in accordance with 10 CFR part 51 of the Commission's regulations and all applicable requirements have been satisfied. The findings set forth above are supported by a safety evaluation dated July 6, 2015.

III

Accordingly, pursuant to Sections 161b, 161i, 161.o, and 184 of the Atomic Energy Act of 1954, as amended (the Act), 42 U.S.C. Sections 2201(b), 2201(i), 2201(o), and 2234; and 10 CFR 50.80, IT IS HEREBY ORDERED that the application regarding the proposed direct license transfers are approved, subject to the following condition:

1. Duke Energy shall provide satisfactory documentary evidence to the Director of the Office of Nuclear Reactor Regulation that it has obtained the appropriate amount of insurance required of a licensee under 10 CFR part 140 within 30 days of the transfer.

IT IS FURTHER ORDERED that consistent with 10 CFR 2.1315(b), the license amendments that make changes, as indicated in Enclosure 4 to the cover letter forwarding this order, to reflect the subject direct transfer, are approved. The amendments shall be issued and made effective at the time the proposed direct transfer action is completed.

IT IS FURTHER ORDERED that after receipt of all required regulatory approvals of the proposed direct transfer action, Duke Energy shall inform the Director of the Office of Nuclear Reactor Regulation in writing of such receipt no later than 2 business days prior to the date of the closing of the direct transfer. Should the proposed direct transfer not be completed within 1 year of this

order's date of issue, this order shall become null and void. However, upon written application and good cause shown, such date may be extended by order.

This order is effective upon issuance.

For further details with respect to this order, see the initial application dated December 22, 2014 (ADAMS Accession No. ML14358A253), as supplemented by letters dated March 4, 2015 (ADAMS Accession No. ML15075A102); June 1, 2015 (ADAMS Accession No. ML15152A205); June 10, 2015 (ADAMS Accession No. ML15161A289); and June 24, 2015 (ADAMS Accession No. ML15175A036), and the safety evaluation dated July 6, 2015 (ADAMS Accession No. ML15159A632), which are available for public inspection at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1–F21, 11555 Rockville Pike, Rockville, Maryland 20852. You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC's PDR reference staff at 1–800–397–4209 or 301–415–4737 or by email to *pdr.resource@nrc.gov*.

Dated at Rockville, Maryland, this 6th day of July 2015.

For the Nuclear Regulatory Commission.

William M. Dean,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–17279 Filed 7–13–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0164]

Memorandum of Understanding Among the Department of Homeland Security, the Department of Transportation, and the Nuclear Regulatory Commission Concerning Cooperation on Radioactive Materials Transportation Security

AGENCY: Nuclear Regulatory Commission.

ACTION: Memorandum of Understanding; issuance.

SUMMARY: The United States (U.S.) Nuclear Regulatory Commission (NRC) is issuing a notice regarding a finalized Memorandum of Understanding (MOU) between the NRC, the U.S. Department of Homeland Security (DHS) and the U.S. Department of Transportation (DOT) that defines a cooperative working relationship between the agencies for radioactive material transportation security. The goal of the MOU is to ensure that the transportation of radioactive material in the U.S. and across U.S. borders is carried out in a secure manner that protects public health and safety, and in a manner that is not inimical to the common defense and security of the U.S.

DATES: The Memorandum of Understanding is available July 14, 2015.

ADDRESSES: Please refer to Docket ID NRC–2015–0164 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0164. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The three sections of the MOU are available in ADAMS under Accession Nos.: ML15057A336, ML13240A347, and ML13240A350, respectively.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Albert Tardiff, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–287–3613, email: *Al.Tardiff@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC, DHS, and DOT have finalized an MOU to define the cooperative working relationship between the agencies for radioactive material transportation security.

II. Summary

The Energy Policy Act of 2005 (Pub. L. 109–58, August 8, 2005) established the Task Force on Radiation Source Protection and Security. Subsequently, the Task Force recommended that the participating departments and agencies develop an interagency MOU for radioactive material transportation security. The MOU establishes a framework for departments and agencies to coordinate, to the maximum extent practicable, their respective responsibilities and activities on security of radioactive material transportation within the U.S. or across U.S. borders. The intent of the MOU is to enhance collaborative exchanges, facilitate the sharing of expertise and information, promote leveraging of mutual interests, and reduce duplication in shared areas of responsibility.

III. Further Information

The Task Force on Radiation Source Protection and Security has produced three reports. The reports were published in 2006, 2010 and 2014. Those reports may be found in the NRC ADAMS public document collection at accession numbers ML062190349, ML102230141 and ML14219A642, for the 2006, 2010 and 2014 reports, respectively.

Dated at Rockville, Maryland, this 7th day of July 2015.

For the Nuclear Regulatory Commission.

Mark Thaggard,

Deputy Director, Division of Security Policy, Office of Nuclear Security and Incident Response.

[FR Doc. 2015–17274 Filed 7–13–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–400; License No. NPF–63; NRC–2015–0101]

In the Matter of Duke Energy Progress, Inc., and North Carolina Eastern Municipal Power Agency; Shearon Harris Nuclear Power Plant, Unit 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct transfer of license, order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an Order to Duke Energy Progress, Inc. (Duke Energy) and North Carolina Eastern Municipal Power Agency (NCEMPA)

approving the direct transfer of control of the Renewed Facility Operating License No. NPF–63, and ownership interest for the Shearon Harris Nuclear Power Plant (Harris), Unit 1, to the extent currently held by NCEMPA. As a result of the transaction, Duke Energy will become the sole owner of the Harris facility and hold 100 percent ownership of the facility. The conforming license amendment will remove references to NCEMPA. No physical changes to the facility or operational changes were proposed in the application and Duke Energy will remain as the licensed operator of the facility. This Order is effective upon issuance.

DATES: The Order was issued on July 6, 2015, and is effective for 1 year.

ADDRESSES: Please refer to Docket ID NRC–2015–0101 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0101. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Martha Barillas, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2760, email: *Martha.Barillas@nrc.gov*.

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated at Rockville, Maryland, this 6th day of July 2015.

For the Nuclear Regulatory Commission.

Martha Barillas,

Project Manager, Plant Licensing Branch II–2, Division of Operator Reactor Licensing, Office of Nuclear Reactor Regulation.

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

In the Matter of DUKE ENERGY PROGRESS, INC., NORTH CAROLINA EASTERN MUNICIPAL POWER AGENCY, Shearon Harris Nuclear Power Plant Unit 1

Docket No. 50–400

License No. NPF–63

ORDER APPROVING DIRECT TRANSFER OF LICENSE AND APPROVING CONFORMING AMENDMENT

I

Duke Energy Progress, Inc. (Duke Energy), and North Carolina Eastern Municipal Power Agency (NCEMPA), are the owners of Shearon Harris Nuclear Power Plant, Unit 1 (Harris). With respect to their ownership, they are co-holders of Renewed Facility Operating License No. NPF–63. The Harris facility consists of a Westinghouse three-loop pressurized-water reactor located in Wake and Chatham Counties, North Carolina. The facility operating license authorizes Duke Energy to possess, use, and operate the Harris facility.

II

By application dated December 22, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14358A253), as supplemented by letters dated March 4, 2015 (ADAMS Accession No. ML15075A102); June 1, 2015 (ADAMS Accession No. ML15152A205); June 10, 2015 (ADAMS Accession No. ML15161A289); and June 24, 2015 (ADAMS Accession No. ML15175A036), Duke Energy and NCEMPA requested, pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.80 (10 CFR 50.80), that the U.S. Nuclear Regulatory Commission (NRC) consent to the direct transfer of Operating License No. NPF–63 for the Harris facility, to the extent currently held by NCEMPA, to co-owner Duke Energy.

The interest in Harris held by Duke Energy is 83.83 percent undivided ownership interest and that held by NCEMPA is 16.17 percent undivided ownership interest. Duke Energy is the licensed operator for the facility. Following approval of the proposed direct transfer of control of the licenses, Duke Energy would acquire NCEMPA's ownership interest in the facility and would hold 100 percent of the facility.

The applicant also requested approval of the conforming license amendment that would remove references to NCEMPA in the license. The proposed direct transfer of control of the Harris operating license will not result in any change in the role of Duke Energy as the licensed operator and owner of the licensed facility and will not result in any changes to its financial qualifications, decommissioning funding assurance, or technical qualifications.

Approval of the direct transfer of the facility operating license and conforming license amendment was requested by Duke Energy and NCEMPA pursuant to 10 CFR 50.80 and 50.90. A notice entitled, ''Notice of Consideration of Approval of Transfer of Licenses and Conforming Amendment,'' was published in the **Federal Register** on April 21, 2015 (80 FR 22224). No comments or hearing requests were received.

Under 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. Upon review of the information in the licensee's application, and other information before the Commission, the NRC staff has determined that Duke Energy is qualified to hold 100 percent of the license as proposed by the transfer of NCEMPA's 16.17 percent ownership interests, and that the transfer of the license is otherwise consistent with the applicable provisions of law, regulations, and orders issued by the NRC and subject to the conditions set forth below. The NRC staff has further found that the application for the proposed license amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I; the facility will operate in conformity with the application, the provisions of the Act and the rules and regulations of the Commission; there is reasonable assurance that the activities authorized by the proposed license amendment can be conducted without endangering the health and safety of the public and that such activities will be conducted in compliance with the Commission's regulations; the issuance of the proposed license amendment will not

be inimical to the common defense and security or to the health and safety of the public; and the issuance of the proposed amendment will be in accordance with 10 CFR part 51 of the Commission's regulations and all applicable requirements have been satisfied. The findings set forth above are supported by a safety evaluation dated July 6, 2015.

III

Accordingly, pursuant to Sections 161b, 161i, 161.o, and 184 of the Atomic Energy Act of 1954, as amended (the Act), 42 U.S.C. Sections 2201(b), 2201(i), 2201(o), and 2234; and 10 CFR 50.80, IT IS HEREBY ORDERED that the application regarding the proposed direct license transfer is approved, subject to the following condition:

1. Duke Energy shall provide satisfactory documentary evidence to the Director of the Office of Nuclear Reactor Regulation that it has obtained the appropriate amount of insurance required of a licensee under 10 CFR part 140 within 30 days of the transfer.

IT IS FURTHER ORDERED that consistent with 10 CFR 2.1315(b), the license amendment that make changes, as indicated in Enclosure 5 to the cover letter forwarding this order, to reflect the subject direct transfer, is approved. The amendment shall be issued and made effective at the time the proposed direct transfer action is completed.

IT IS FURTHER ORDERED that after receipt of all required regulatory approvals of the proposed direct transfer action, Duke Energy shall inform the Director of the Office of Nuclear Reactor Regulation in writing of such receipt no later than 2 business days prior to the date of the closing of the direct transfer. Should the proposed direct transfer not be completed within 1 year of this order's date of issue, this order shall become null and void. However, upon written application and good cause shown, such date may be extended by order.

This order is effective upon issuance.

For further details with respect to this order, see the initial application dated December 22, 2014 (ADAMS Accession No. ML14358A253), as supplemented by letters dated March 4, 2015 (ADAMS Accession No. ML15075A102); June 1, 2015 (ADAMS Accession No. ML15152A205); June 10. 2015 (ADAMS Accession No. ML15161A289); and June 24, 2015 (ML15175A036), and the safety evaluation dated July 6, 2015 (ADAMS Accession No. ML15159A632), which are available for public inspection at the NRC's Public Document Room (PDR), located at One White Flint North, Room O1–F21, 11555 Rockville Pike, Rockville, Maryland 20852. You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC's PDR reference staff at 1–800–397–4209 or 301–415–4737 or by email to *pdr.resource@nrc.gov*.

Dated at Rockville, Maryland, this 6th day of July 2015.

For the Nuclear Regulatory Commission.

William M. Dean,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–17278 Filed 7–13–15; 8:45 am]

BILLING CODE 7590–01–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and purpose of information collection: Employer's Quarterly Report of Contributions under the Railroad Unemployment Insurance Act; OMB 3220–0012.

Under Section 8 of the Railroad Unemployment Insurance Act (RUIA), as amended by the Railroad Unemployment Improvement Act of 1988 (Pub. L. 100–647), the RRB determines the amount of an employer's contribution, primarily on the basis of the RUIA benefits paid, both unemployment and sickness, to the employees of the railroad employer. These experienced-based contributions take into account the frequency, volume, and duration of the employees' unemployment and sickness benefits. Each employer's contribution rate includes a component for administrative expenses as well as a component to cover costs shared by all employers. The regulations prescribing the manner and conditions for remitting the contributions and for adjusting overpayments or underpayments of contributions are contained in 20 CFR 345.

RRB Form DC–1, Employer's Quarterly Report of Contributions under the Railroad Unemployment Insurance Act, is used by railroad employers to report and remit their quarterly contributions to the RRB. Employers can use either the manual version of the form or its Internet equivalent. One response is requested quarterly of each respondent and completion is mandatory. The RRB proposes no changes to Form DC–1.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
DC–1 (Manual)	1,235	25	515
DC–1 (Internet)	1,365	25	569
Total	2,600		1,084

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.* Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or emailed to

Charles.Mierzwa@RRB.GOV. Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2015–17244 Filed 7–13–15; 8:45 am]

BILLING CODE 7905–01–P

RAILROAD RETIREMENT BOARD

Sunshine Act; Notice of Public Meeting

Notice is hereby given that the Railroad Retirement Board will hold a meeting on July 29, 2015, 10 a.m., at the Board's meeting room on the 8th floor of its headquarters building, 844 North Rush Street, Chicago, Illinois, 60611. The agenda for this meeting follows:

Portion open to the public:

(1) Executive Committee Reports

(2) Labor Member's Comments on Changes to the Disability Program

The person to contact for more information is Martha P. Rico, Secretary to the Board, Phone No. 312–751–4920.

Dated: July 10, 2015.

Martha P. Rico,

Secretary to the Board.

[FR Doc. 2015–17321 Filed 7–10–15; 11:15 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75391; File No. SR–NASDAQ–2015–061]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Volume-Based and Multi-Trigger Thresholds

July 8, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 23, 2015, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes to amend Chapter VII, Section 6, entitled ''Market Maker Quotations,'' of the rules governing the NASDAQ Options Market (''NOM'' or ''Exchange''). The Exchange proposes to adopt two new NOM Market Maker [3] optional risk protections, a volume-based threshold and a multi-trigger threshold.[4]

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaq.cchwallstreet.com*, at the principal office of the Exchange, 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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the filing is to adopt two new risk protections for NOM Market Maker's to monitor marketplace risk. These protections are intended to assist NOM Market Makers to control their trading risks.[5] Quoting across many series in an option creates the possibility of ''rapid fire'' executions that can create large, unintended principal positions that expose NOM Market Makers, who are required to continuously quote in assigned options, to potentially significant market risk. Today, the Exchange's rules permit NOM Market Makers to monitor risk arising from multiple executions across multiple options series of a single underlying security.[6]

The Exchange is proposing to offer a new volume-based and multi-trigger threshold protection to NOM Market Makers. The Exchange proposes to amend NOM's Rules at Chapter VII, Section 6(f) to establish: (1) A threshold used to calculate each NOM Market Maker's total volume executed in all series of a given underlying security within a specified time period and compares that to a pre-determined threshold (''Volume-Based Threshold''), and (2) a threshold which measures the number of times the System has triggered [7] based on the Risk Monitor Mechanism (''Percentage-Based Threshold'') pursuant to Chapter VI, Section 19 and Volume-Based Thresholds within a specified time period and compares that total to a pre-determined threshold (''Multi-Trigger Threshold'').

Volume-Based Threshold

In connection with offering these two new threshold protections, a NOM Market Maker would provide a specified time period and volume threshold by which the Exchange's System would automatically remove the NOM Market Maker's quotes and orders in an options class, depending on the threshold utilized, submitted through designated NOM protocols, as specified by the Exchange. The Exchange counts Specialized Quote Feed (''SQF'') [8] quotes and OTTO [9] orders only in determining the number of contracts traded and removed by the System.[10]

The Volume-Based Threshold will determine, during a specified time period established by the NOM Market

[3] The term ''NOM Market Maker'' means a Participant that has registered as a Market Maker on NOM pursuant to Chapter VII, Section 2, and must also remain in good standing pursuant to Chapter VII, Section 4.

[4] Market Makers will be required to continue to utilize the Risk Monitor Mechanism in Chapter VI, Section 19, as is the case today.

[5] Pursuant to NOM Rules at Chapter VII, Section 5, entitled ''Obligations of Market Makers'', in registering as a market maker, an Options Participant commits himself to various obligations. Transactions of a NOM Market Maker must constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and Market Makers should not make bids or offers or enter into transactions that are inconsistent with such course of dealings. Further, all Market Makers are designated as specialists on NOM for all purposes under the Act or rules thereunder. *See* Chapter VII, Section 2.

[6] *See* NOM Chapter VI, Section 19, ''Risk Monitor Mechanism.''

[7] A trigger is defined as the event which causes the System to automatically remove all quotes and orders in all options series in an underlying issue.

[8] SQF permits the receipt of quotes. SQF Auction Responses and market sweeps are also not included.

[9] OTTO immediate or cancel orders will not be included. OTTO provides a method for subscribers to send orders and receive status updates on those orders. OTTO accepts limit orders from System subscribers, and if there is a matching order, the orders will execute. Non-matching orders are added to the limit order book, a database of available limit orders, where they are matched.

[10] Financial Information Exchange (''FIX'') Orders are not counted in determining the number of contracts traded and removed by the System.

Maker not to exceeds 15 seconds (''Volume-Based Specified Time Period''), whether a NOM Market Maker executed a number of contracts which equals or exceeds the designated number of contracts specified by the NOM Market Maker in all series of an underlying security to determine whether to remove the NOM Market Maker's quotes and orders in all series of the underlying security.[11] The Volume-Based Threshold will be based on the total number of contracts executed in the market in the same options series in an underlying security and will not offset the number of contracts executed on the opposite side of the market. Once the System determines that the number of contracts executed equals or exceeds a number established by the NOM Market Maker during the Volume-Based Specified Time Period, the System will remove the NOM Market Maker's quotes and orders. The Volume-Based Specified Time Period designated by the NOM Market Maker must be the same length of time as designated for purposes of the Percentage-Based Threshold in Rule 1093 [sic].[12]

A Volume-Based Specified Time Period will commence for an option every time an execution occurs in any series in such option and will continue until the System automatically removes quotes and orders as described in newly proposed sections (f)(iv) or (f)(v) or the Volume-Based Specified Time Period expires. The Volume-Based Specified Time Period operates on a rolling basis among all series in an option in that there may be multiple Volume-Based Specified Time Periods occurring simultaneously and such Volume-Based Specified Time Periods may overlap.[13]

Multi-Trigger Threshold

A NOM Market Maker or NOM Market Maker Group, which is defined as multiple affiliated NOM Market Makers,[14] may provide the specified time period and number of allowable triggers by which the Exchange will automatically remove quotes and orders in all options series in all underlying securities issues submitted through designated NOM protocols, as specified by the Exchange (''Multi-Trigger Threshold''). During a specified time period established by the NOM Market Maker not to exceed 15 seconds (''Multi-Trigger Specified Time Period''), the number of times the System automatically removes the NOM Market Maker's or Group's quotes and orders in all options series will be based on the number of triggers of the Percentage-Based Threshold, described in proposed (f)(ii), as well as the Volume-Based Threshold described in proposed (f)(ii).[15] For purposes of this rule, a trigger shall be defined as the event which causes the System to automatically remove quotes and orders in all options series in an underlying issue. Once the System determines that the number of triggers equals or exceeds a number established by either the NOM Market Maker or Group, during a Multi-Trigger Specified Time Period, the System will automatically remove all quotes and orders in all options series in all underlying issues for that NOM Market Maker or Group. A Multi-Trigger Specified Time Period will commence after every trigger of either the Percentage-Based Threshold or the Volume-Based Threshold and will continue until the System removes quotes and orders as described in section (f)(iv) of the proposed rule or the Multi-Trigger Specified Time Period expires. Participants may configure the Multi-Trigger Threshold at the badge level (by NOM Market Maker) or by Group (multiple affiliated NOM Market Makers), but not both. This is different as compared to the Percentage-Based Threshold in Chapter VI, Section 19 or the newly proposed Volume-Based Thresholds that are configured only on the badge level (by NOM Market Maker).[16] The System counts triggers within a Multi-Trigger Specified Time Period across all options for the NOM Market Maker or Group. A Multi-Trigger Specified Time Period operates in that there may be multiple Multi-Trigger Specified Time Periods occurring simultaneously and such Multi-Trigger Specified Time Periods may overlap.

The System will automatically remove quotes in all options in an underlying security when the Volume-Based Threshold has been reached. The System will automatically remove quotes in all options in all underlying securities when the Multi-Trigger Threshold has been reached.[17] The System will send a Purge Notification Message[18] to the NOM Market Maker for all affected options when the above thresholds have been reached.

The two thresholds, Volume-Based Threshold and Multi-Trigger Threshold, operate independently of each other. The triggering of the Volume-Based Threshold would occur independently of the Multi-Trigger Threshold. The Multi-Trigger Threshold is somewhat dependent on the Volume-Based Threshold to the extent that the Volume-Based Threshold serves as a trigger for the Multi-Trigger Threshold. Quotes and orders will be automatically executed up to the NOM Market Maker's size regardless of whether the quote exceeds the Volume-Based threshold.[19]

If a NOM Market Maker requests the System to remove quotes and orders in all options series in an underlying issue, the System will automatically reset the Volume-Based Specified Time Period(s). The Multi-Trigger Specified Time Period(s) will not automatically reset for the Multi-Trigger Threshold.[20]

When the System removes quotes and orders as a result of the Volume-Based Threshold, the NOM Market Maker must send a re-entry indicator to re-enter the System. When the System removes quotes and orders as a result of the Multi-Trigger Threshold, the System will not accept quotes and orders through designated protocols until the NOM Market Maker manually requests re-entry.[21] After quotes and orders are removed as a result of the Multi-Trigger Threshold, Exchange staff must set a re-entry indicator in this case to enable re-entry, which will cause the System to send a Reentry Notification Message to the NOM Market Maker for all options

[11] The System counter is based on trading interest resting on the Exchange book.

[12] *See* proposed new Chapter VII, Section 6(f)(ii).

[13] *Id.*

[14] This would be more than one NOM Market Maker, but does not require the aggregation of all of the Participant's Market Makers. A Group would be comprised of NOM Market Makers affiliated with one Participant. The Participant would be required to define a Group by providing a list of such affiliated NOM Market Makers to the Exchange.

[15] Today, ISE's functionality permits market maker quotes to be removed from the ISE trading system if a specified number of curtailment events occur across both ISE and ISE Gemini, LLC (''ISE Gemini''). ISE and ISE Gemini's trading systems will count the number of times a market maker's pre-set curtailment events occur on each exchange and aggregate them. Once a market maker's specified number of curtailment events across both markets is reached, the trading systems will remove the market maker's quotes in all classes on both ISE and ISE Gemini. ISE will then reject any quotes sent by the market maker after the parameters across both exchanges have been triggered until the market maker notifies the market operations staff of ISE that it is ready to come out of its curtailment. *See* Securities Exchange Release No. 73147 (September 19, 2014), 79 FR 57639 (September 25, 2014) (SR–ISE–2014–09) (Order approving proposed rule change related to market maker risk parameters).

[16] *See* proposed new Chapter VII, Section 6(f)(iii).

[17] The specified time period for the Volume-Based Threshold and the Multi-Trigger Threshold may differ. The specified time period for the Volume-Based Threshold must be the same as the Percentage-Based Threshold in Chapter VI, Section 19.

[18] A message entitled ''Purge Notification Message'' is systemically sent to the BX Marker Maker upon the removal of quotes due to Volume-Based Threshold or Multi-Trigger Threshold.

[19] *See* proposed new Chapter VII, Section 6(f)(iii).

[20] *See* proposed new Chapter VII, Section 6(f)(iv).

[21] In the interest of maintaining fair and orderly markets, the Exchange believes it is important that NOM Market Makers communicate their readiness to Exchange staff in a non-automated manner, such as by email or telephone.

series in all underlying issues.[22] The NOM Market Maker's Clearing Firm will be notified regarding the trigger and re-entry into the System after quotes and orders are removed as a result of the Multi-Trigger Threshold, provided the NOM Market Maker's Clearing Firm has requested to receive such notification.[23] The System will then reset all counters to zero and re-entry and continued trading will be permitted. A NOM Market Maker is subject to continuous quoting obligations [24] despite the removal of quotes and orders from the System and approval process for re-entry.

Today, the Exchange provides NOM Market Makers with the Percentage-Based Threshold in Rule 1093 to monitor risk.[25] The Exchange will continue to require NOM Market Makers to utilize the Percentage-Based Threshold. The Volume-Based Threshold and the Multi-Trigger Threshold will be optional.

The Exchange reserved subsection (f)(i) for future modifications to this rule.

The Exchange proposes to implement these rule changes within 30 days of the operative day of this rule change.

Example #1 of the Volume-Based Threshold is displayed below. Presume the following Order Book:

Series of underlying XYZ	Size on bid × offer for MM1
100 Strike Call	300 × 300
100 Strike Put	50 × 50
110 Strike Call	200 × 200
110 Strike Put	150 × 150

In this example, assume the Specified Time Period designated by the Market Maker #1 is 10 seconds and the designated number of contracts permitted for the Volume-Based Threshold is 250 contracts. Assume at 12:00:00, the Market Maker #1 executes all of his offer size, 200 contracts, in the 110 Strike Calls. The System will initiate the Specified Time Period and for 10 seconds the System will count all volume executed in series of underlying XYZ. If at any point during that 10 second period, the Market Maker #1 executes additional contracts in any series of underlying XYZ, those contracts will be added to the initial execution of 200 contracts. To illustrate, assume at 12:00:05 the Market Maker #1 executes 60 contracts of his offer in the 100 Strike Calls. The total volume executed is now 260 contracts. Since that volume exceeds the Market Maker #1's designated number of contracts for the Volume-Based Threshold (250 contracts), all of his quotes in all series of underlying XYZ over the designated protocols will be removed from the System; no further quotes or orders will be executed until re-entry. The Volume-Based Specified Time Period will be reset for Market Maker #1 in underlying XYZ and Market Maker #1 will need to send a re-entry indicator in order to re-enter quotes in options series for underlying XYZ into the System.

Example #2 of the Volume-Based Threshold: Similar to the example above, assume the Specified Time Period is 10 seconds and the designated number of contracts permitted for the Volume-Based Threshold is 250 contracts. Assume at 12:00:00, Market Maker #1 executes all of his offer size, 200 contracts, in the 110 Strike Calls. The System will initiate the Specified Time Period and for 10 seconds the System will count all volume executed in series of underlying XYZ. If at any point during that 10 second period, Market Maker #1 executes additional contracts in any series of underlying XYZ, those contracts will be added to the initial execution of 200 contracts. Then assume at 12:00:05 Market Maker #1 executes 20 contracts of his offer in the 100 Strike Calls. The total volume executed is 220 contracts which does not exceed the Volume-Based Threshold. This second execution initiates another Specified Time Period so there are two open time periods, the first with 5 seconds remaining and a new 10 second time period. At 12:00:10, the first timer period expires and the initial execution of 200 contracts is no longer counted toward the designated number of contracts permitted for the Volume-Based Threshold. Further assume at 12:00:12, which is outside of the initial time period but still within 10 seconds of the second execution of 20 contracts, another execution occurs with Market Maker #1 executing 230 contracts of his bid in the 100 Strike Calls. This total volume executed toward the Volume-Based Threshold within the Specified Time Period is now 250 contracts which equals the designated number of contracts permitted causing the System to remove all quotes in all series of underlying XYZ over the designated protocols for Market Maker #1 to be removed from the System no further quotes or orders will be executed until re-entry. The Volume-Based Specified Time Period will be reset for Market Maker #1 in underlying XYZ and Market Maker #1 will need to send a re-entry indicator in order to re-enter quotes in options series for underlying XYZ into the System. This example displays the rolling basis in which the Specified Time Period operates.

Example #3: In order to illustrate the Multi-Trigger Threshold, assume Example #1 and Example #2 provided above occurred in options series of two different underlyings rather than all in options series of underlying XYZ and for two separate Market Makers (MM#1 for Example #1 and MM#2 for Example #2) of the same member organization. Assume a Group is defined by the member organization and is comprised of the MM #1 and MM #2. Further assume the member organization has defined the Multi-Trigger Specified Time Period as 10 seconds and the number of allowable triggers as two. Based on the aforementioned examples, a Multi-Trigger Specified Time Period commences at 12:00:05 when MM #1 triggers the Volume-Based Threshold. This Volume-Based Threshold triggers counts as the first trigger toward the Multi-Trigger Threshold for the Group. Another Multi-Trigger Specified Time Period is initiated at 12:00:12 when MM #2 triggers the Volume-Based Threshold (per Example #2). This Volume-Based Threshold trigger counts as the second trigger toward the Multi-Trigger Threshold for the Group since it is within the Multi-Trigger Specified Time Period of the first trigger. Since the member organization designated two triggers for the number of allowable triggers, the Group, both MM #1 and MM #2, quotes in all option series in all underlying issues for the Group are automatically removed from the System and Purge Notification Messages are sent to the Group; no further quotes or orders will be executed until re-entry. The member organization will need to contact the Exchange to request Exchange staff to enable re-entry into the System.

The Exchange proposes to implement this rule within thirty (30) days of the operative date. The Exchange will issue an Options Trader Alert in advance to inform market participants of such date.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [26] in general, and furthers the objectives of Section 6(b)(5) of the Act [27] in particular, in that it is designed to promote just and equitable principles of

[22] *See* proposed new Chapter VII, Section 6(f)(v).

[23] NOM Rules at Chapter VI, Section 20 permits the Exchange to share NOM Market Maker designated risk settings in the System with the Clearing Firm.

[24] *See* note 5.

[25] An initial default value is set for each NOM Market Maker.

[26] 15 U.S.C. 78f(b).

[27] 15 U.S.C. 78f(b)(5).

trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by enhancing the risk protections available to Exchange members. The proposal promotes policy goals of the Commission which has encouraged execution venues, exchange and non-exchange alike, to enhance risk protection tools and other mechanisms to decrease risk and increase stability.

The individual firm benefits of enhanced risk protections flow downstream to counter-parties both within and without the Exchange, thereby increasing systemic protections as well. Additionally, because the Exchange offers these risk tools to NOM Market Makers, in order to encourage them to provide as much liquidity as possible and encourage market making generally, the proposal removes impediments to and perfects the mechanism of a free and open market and a national market system and protect investors and the public interest.

With respect to permitting the Multi-Trigger Threshold to be set either to one NOM Market Maker or to a number of specified NOM Market Makers affiliated with a member, it is important to note that the risk to NOM Market Makers is not limited to a single series in an option but to all series in an option. NOM Market Makers that quote in multiple series of multiple options have significant exposure, requiring them to offset or hedge their overall positions. The proposed functionality will be useful for NOM Market Makers, who are required to continuously quote in assigned options classes on the Exchange. Quoting across many series in an option or multiple options creates the possibility of executions that can create large, unintended principal positions that could expose market makers to unnecessary risk. The Multi-Trigger Threshold functionality is intended to assist NOM Market Makers manage that risk at the Group level so that NOM Market Makers may provide deep and liquid markets to the benefit of all investors.

The Exchange further represents that its proposal will operate consistently with the firm quote obligations of a broker-dealer pursuant to Rule 602 of Regulation NMS and that the functionality is not mandatory. Specifically, any interest that is executable against a NOM Market Maker's quotes that are received [28] by the Exchange prior to the time either of these functionalities are engaged will be automatically executed at the price up to the NOM Market Maker's size, regardless of whether such execution results in executions in excess of the NOM Market Maker's pre-set parameters.

With respect to providing risk settings to the NOM Market Maker's Clearing Member, each Member that transacts through a Clearing Member on the Exchange executes a Letter of Guarantee wherein the Clearing Member accepts financial responsibility for all Exchange transactions made by the Participant on whose behalf the Clearing Member submits the letter of guarantee. The Exchange believes that because Clearing Members guarantee all transactions on behalf of a Participant, and therefore, bear the risk associated with those transactions, it is appropriate for Clearing Members to have knowledge of what risk settings a NOM Market Maker may utilize within the System and receive and receive notice of re-entry into the System after triggering the Multi-Trigger Threshold.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the proposal will not impose a burden on intra-market or inter-market competition, rather it provides NOM Market Makers with the opportunity to avail themselves of similar risk tools which are currently available on other exchanges.[29] The proposal does not impose a burden on inter-market competition, because Participants may choose to become market makers on a number of other options exchanges, which may have similar but not identical features.[30] The proposed rule change is meant to protect NOM Market Makers from inadvertent exposure to excessive risk. Accordingly, the proposed rule change will have no impact on competition.

Further, the Exchange is proposing this rule change at the request of its NOM Market Makers to further reduce their risk in the event the NOM Market Maker is suffering from a systems issue or due to the occurrence of unusual or unexpected market activity. The proposed Group parameter for the Multi-Trigger threshold will protect NOM Market Makers from inadvertent exposure to excessive risk at the Group level. Reducing such risk will enable NOM Market Makers to enter quotations without any fear of inadvertent exposure to excessive risk, which in turn will benefit investors through increased liquidity for the execution of their orders. Such increased liquidity benefits investors because they receive better prices and because it lowers volatility in the options market.

The Exchange believes that requiring NOM Market Makers to enter values for the Percentage-Based Threshold is not unreasonably burdensome because NOM Market Makers can enter an out-of-range values so that the Exchange-provided risk protections will not be triggered. Reducing risk by utilizing the proposed risk protections will enable NOM Market Makers to enter quotations with larger size, which in turn will benefit investors through increased liquidity for the execution of their orders. Such increased liquidity benefits investors because they receive better prices and because it lowers volatility in the options market.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [31] and subparagraph (f)(6) of Rule 19b–4 thereunder.[32] The Exchange has requested that the Commission waive the thirty-day operative delay so that the proposal may become operative immediately. The Exchange states that waiving the thirty-day operative delay will enable Market Makers to enhance their risk controls and risk management processes without additional delay. The Commission believes that waiving the thirty day delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the thirty-day operative

[28] The time of receipt for an order or quote is the time such message is processed by the Exchange book.

[29] *See* Section 8 of the 19b4.

[30] *See* BATS Rule 21.16, BOX Rules 8100 and 8110, C2 Rule 8.12, CBOE Rule 8.18, ISE Rule 804(g), MIAX Rule 612, NYSE MKT Rule 928NY and NYSE Arca Rule 6.40.

[31] 15 U.S.C. 78s(b)(3)(a)(ii).

[32] 17 CFR 240.19b–4(f)(6).

delay and designates the proposal effective upon filing.[33]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved. The Exchange has provided the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

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–2015–061 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2015–061. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2015–061 and should be submitted on or before August 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17169 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

[33] For purposes of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75397; File No. SR–EDGX–2015–28]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Market Data Section of Its Fee Schedule

July 8, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2015, EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the Market Data section of its fee schedule to: (i) Adopt User fees, an Enterprise fee, and a Digital Media Enterprise fee for the EDGX Top and EDGX Last Sale feeds; and (ii) make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, 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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Market Data section of its fee schedule to: (i) Adopt User fees, an Enterprise fee, and a Digital Media Enterprise fee for the EDGX Top and EDGX Last Sale feeds; and (ii) make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

EDGX Top and Last Sale Fees

EDGX Top is a market data feed that includes top of book quotations and execution information for all equity securities traded on the Exchange.[5] EDGX Last Sale is a market data feed that includes last sale information for all equity securities traded on Exchange.[6]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] *See* Exchange Rule 13.8(c).

[6] *See* Exchange Rule 13.8(d).

Currently, the Exchange only charges fees for both internal and external distribution of the EDGX Last Sale and EDGX Top feeds. The cost of EDGX Last Sale for an Internal Distributor [7] is $500 per month. Likewise, the cost of EDGX Top for an Internal Distributor is also $500 per month. The Exchange currently does not charge per User [8] fees for either EDGX Last Sale or EDGX Top. Therefore, the Exchange does not currently require an External Distributor [9] of EDGX Last Sale or EDGX Top to count, classify (*e.g.,* professional or non-professional), or report to the Exchange information regarding the customers to which they provide the data. Instead, the Exchange charges an External Distributor of EDGX Last Sale a flat fee of $1,250 per month. The Exchange also separately charges an External Distributor of EDGX Top a flat fee of $1,250 per month. End Users currently do not pay the Exchange for EDGX Last Sale or EDGX Top, nor are End Users required to enter into contracts with the Exchange.

Subscribers to either EDGX Top or EDGX Last Sale are able to receive, upon request and at no additional cost, EDGX Last Sale or EDGX Top, as applicable. The Exchange also offers a New External Distributor Credit under which new External Distributors of EDGX Top or EDGX Last Sale will not be charged a Distributor Fee for their first three (3) months.

The Exchange now proposes to amend its fee schedule to incorporate additional fees related to the EDGX Top or EDGX Last Sale feeds.[10] These fees include the following, each of which are described in detail below: (i) Usage Fees for both Professional [11] and Non-Professional [12] Users; [13] (ii) Enterprise Fees; [14] and (iii) a Digital Media Enterprise Fee.

User Fees. The Exchange proposes to charge those who receive either EDGX Top or EDGX Last Sale from External Distributors different fees for both their Professional Users and Non-Professional Users. The Exchange will assess a monthly fee for Professional Users of $2.00 per User. Non-Professional Users will be assessed a monthly fee of $0.05 per User.[15] The Exchange does not propose to charge per User fees to Internal Distributors.

External Distributors would be required to count every Professional User and Non-Professional User to which they provide EDGX Top and/or EDGX Last Sale, the requirements for which are identical to that currently in place for the BATS One Feed.[16] Thus, the External Distributor's count will include every person and device that accesses the data regardless of the purpose for which the individual or device uses the data. External Distributors must report all Professional and Non-Professional Users in accordance with the following:

- In connection with an External Distributor's distribution of EDGX Top or EDGX Last Sale, the Distributor should count as one User each unique User that the Distributor has entitled to have access to EDGX Top or EDGX Last Sale. However, where a device is dedicated specifically to a single individual, the Distributor should count only the individual and need not count the device.
- The External Distributor should identify and report each unique User. If a User uses the same unique method to gain access to EDGX Top or EDGX Last Sale, the Distributor should count that as one User. However, if a unique User uses multiple methods to gain access to EDGX Top or EDGX Last Sale (*e.g.,* a single User has multiple passwords and user identifications), the External Distributor should report all of those methods as an individual User.
- External Distributors should report each unique individual person who receives access through multiple devices as one User so long as each device is dedicated specifically to that individual.
- If an External Distributor entitles one or more individuals to use the same device, the External Distributor should include only the individuals, and not the device, in the count.

Each External Distributor will receive a credit against its monthly Distributor

[7] An ''Internal Distributor'' is defined as ''a Distributor that receives the Exchange Market Data product and then distributes that data to one or more Users within the Distributor's own entity.'' *See* the Exchange Fee Schedule *available at http://batstrading.com/support/fee_schedule/edgx/.* A ''Distributor'' is defined as ''any entity that receives the Exchange Market Data product directly from the Exchange or indirectly through another entity and then distributes it internally or externally to a third party.'' *Id.*

[8] A ''User'' is defined as ''a natural person, a proprietorship, corporation, partnership, or entity, or device (computer or other automated service), that is entitled to receive Exchange data.'' *Id.*

[9] An ''External Distributor'' is defined as ''a Distributor that receives the Exchange Market Data product and then distributes that data to a third party or one or more Users outside the Distributor's own entity.'' *Id.*

[10] The Exchange notes that EDGA Exchange, Inc. (''EDGA''), BATS Y-Exchange, Inc. (''BYX'') and BATS Exchange, Inc. (''BZX'', together with the Exchange, EDGA and BYX, the ''BATS Exchanges'') also filed proposed rule changes with Commission to adopt similar fees for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–BYX–2015–30, and SR–BATS–2015–48. The Exchange represents that the proposed fees will not cause the combined cost of subscribing to each of the BATS Exchanges' individual Top and Last Sale feeds to be greater than those currently charged to subscribe to the BATS One Feed. *See* Securities Exchange Act Release Nos. 74285 (February 18, 2015), 80 FR 9828 (February 24, 2015) (SR–BATS–2015–11); 74283 (February 18, 2015), 80 FR 9809 (February 24, 2015) (SR–EDGA–2015–09); 74282 (February 17, 2015), 80 FR 9487 (February 23, 2015) (SR–EDGX–2015–09); *and* 74284 (February 18, 2015), 80 FR 9792 (February 24, 2015) (SR–BYX–2015–09) (''Initial BATS One Feed Fee Filings''). In these filings, the Exchange represented that the cost of subscribing to each of the underlying individual feeds necessary to create the BATS One Feed would not be greater than the cost of subscribing to the BATS One Feed. *Id.*

[11] A ''Professional User'' is defined as ''any User other than a Non-Professional User.'' *See* the Exchange Fee Schedule *available at http://batstrading.com/support/fee_schedule/edgx/.*

[12] A ''Non-Professional User'' is defined as ''a natural person who is not: (i) Registered or qualified in any capacity with the Commission, the Commodity Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an ''investment adviser'' as that term is defined in Section [202(a)(11)] of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt.'' *Id.*

[13] The Exchange notes that User fees as well as the distinctions based on professional and non-professional users have been previously filed with or approved by the Commission by the BATS Exchanges and the Nasdaq Stock Market LLC (''Nasdaq''). *See* Securities Exchange Act Release No. 59582 (March 16, 2009), 74 FR 12423 (March 24, 2009) (Order approving SR-Nasdaq-2008–102). *See also* the Initial BATS One Feed Fee Filings, *supra* note 10.

[14] The Exchange notes that Enterprise fees have been previously filed with or approved by the Commission by the Exchange, EDGA, BYX, BZX, Nasdaq, NYSE, and the CTA/CQ Plans. *See* Nasdaq Rule 7047. Securities Exchange Act Release Nos. 71507 (February 7, 2014), 79 FR 8763 (February 13, 2014) (SR–NASDAQ–2014–011); 70211 (August 15, 2013), 78 FR 51781 (August 21, 2013) (SR–NYSE–2013–58); *and* 70010 (July 19, 2013) (File No. SR–CTA/CQ–2013–04). *See also* the Initial BATS One Feed Fee Filings, *supra* note 10.

[15] The Exchange notes that EDGA, BYX and BZX also filed proposed rule changes with Commission to adopt User fees for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–BYX–2015–30, and SR–BATS–2015–48 (proposing a monthly fee of $2.00 per Professional User and of $0.05 per Non-Professional User for EDGA and BYX and a monthly fee of $4.00 per Professional User and of $0.10 per Non-Professional User for BZX). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 10. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total of $10.00 per month per Professional User and $0.25 per month per Non-Professional User. This amount is equal to, and not greater than the User Fees charged for the BATS One Summary Feed. *Id.* (adopting fees of $10.00 per month per Professional User and $0.25 per month per Non-Professional User as well as a separate $1,000 per month Data Consolidation Fee for the BATS One Summary Feed).

[16] *See* the Initial BATS One Feed Fee Filings, *supra* note 10.

Fee for EDGX Top or EDGX Last Sale equal to the amount of its monthly Usage Fees up to a maximum of the Distributor Fee for EDGX Top or EDGX Last Sale. For example, an External Distributor will be subject to a $1,250 monthly Distributor Fee where they elect to receive EDGX Top. If that External Distributor reports User quantities totaling $1,250 or more of monthly usage of EDGX Top, it will pay no net Distributor Fee, whereas if that same External Distributor were to report User quantities totaling $1,000 of monthly usage, it will pay a net of $250 for the Distributor Fee. External Distributors will remain subject to the per User fees discussed above. The same would apply to receipt of EDGX Last Sale.

Enterprise Fee. The Exchange also proposes to establish a $15,000 per month Enterprise Fee that will permit a recipient firm who receives EDGX Top or EDGX Last Sale from an External Distributor to receive the data for an unlimited number of Professional and Non-Professional Users.[17] For example, if a recipient firm had 15,000 Professional Users who each receive EDGX Top or EDGX Last Sale at $2.00 per month, then that recipient firm will pay $30,000 per month in Professional Users fees. Under the proposed Enterprise Fee, the recipient firm will pay a flat fee of $15,000 for an unlimited number of Professional and Non-Professional Users for EDGX Top or EDGX Last Sale. A recipient firm must pay a separate Enterprise Fee for each External Distributor that controls display of EDGX Top or EDGX Last Sale if it wishes such User to be covered by an Enterprise Fee rather than by per User fees. A recipient firm that pays the Enterprise Fee will not have to report its number of such Users on a monthly basis. However, every six months, a recipient firm must provide the Exchange with a count of the total number of natural person users of each product, including both Professional and Non-Professional Users. Lastly, the proposed Enterprise Fee would be counted towards the Distributor Fee credit described above, under which an External Distributor receives a credit towards its Distributor Fee equal to the amount of its monthly EDGX Top or EDGX Last Sale usage fees.

Digital Media Enterprise Fee. The Exchange proposes to adopt a Digital Media Enterprise Fee of $2,500 per month for EDGX Top and EDGX Last Sale.[18] As an alternative to proposed User fees discussed above, a recipient firm may purchase a monthly Digital Media Enterprise license to receive EDGX Top and EDGX Last Sale from an External Distributor to distribute to an unlimited number of Professional and Non-Professional Users for viewing via television, Web sites, and mobile devices for informational and non-trading purposes only without having to account for the extent of access to the data or the report the number of Users to the Exchange. Lastly, the proposed Digital Media Enterprise Fee would be counted towards the Distributor Fee credit described above, under which an External Distributor receives a credit towards its Distributor Fee equal to the amount of its monthly EDGX Top and/or EDGX Last Sale usage fees.

Non-Substantive, Corrective Changes

The Exchange proposes to make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

First, the proposed change to the description of the BATS One Feed[19] Enterprise Fee is intended to align with the descriptions of the Enterprise Fees for EDGX Top and EDGX Last Sale proposed above. The fee schedule currently states that:

> [a]s an alternative to User fees, a recipient firm may purchase a monthly Enterprise license to receive the BATS One Feed from an External Distributor to an unlimited number of Professional and Non-Professional Users. A recipient firm must pay a separate Enterprise Fee for each External Distributor that controls the display of the BATS One Feed if it wishes such User to be covered by the Enterprise Fee. The Enterprise Fee is in addition to the Distributor Fee.

The Exchange proposes to delete the last sentence of the above description stating that the Enterprise Fee is in addition to the Distributor Fee. The original purpose of this sentence was to clarify that the Distributor Fee and Enterprise Fee were separate fees. However, the Exchange understands that this sentence has led to confusion for the following reason. As is the case for the proposed Enterprise Fees for EDGX Top and EDGX Last Sale described above, the BATS One Feed Enterprise Fee is counted towards the Distributor Fee credit, under which an External Distributor receives a credit towards its Distributor Fee equal to the amount of its monthly BATS One Feed Usage Fees. Stating that the Enterprise and Distributor fees were separate fees has caused confusion regarding the application of the Distributor Fee Usage Fee credit. Therefore, the Exchange proposes to delete the last sentence stating that the Enterprise Fee is in addition to the Distributor Fee. Deleting this sentence does not alter the manner in which the Enterprise Fee is charged. Rather, it is intended to avoid confusion and align the description with that of the proposed Enterprise Fees for EDGX Top and EDGX Last Sale described above.

Second, the Exchange proposes to correct a cross-reference within the

[17] The Exchange notes that EDGA, BYX and BZX also filed proposed rule changes with Commission to adopt Enterprise Fees for their respective Top and Last Sale market data product. File Nos. SR–EDGA–2015–25, SR–BYX–2015–30, and SR–BATS–2015–48 (proposing a monthly Enterprise Fee of $15,000 for BZX Top and BZX Last Sale and $10,000 for EDGA Top and Last Sale as well as BYX Top and Last Sale). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 10. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total monthly Enterprise Fee of $50,000. This amount is equal to, and not greater than the Enterprise Fee charged for the BATS One Summary Feed. *Id.* (adopting a monthly Enterprise Fee of $50,000 as well as a separate $1,000 per month Data Consolidation Fee for the BATS One Summary Feed).

[18] The Exchange notes that EDGA, BYX and BZX also filed proposed rule changes with Commission to adopt a Digital Media Enterprise Fee for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–BYX–2015–30, and SR–BATS–2015–48 (proposing a monthly Digital Media Enterprise Fee of $2,500 for their respective Top and Last Sale feeds). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 10. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total monthly Digital Media Enterprise Fee of $10,000. This amount is less than the Digital Media Enterprise Fee charged for the BATS One Summary Feed. *See* Securities Exchange Act Release Nos. 74598 (March 27, 2015), 80 FR 17791 (April 2, 2015) (SR–BATS–2015–24); 74599 (March 27, 2015), 80 FR 17812 (April 2, 2015) (SR–BYX–2015–19); 74600 (March 27, 2014), 80 FR 17797 (April 2, 2015) (SR–EDGA–2015–14); *and* 74601 (March 27, 2015), 80 FR 17804 (April 2, 2015) (SR–EDGX–2015–14) (adopting a monthly Digital Media Enterprise Fee of $15,000 for the BATS One Summary Feed).

[19] In sum, the BATS One Feed is a data feed that disseminates, on a real-time basis, the aggregate best bid and offer (''BBO'') of all displayed orders for securities traded on EDGX and its affiliated exchanges and for which the BATS Exchanges report quotes under the Consolidated Tape Association (''CTA'') Plan or the Nasdaq/UTP Plan. The BATS One Feed also contains the individual last sale information for the BATS Exchanges (collectively with the aggregate BBO, the ''BATS One Summary Feed''). In addition, the BATS One Feed contains optional functionality which enables recipients to receive aggregated two-sided quotations from the BATS Exchanges for up to five (5) price levels (''BATS One Premium Feed''). *See* Securities Exchange Act Release No. 73918 (December 23, 2014), 79 FR 78920 (December 31, 2014) (File Nos. SR–EDGX–2014–25; SR–EDGA–2014–25; SR–BATS–2014–055; SR–BYX–2014–030) (Notice of Amendments No. 2 and Order Granting Accelerated Approval to Proposed Rule Changes, as Modified by Amendments Nos. 1 and 2, to Establish a New Market Data Product called the BATS One Feed) (''BATS One Approval Order'').

definition of ''Non-Professional User''. In part, a ''Non-Professional User'' is currently defined as ''a natural person who is not: . . . engaged as an ''investment adviser'' as that term is defined in Section 201(11) of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act) . . .'' The definition incorrectly states that the term ''investment adviser is defined under Section 201(11) of the Investment Advisers Act of 1940, when it is, in fact, defined under Section 202(a)(11) of the Investment Advisers Act of 1940. Therefore, the Exchange proposes to replace the reference to Section 201(11) with Section 202(a)(11) within the definition of Non-Professional User.

Implementation Date

The Exchange proposes to implement the proposed changes to its fee schedule on July 1, 2015.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[20] in general, and furthers the objectives of Section 6(b)(4),[21] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all recipients of Exchange data. The Exchange believes the proposed fees are competitive with those charged by other venues and, therefore, reasonable and equitably allocated to recipients. Lastly, the Exchange also believes that the proposed fees are reasonable and non-discriminatory because they will apply uniformly to all recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act [22] in that it supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Furthermore, the proposed rule change is consistent with Rule 603 of Regulation NMS,[23] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory. In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data.

In addition, the proposed fees would not permit unfair discrimination because all of the Exchange's customers and market data vendors will be subject to the proposed fees on an equivalent basis. EDGX Last Sale and EDGX Top are distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Accordingly, Distributors and Users can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Firms have a wide variety of alternative market data products from which to choose, such as similar proprietary data products offered by other exchanges and consolidated data. Moreover, the Exchange is not required to make any proprietary data products available or to offer any specific pricing alternatives to any customers.

In addition, the fees that are the subject of this rule filing are constrained by competition. As explained below in the Exchange's Statement on Burden on Competition, the existence of alternatives to EDGX Top and EDGX Last Sale further ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect such alternatives. That is, the Exchange competes with other exchanges (and their affiliates) that provide similar market data products. If another exchange (or its affiliate) were to charge less to consolidate and distribute its similar product than the Exchange charges to consolidate and distribute EDGX Top or EDGX Last Sale, prospective Users likely would not subscribe to, or would cease subscribing to, the EDGX Top or EDGX Last Sale.

The Exchange notes that the Commission is not required to undertake a cost-of-service or rate-making approach. The Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for non-core market data would be so complicated that it could not be done practically.[24]

User Fees. The Exchange believes that implementing the Professional and Non-Professional User fees for EDGX Top and EDGX Last Sale is equitable and reasonable because it will result in greater availability to Professional and Non-Professional Users. Moreover, introducing a modest Non-Professional User fee for EDGX Top and EDGX Last Sale is reasonable because it provides an additional method for retail investors to access EDGX Top and EDGX Last Sale data by providing the same data that is available to Professional Users. The Exchange believes that the proposed fees are equitable and not unfairly discriminatory because they will be charged uniformly to recipient firms and Users. The fee structure of differentiated Professional and Non-Professional fees is utilized by the Exchange for the BATS One Feed and has long been used by other exchanges for their proprietary data products, and by the Nasdaq UTP and the CTA and CQ Plans in order to reduce the price of data to retail investors and make it more broadly available.[25] Offering EDGX Top and EDGX Last Sale to Non-Professional Users with the same data available to

[20] 15 U.S.C. 78f.

[21] 15 U.S.C. 78f(b)(4).

[22] 15 U.S.C. 78k–1.

[23] *See* 17 CFR 242.603.

[24] The Exchange believes that cost-based pricing would be impractical because it would create enormous administrative burdens for all parties, including the Commission, to cost-regulate a large number of participants and standardize and analyze extraordinary amounts of information, accounts, and reports. In addition, it is impossible to regulate market data prices in isolation from prices charged by markets for other services that are joint products. Cost-based rate regulation would also lead to litigation and may distort incentives, including those to minimize costs and to innovate, leading to further waste. Under cost-based pricing, the Commission would be burdened with determining a fair rate of return, and the industry could experience frequent rate increases based on escalating expense levels. Even in industries historically subject to utility regulation, cost-based ratemaking has been discredited. As such, the Exchange believes that cost-based ratemaking would be inappropriate for proprietary market data and inconsistent with Congress's direction that the Commission use its authority to foster the development of the national market system, and that market forces will continue to provide appropriate pricing discipline. *See* Appendix C to NYSE's comments to the Commission's 2000 Concept Release on the Regulation of Market Information Fees and Revenues, which can be found on the Commission's Web site at *http://www.sec.gov/rules/concept/s72899/buck1.htm. See also* Securities Exchange Act Release No. 73816 (December 11, 2014), 79 FR 75200 (December 17, 2014) (SR–NYSE–2014–64) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Establish an Access Fee for the NYSE Best Quote and Trades Data Feed, Operative December 1, 2014).

[25] *See* the Initial BATS One Feed Fee Filings, *supra* note 10. *See also, e.g.,* Securities Exchange Act Release No. 20002, File No. S7–433 (July 22, 1983) (establishing nonprofessional fees for CTA data); Nasdaq Rules 7023(b), 7047.

Professional Users results in greater equity among data recipients.

In addition, the proposed fees are reasonable when compared to similar fees for comparable products offered by the NYSE. Specifically, NYSE offers NYSE BBO, which includes best bid and offer for NYSE traded securities, for a monthly fee of $4.00 per professional subscriber and $0.20 per non-professional subscriber.[26] NYSE also offers NYSE Trades, which is a data feed that provides the last sale information for NYSE traded securities, for the same price as NYSE BBO. The Exchange's proposed per User Fees for EDGX Top and EDGX Last Sale are less than the NYSE's fees for NYSE Trades and NYSE BBO.

Enterprise Fee. The proposed Enterprise Fee for EDGX Top and EDGX Last Sale are equitable and reasonable as the fees proposed are less than the enterprise fees currently charged for NYSE Trades and NYSE BBO. The NYSE charges a separate enterprise fee of $190,000 per month for NYSE Trades and NYSE BBO.[27] In addition, the Enterprise Fee proposed by the Exchange could result in a fee reduction for recipient firms with a large number of Professional and Non-Professional Users. If a recipient firm has a smaller number of Professional Users of EDGX Top or EDGX Last Sale, then it may continue using the per User structure and benefit from the per User Fee reductions. By reducing prices for recipient firms with a large number of Professional and Non-Professional Users, the Exchange believes that more firms may choose to receive and to distribute the EDGX Top or EDGX Last Sale, thereby expanding the distribution of this market data for the benefit of investors.

The Exchange further believes that the proposed Enterprise Fee is reasonable because it will simplify reporting for certain recipients that have large numbers of Professional and Non-Professional Users. Firms that pay the proposed Enterprise Fee will not have to report the number of Users on a monthly basis as they currently do, but rather will only have to count natural person users every six months, which is a significant reduction in administrative burden. Finally, the Exchange believes that it is equitable and not unfairly discriminatory to establish an Enterprise Fee because it reduces the Exchange's costs and the Distributor's administrative burdens in tracking and auditing large numbers of Users.

Digital Media Enterprise Fee. The Exchange believes that the proposed Digital Media Enterprise Fee for EDGX Top and EDGX Last Sale provides for an equitable allocation of reasonable fees among recipients of the data and is not designed to permit unfair discrimination among customers, brokers, or dealers. In establishing the Digital Media Enterprise Fee, the Exchange recognizes that there is demand for a more seamless and easier-to-administer data distribution model that takes into account the expanded variety of media and communication devices that investors utilize today. The Exchange believes the Digital Media Enterprise Fee will be easy to administer because data recipients that purchase it would not be required to differentiate between Professional and Non-Professional Users, account for the extent of access to the data, or report the number of Users. This is a significant reduction on a recipient firm's administrative burdens and is a significant value to investors. For example, a television broadcaster could display EDGX Top and/or EDGX Last Sale data during market-related programming and on its Web site or allow viewers to view the data via their mobile devices, creating a more seamless distribution model that will allow investors more choice in how they receive and view market data, all without having to account for and/or measure who accesses the data and how often they do so.

The proposed Digital Media Enterprise Fee is equitable and reasonable because it will also enable recipient firms to more widely distribute data from EDGX Top and EDGX Last Sale to investors for informational purposes at a lower cost than is available today. For example, a recipient firm may purchase an Enterprise license in the amount of $15,000 per month for to receive EDGX Top and/or EDGX Last Sale from an External Distributor for an unlimited number of Professional and Non-Professional Users, which is greater than the proposed Digital Media Enterprise Fee. The Exchange also believes the amount of the Digital Media Enterprise Fee is reasonable as compared to the existing enterprise fees discussed above because the distribution of EDGX Top and EDGX Last Sale data is limited to television, Web sites, and mobile devices for informational purposes only, while distribution of EDGX Top and EDGX Last Sale data pursuant to an Enterprise license contains no such limitation. The Exchange also believes that the proposed Digital Media Enterprise Fee is equitable and reasonable because it is less than similar fees charged by other exchanges.[28]

Non-Substantive, Corrective Changes. The Exchange believes that the proposed non-substantive, corrective changes are consistent with Section 6(b) of the Act,[29] in general, and Section 6(b)(4) of the Act,[30] in particular, in that they provide for an equitable allocation of reasonable fees among recipients of the data and is not designed to permit unfair discrimination among customers, brokers, or dealers. These proposed changes are equitable and reasonable because the changes are designed to clarify the fee schedule and avoid potential investor confusion. The amendment to the BATS One Enterprise Fee is also intended to align the description with that of the proposed Enterprise Fees for EDGX Top and EDGX Last Sale described above. The proposed changes are also non-discriminatory as they would apply to all recipient firms uniformly.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

EDGX Top and EDGX Last Sale

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The Exchange's ability to price EDGX Last Sale and EDGX Top are constrained by: (i) Competition among exchanges, other trading platforms, and Trade Reporting Facilities (''TRF'') that compete with each other in a variety of dimensions; (ii) the existence of inexpensive real-time consolidated data and market-specific data and free delayed data; and (iii) the inherent contestability of the market for proprietary data.

The Exchange and its market data products are subject to significant competitive forces and the proposed fees represent responses to that competition. To start, the Exchange competes intensely for order flow. It

[26] *See* NYSE Market Data Pricing dated May 2015 *available at http://www.nyxdata.com/.*

[27] *Id.*

[28] The Nasdaq Stock Market offers proprietary data products for distribution over the internet and television under alternative fee schedules that are subject to maximum fee of $50,000 per month. *See* Nasdaq Rule 7039(b). The NYSE charges a Digit Media Enterprise fee of $40,000 per month for the NYSE Trade Digital Media product. *See* Securities Exchange Act Release No. 69272 (April 2, 2013), 78 FR 20983 (April 8, 2013) (SR–NYSE–2013–23).

[29] 15 U.S.C. 78f.

[30] 15 U.S.C. 78f(b)(4).

competes with the other national securities exchanges that currently trade equities, with electronic communication networks, with quotes posted in FINRA's Alternative Display Facility, with alternative trading systems, and with securities firms that primarily trade as principal with their customer order flow.

In addition, EDGX Last Sale and EDGX Top compete with a number of alternative products. For instance, EDGX Last Sale and EDGX Top do not provide a complete picture of all trading activity in a security. Rather, the other national securities exchanges, the several TRFs of FINRA, and Electronic Communication Networks (''ECN'') that produce proprietary data all produce trades and trade reports. Each is currently permitted to produce last sale information products, and many currently do, including Nasdaq and NYSE. In addition, market participants can gain access to EDGX last sale prices and top-of-book quotations, though integrated with the prices of other markets, on feeds made available through the SIPs.

In sum, the availability of a variety of alternative sources of information imposes significant competitive pressures on Exchange data products and the Exchange's compelling need to attract order flow imposes significant competitive pressure on the Exchange to act equitably, fairly, and reasonably in setting the proposed data product fees. The proposed data product fees are, in part, responses to that pressure. The Exchange believes that the proposed fees would reflect an equitable allocation of its overall costs to users of its facilities.

In addition, when establishing the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish fair, reasonable, and not unreasonably discriminatory fees and an equitable allocation of fees among all Users. The existence of alternatives to EDGX Last Sale and EDGX Top, including existing similar feeds by other exchanges, consolidated data, and proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if its cost to purchase is not justified by the returns any particular vendor or subscriber would achieve through the purchase.

Non-Substantive, Corrective Changes

The proposed non-substantive, corrective changes to the fee schedule will not have any impact on completion. The proposed changes are designed to clarify the fee schedule and avoid potential investor confusion.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [31] and paragraph (f) of Rule 19b–4 thereunder.[32] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EDGX–2015–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGX–2015–28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGX–2015–28, and should be submitted on or before August 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17175 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

[31] 15 U.S.C. 78s(b)(3)(A).

[32] 17 CFR 240.19b–4(f).

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75390; File No. SR–EDGA–2015–26]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees for Use of EDGA Exchange, Inc.

July 8, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 26, 2015, EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members [5] and non-members of the Exchange pursuant to EDGA Rules 15.1(a) and (c). Changes to the fee schedule pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, 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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to modify its fees for physical connectivity. A physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently maintains a presence in two third-party data centers: (i) The primary data center where the Exchange's business is primarily conducted on a daily basis, and (ii) a secondary data center, which is predominantly maintained for business continuity purposes. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $500 per physical port that connects to the System [6] via 1 gigabyte copper circuit; $1,000 per physical port that connects to the System via 1 gigabyte fiber circuit; and $2,000 per physical port that connects to the System via 10 gigabyte fiber circuit.

The Exchange now proposes to amend its physical connectivity fees to align the Exchange's fees with its affiliates.[7] First, the Exchange proposes to amend its Fee Schedule to no longer distinguish between fiber and copper circuits. Therefore, it proposes to delete the charge of $500 per month per physical port that connects to the System via 1 gigabyte copper circuit and to assess a monthly fee of $2,000 per physical port that connects to the System via 1 gigabyte circuit regardless of the type of connection. Second, the Exchange proposes to increase the fee per physical port that connects to the System via 10 gigabyte circuit from $2,000 per month to $4,000 per month. The Exchange also proposes to replace the reference to ''fiber'' with ''physical port'' within the description of the 1 gigabyte and 10 gigabyte physical connectivity fees as it proposes to no longer distinguish between fiber and copper circuits within its Fee Schedule.

Lastly, to further align its physical connectivity fees with its affiliates, the Exchange proposes to pass through in full any hardware costs or connectivity fees incurred that are directly related to completing a cross-connect where the expense to the Exchange billed by a third party exceeds $1,000.[8] The Exchange proposes to pass through the expense as an alternative to the flat installation fees charged by the Exchange's primary competitors. The Exchange does not anticipate that passing through these expenses will affect many of the Exchange's constituents, because the majority of cross-connect completions cost less than $1,000. For this reason, the Exchange proposes to pass-through the charges associated with cross-connect completions that cost more than $1,000 rather than to charge an installation fee for all completions regardless of their cost.

Implementation Date

The Exchange proposes to implement this amendment to its Fee Schedule on July 1, 2015.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[9] in general, and furthers the objectives of Section 6(b)(4),[10] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

The Exchange believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges as its fees for physical connectivity are reasonably constrained by competitive alternatives. If a particular exchange charges excessive fees for connectivity, affected Members and non-Members may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

[6] The term ''System'' is defined as ''the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.'' *See* Exchange Rule 1.5(cc).

[7] The Exchange's affiliates are EDGX Exchange, Inc. (''EDGX''), BATS Y-Exchange, Inc. (''BYX'') and BATS Exchange, Inc. (''BZX'', together with the Exchange, EDGX and BYX, the ''BATS Exchanges''). The Exchange notes that each of its affiliates will also file proposed rule changes with Commission to adopt similar physical connectivity fees to be effective July 1, 2015.

[8] *See* BZX fee schedule *available at http://batstrading.com/support/fee_schedule/bzx/ and* the BYX fee schedule *available at http://batstrading.com/support/fee_schedule/byx/.*

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4).

exchange to charge unreasonable fees for connectivity.

Furthermore, the proposed rule change is also an equitable allocation of reasonable dues, fees, and other charges as the Exchange believes that the increased fees obtained will enable it to cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems. The additional revenue from the increased fees will also enable the Exchange to continue to maintain and improve its market technology and services. The Exchange believes that the proposed fees for 1 gigabyte circuit of $2,000 per month and for 10 gigabyte circuit of $4,000 per month are reasonable in that they are less than analogous fees charged by the Nasdaq Stock Market LLC (''Nasdaq''), which are $2,500 per month for 1 gigabyte connectivity and range from $10,000—$15,000 per month for 10 gigabyte circuits.[11] In addition, the Exchange proposed physical connectivity fees are designed to align the Exchange's fees with its affiliates.[12]

The Exchange also believes that passing through the cross-connect related expenses in excess of $1,000 as an alternative to the flat installation fees is equitable and reasonable. The proposed pass through would be in lieu of the flat installation fees charged by the Exchange's primary competitors. The Exchange does not anticipate that passing through these expenses will affect many of the Exchange's constituents, because the majority of cross-connect completions cost less than $1,000.

Finally, the Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members and non-Members. Members and non-Members will continue to choose whether they want more than one physical port and choose the method of connectivity based on their specific needs. All Exchange Members that voluntarily select various service options will be charged the same amount for the same services. As is true of all physical connectivity, all Members and non-Members have the option to select any connectivity option, and there is no differentiation with regard to the fees charged for the service.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. Further, excessive fees for connectivity, including port fee access, would serve to impair an exchange's ability to compete for order flow rather than burdening competition. The proposal to increase the fees for physical connectivity would bring the fees charged by the Exchange closer to similar fees charged for physical connectivity by other exchanges.[13] In addition, the proposal to pass through cross-connect installation related expenses serves as an alternative to the flat installation fees charged by the Exchange's primary competitors.

Lastly, the proposed rule change does not impose any burden on intramarket competition as the fees are uniform for all Members and non-Members. The Exchange notes that Members and non-Members also have the ability to obtain access to these services without the need for an independent physical port connection, such as through alternative means of financial extranets and service bureaus that act as a conduit for orders entered by Members and non-Members.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and paragraph (f) of Rule 19b–4 thereunder.[15] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EDGA–2015–26 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGA–2015–26. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGA–2015–26 and should be submitted on or before August 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17168 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

[11] *See* Nasdaq Rule 7034(b).

[12] *See supra* note 7.

[13] *See supra* note 11.

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75396; File No. SR–ICC–2015–006]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Withdrawal of Proposed Rule Change to Provide for the Clearance of an Additional Standard Emerging Market Sovereign Single Name

July 8, 2015.

On March 27, 2015, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–ICC–2015–006 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] to amend Subchapter 26D of its rules to provide for the clearance of an additional Standard Emerging Market Sovereign CDS contract, namely Ukraine. Notice of the proposed rule change was published for comment in the **Federal Register** on April 15, 2015.[3] On May 22, 2015, ICC extended the time period for the Commission to approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change to July 14, 2015. The Commission received no comment letters regarding the proposed rule change.

On July 1, 2015, ICC withdrew the proposed rule change (File No. SR–ICC–2015–006).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[4]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17174 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–74688 (Apr. 9, 2015), 80 FR 20280 (Apr. 15, 2015) (SR–ICC–2015–006).

[4] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75317; File No. SR–CBOE–2015–012]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Granting Approval of Proposed Rule Change Relating to Trading Permit Holder Qualifications

June 26, 2015.

I. Introduction

On May 4, 2015, Chicago Board Options Exchange Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''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 its rules related to Trading Permit Holder requirements and direct access to the Exchange's Hybrid Trading System (''System''). The proposed rule change was published for comment in the **Federal Register** on May 20, 2015.[3] The Commission received no comments on the proposed rule change. This order approves the proposed rule change.

II. Description of Proposed Rule Change

The Exchange proposes to amend its rules by (i) adopting new CBOE Rule 3.4A (Additional Trading Permit Holder Qualifications)to add additional qualification requirements for persons seeking to become and remain Trading Permit Holders, (ii) adding a requirement regarding access by Sponsored Users in CBOE Rule 6.20A (Sponsored Users), (iii) adding a requirement regarding access to the System in CBOE Rule 6.23A (Trading Permit Holder Connectivity), and (iv) making nonsubstantive changes to renumber the paragraphs in CBOE Rule 3.4 (Foreign Trading Permit Holders). The Exchange states that the proposed rule change is intended to accommodate the potential interest of non-U.S. persons or organizations in becoming Trading Permit Holders or accessing the System from foreign jurisdictions following the launch of Extended Trading Hours on the Exchange.[4]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74963 (May 14, 2015), 80 FR 29131 (May 20, 2015) (''Notice'').

[4] *See* Securities Exchange Act Release No. 73704 (November 28, 2014), 79 FR 72044 (December 4, 2014).

Trading Permit Holder Requirements

The Exchange proposes to add additional requirements that will be applicable to all Trading Permit Holders through new proposed CBOE Rule 3.4A. Currently, CBOE Rules 3.2 (Qualifications of Individual Trading Permit Holders) and 3.3 (Qualifications of TPH Organizations) set forth the requirements for individuals and organizations, respectively, to become and remain Trading Permit Holders. For an individual to become and remain a Trading Permit Holder, CBOE Rule 3.2 requires the individual to (i) to be at least 21 years of age, (ii) be registered as a broker or dealer pursuant to Section 15 of the Act, or be associated with a Trading Permit Holder organization that is registered as a broker or dealer pursuant to Section 15 of the Act, and (iii) meet the qualification requirements to be a Trading Permit Holder under the Exchange's bylaws and rules. Similarly, for an organization to become and remain a Trading Permit Holder, CBOE Rule 3.3 requires the organization to (i) be a corporation, partnership, or limited liability company, (ii) be registered as a broker or dealer pursuant to Section 15 of the Act, and (iii) meet the qualification requirements to be a Trading Permit Holder under the Exchange's bylaws and rules.

Further, CBOE Rule 3.4 imposes additional qualifications on Trading Permit Holders that do not maintain an office in the United States that prepares and maintains financial and other reports required to be filed with the Commission and the Exchange. These foreign Trading Permit Holders must (i) prepare all such reports, and maintain a general ledger chart of account and any description thereof, in English and U.S. Dollars, (ii) reimburse the Exchange for any expense incurred in connection with examinations of the Trading Permit Holder to the extent that such expenses exceed the cost of examining a Trading Permit Holder located within the United States, and (iii) ensure the availability of an individual fluent in English knowledgeable in securities and financial matters to assist the representatives of the Exchange during examinations.[5]

Proposed CBOE Rule 3.4A(a) provides that, in addition to the requirements set forth in CBOE Rules 3.2 through 3.4, a Trading Permit Holder applicant must satisfy several new requirements. First, proposed CBOE Rule 3.4A(a)(i) provides that a Trading Permit Holder applicant must be domiciled in (with respect to

[5] The proposed rule change makes nonsubstantive formatting changes to CBOE Rule 3.4 to revise the numbering of the paragraphs.

individuals), or organized under the laws of (with respect to organizations), a jurisdiction expressly approved by the Exchange. The proposed rule provides that when determining whether to approve a jurisdiction, the Exchange will consider whether: (i) The applicant will be able to supply the Exchange with such information with respect to the applicant's dealings with the Exchange as set forth in CBOE's rules, (ii) the Exchange will be able to examine the applicant's books and records to verify the accuracy of any information so supplied, (iii) approval of such application will comply with all applicable laws, rules, and regulations, and (iv) other factors that the Exchange reasonably and objectively determines may impact the applicant's ability to comply with the Exchange's rules and the Act or the Exchange's ability to accept Trading Permit Holders from the applicable jurisdiction. The proposed rule also provides that this approval may be limited to one or more specified categories of Trading Permit Holders or Trading Permit Holder activities in a jurisdiction or be contingent upon the satisfaction of specified conditions by all applicants from a jurisdiction to the extent such limits or conditions are necessary to satisfy clauses (i) through (iv).

Second, proposed CBOE Rule 3.4(a)(ii) provides that a Trading Permit Holder applicant must be subject to the jurisdiction of the federal courts of the United States and the courts of the state of Illinois.

Finally, proposed CBOE Rule 3.4(a)(iii) provides that a Trading Permit Holder applicant, prior to acting as agent for a customer, must be able to provide information regarding the customer and the customer's trading activities to the Exchange in response to a regulatory request for information pursuant to the CBOE's rules. To the extent an individual or organization is required by an applicable law, rule, or regulation to obtain written consent from a customer to permit the provision of this information to the Exchange, the applicant must obtain such consent.[6]

The Exchange intends to provide a list of approved jurisdictions and notify market participants, both initially and when updated, in a Regulatory Circular.[7] Additionally, the Exchange intends to have a Web site that lists currently approved jurisdictions.

Proposed CBOE Rule 3.4A(b) allows the Exchange to determine at any time that a Trading Permit Holder can no longer comply with proposed CBOE Rule 3.4A. For example, this scenario could arise if the laws in the Trading Permit Holder's jurisdiction change in a manner that prevents compliance with CBOE Rule 3.4A. If the Exchange determines that the Trading Permit Holder is not in compliance with CBOE Rule 3.4A, then the Trading Permit Holder will have three months following the date of this determination to come into compliance. If the Trading Permit Holder does not come into compliance during that time period, the Exchange may terminate the Trading Permit Holder's status as a Trading Permit Holder.[8]

The Exchange states that these proposed requirements will enhance the Exchange's regulatory oversight of its Trading Permit Holders' activity and its ability to monitor Trading Permit Holders' compliance with Exchange rules and the Act.[9] While the proposed changes apply to all Trading Permit Holders, the Exchange indicates that certain jurisdictions may limit market participants' ability to share or access certain information.[10] The Exchange states that the additional requirements are intended to assure the Exchange that it will be able to obtain the information necessary to perform its self-regulatory obligations and to comply with the applicable regulatory requirements in jurisdictions in which Trading Permit Holders are located.[11]

System Access and Sponsored Users

The Exchange proposes to amend CBOE Rule 6.23A to provide that Trading Permit Holders, persons associated with Trading Permit Holders, and Sponsored Users with authorized access may only directly access the System from a jurisdiction expressly approved by the Exchange pursuant to CBOE Rule 3.4A(a).[12] The Exchange asserts that the laws, rules, and regulations of a jurisdiction relating to exchange membership apply in the same manner to persons or entities accessing the System from such jurisdiction.[13] For example, restrictions on supplying an exchange with certain information or providing access to books and records would apply whether the Trading Permit Holder was domiciled in such jurisdiction or was directly accessing the System from such jurisdiction. Accordingly, the Exchange asserts that direct access should only be permitted from approved jurisdictions for the same reasons discussed above.[14]

The Exchange also proposes to amend CBOE Rule 6.20A to require Sponsoring Trading Permit Holders to ensure that a Sponsored User satisfies the requirements of CBOE Rule 3.4A(a) and only directly accesses the System from an approved jurisdiction as set forth in CBOE Rule 6.23A(d). The Exchange asserts it would need the same information from Sponsored Users as it does from Trading Permit Holders and therefore the same requirements should apply.[15]

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.[16] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[17] which requires, among other things, that the rules of a national securities exchange be 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 regulating, clearing, settling, processing

[6] The Exchange also proposes to amend Rule 6.20A pertaining to Sponsoring Trading Permit Holders. The Exchange asserts that it needs the same information from Sponsored Users as it does from Trading Permit Holders. *See* Notice, *supra* note 3, at n. 7. Proposed new paragraph (c) under Rule 6.20A requires Sponsored Users to satisfy the requirements of CBOE Rule 3.4A(a) and only access the System from an approved jurisdiction.

[7] Regulatory Circulars are publicly available on the Exchange's Web site. The Exchange states that it will issue a Regulatory Circular notifying market participants if it no longer intends to issue a Regulatory Circular to announce changes to the list of approved jurisdictions and only update the Web site. *See* Notice, *supra* note 3, at 29132. *See also* Regulatory Circular RG15–014 (question #5 includes a current list of approved jurisdictions, subject to Commission approval of this proposed rule change).

[8] The Exchange asserts that this rule change is consistent with CBOE Rule 3.5(d), which among other things, permits the Exchange to determine not to permit a Trading Permit Holder to continue being a Trading Permit Holder if it fails to meet any qualification requirements for being a Trading Permit Holder after approval as a Trading Permit Holder. *See* Notice, *supra* note 3, at n. 5.

[9] *See id.* at 29133.

[10] *See id.*

[11] *See id.*

[12] The Exchange asserts that it currently has similar authority under CBOE Rule 6.23A(e) to prescribe technical specifications regarding the establishment of an electronic connection to the System, arguing proposed CBOE Rule 6.23A(c) is similar to a ''specification'' because the location requirement will be part of the same process which the Trading Permit Holder must comply when establishing a connection to the Exchange. *See id.* at 29134.

[13] *See id.* at 29133.

[14] *See id.* at 29133–34.

[15] *See id.* at n. 7.

[16] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(5).

information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Commission also finds that the proposal is designed to not permit unfair discrimination between customers, issuers, brokers, or dealers pursuant to Section 6(b)(5) of the Act.[18] Further, the Commission finds that the proposed rule change is consistent with Section 6(b)(1) of the Act,[19] which provides that an exchange must be so organized and have the capacity to be able to carry out the purposes of this Act and to comply, and to enforce compliance by its members and persons associated with its members, with the Act, the rules and regulations thereunder, and the rules of the exchange.

The Commission believes that the additional requirements prescribed by CBOE Rules 3.4A, 6.20A, and 6.23A are reasonably designed to assure the Exchange that it will be able to obtain the information necessary to perform its self-regulatory obligations. In this regard, the Commission notes that certain foreign jurisdictions may have laws, rules, or regulations that prohibit or restrict the sharing of certain information that would be necessary for the Exchange to adequately oversee the trading activity of Trading Permit Holders from such jurisdictions. Accordingly, the Commission believes that it is appropriate and consistent with the Act for the Exchange to require Trading Permit Holders to be domiciled in, or only directly access the System from, jurisdictions that would not impede the Exchange's ability to carry out its regulatory responsibilities, and that Trading Permit Holders are otherwise able to provide to CBOE pertinent information regarding their customers and their customers' trading activities in response to a regulatory request.

The Commission believes that these new CBOE requirements will help facilitate the Exchange's surveillance, examinations, and inspections of Trading Permit Holders by helping to ensure that the Exchange has access to information necessary for it to enforce compliance by all Trading Permit Holders with CBOE's rules and the federal securities laws, consistent with the Act.[20] With unencumbered access to the same level of information from each member, without regard to whether such members are located within or outside the U.S., the proposal is designed to support CBOE's ability to fulfil its regulatory mandate to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, and protect investors and the public interest, consistent with Section 6(b)(5) of the Act.[21]

The Commission believes that the factors enumerated in CBOE Rule 3.4A(a)(i) for determining whether to approve a jurisdiction are objective and reasonably designed to achieve the purposes discussed above. Further, the Commission notes that the Exchange represents that it will consider all of the factors for all of the jurisdictions in the same manner and that such consideration will include reviews of the applicable laws, rules, and regulations of a jurisdiction to determine whether the factors enumerated in the Rule can be satisfied.[22] In addition, while the Rule allows the Exchange to limit approval to specified categories of Trading Permit Holders or activities in a jurisdiction or impose other specified conditions, this provision provides CBOE with limited discretion as any such conditions must be imposed on all applicants from a given jurisdiction and only to the extent that such limits or conditions are necessary to satisfy the factors of CBOE Rule 3.4A(a)(i)(A)–(D). For example, the Exchange notes that a foreign jurisdiction may permit only certain activities on the Exchange by market participants in that jurisdiction.[23] This provision would allow the Exchange to permit Trading Permit Holders from such a jurisdiction, subject to certain conditions that enable the Exchange to comply with the laws, rules, or regulations of such jurisdiction. The Commission also notes that the Exchange represents that it will determine in the same manner for all jurisdictions whether to impose any such limits or conditions on Trading Permit Holders.[24] The Commission therefore believes that the proposed rule is not designed to permit CBOE to apply the new requirements in an arbitrary or discriminatory manner and similarly situated applicants should therefore be treated consistently.

Further, the Commission notes that the Exchange will publish a list of approved jurisdictions in a Regulatory Circular and on a dedicated Web site. Making the jurisdictional determinations available publicly will provide transparency to CBOE's determinations under the proposed Rule, as well as provide notice to market participants and prospective Trading Permit Holders of the approved jurisdictions.

Finally, the Commission believes that the requirement in CBOE Rule 3.4A(a)(ii) that an applicant be subject to the jurisdiction of the federal courts of the United States and the courts of the state of Illinois is reasonable. Among other things, this provision could be useful to a U.S. person involved in a dispute with a Trading Permit Holder or Sponsored User as it may provide a forum in which such aggrieved party could pursue any available legal or equitable remedies against such party.

IV. Conclusion

It is therefore ordered pursuant to Section 19(b)(2) of the Act,[25] that the proposed rule change (SR–CBOE–2015–012) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–17290 Filed 7–13–15; 8:45 am]

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[18] *Id.*

[19] 15 U.S.C. 78f(b)(1).

[20] 15 U.S.C. 78f(b). In this regard, as noted above, the Rule provides that in approving a given jurisdiction, among other things, the Exchange will consider whether: The applicant will be able to supply the Exchange with such information with respect to its dealings on the Exchange, the Exchange will be able to examine the applicant's books and records to verify the accuracy of any information so supplied, and other factors that the Exchange reasonably and objectively determines may impact the applicant's ability to comply with the Exchange's rules and the Act. *See* CBOE Rule 3.4A(a)(i). Further, it requires that a Trading Permit Holder, prior to acting as agent for a customer, must be able to provide information regarding the customer and the customer's trading activities to the Exchange in response to a regulatory request for information. To the extent that an individual or organization is required by an applicable, law, rule, or regulation to obtain written consent from a customer to permit the provision of this information to the Exchange, the applicant must obtain such consent. *See* CBOE Rule 3.4A(a)(iii).

[21] 15 U.S.C. 78f(b)(5).

[22] *See* Notice, *supra* note 3, at 29133.

[23] *See id.*

[24] *See id.*

[25] 15 U.S.C. 78s(b)(2).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75392; File No. SR–BX–2015–036]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by NASDAQ OMX BX, Inc. Relating to the Volume-Based and Multi-Trigger Threshold

July 8, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

(''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 23, 2015, NASDAQ OMX BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

BX proposes to amend Chapter VII, Section 6, entitled ''Market Maker Quotations,'' of the rules governing BX. The Exchange proposes to adopt two new BX Market Maker[3] optional risk protections, a volume-based threshold and a multi-trigger threshold.[4]

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxbx.cchwallstreet.com,* at the principal office of the Exchange, 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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the filing is to adopt two new risk protections for BX Market Maker's to monitor marketplace risk. These protections are intended to assist BX Market Makers to control their trading risks.[5] Quoting across many series in an option creates the possibility of ''rapid fire'' executions that can create large, unintended principal positions that expose BX Market Makers, who are required to continuously quote in assigned options, to potentially significant market risk. Today, the Exchange's rules permit BX Market Makers to monitor risk arising from multiple executions across multiple options series of a single underlying security.[6]

The Exchange is proposing to offer a new volume-based and multi-trigger threshold protection to BX Market Makers. The Exchange proposes to amend BX's Rules at Chapter VII, Section 6(f) to establish: (1) A threshold used to calculate each BX Market Maker's total volume executed in all series of a given underlying security within a specified time period and compares that to a pre-determined threshold (''Volume-Based Threshold''), and (2) a threshold which measures the number of times the System has triggered[7] based on the Risk Monitor Mechanism (''Percentage-Based Threshold'') pursuant to Chapter VI, Section 19 and Volume-Based Thresholds within a specified time period and compares that total to a pre-determined threshold (''Multi-Trigger Threshold'').

Volume-Based Threshold

In connection with offering these two new threshold protections, a BX Market Maker would provide a specified time period and volume threshold number of allowable triggers by which the Exchange's System would automatically remove the BX Market Maker's quotes in all options series in an options class, depending on the threshold utilized, submitted through designated BX protocols, as specified by the Exchange. The Exchange counts Specialized Quote Feed (''SQF'')[8] quotes only in determining the number of contracts traded and removed by the System.

The Volume-Based Threshold will determine, during a specified time period established by the BX Market Maker not to exceed 15 seconds (''Volume-Based Specified Time Period''), whether a BX Marker Maker executed a number of contracts which equals or exceeds the designated number of contracts specified by the BX Market Maker in all series of an underlying security to determine whether to remove the BX Market Maker's quotes in all series of the underlying security.[9] The Volume-Based Threshold will be based on the total number of contracts executed in the market in the same options series in an underlying security and will not offset the number of contracts executed on the opposite side of the market. Once the System determines that the number of contracts executed equals or exceeds a number established by the BX Market Maker during the Volume-Based Specified Time Period, the System will remove the BX Market Maker's quotes. The Volume-Based Specified Time Period designated by the BX Market Maker must be the same length of time as designated for purposes of the Percentage-Based Threshold in Chapter VI, Section 19.[10]

A Volume-Based Specified Time Period will commence for an option every time an execution occurs in any series in such option and will continue until the System automatically removes quotes as described in newly proposed sections (f)(iv) or (f)(v) or the Volume-Based Specified Time Period expires. The Volume-Based Specified Time Period operates on a rolling basis among all series in an option in that there may be multiple Volume-Based Specified Time Periods occurring simultaneously and such Volume-Based Specified Time Periods may overlap.[11]

Multi-Trigger Threshold

A BX Market Maker or BX Market Maker Group, which is defined as multiple affiliated BX Market Makers,[12] may provide the specified time period and number of allowable triggers by which the Exchange will automatically remove quotes in all options series in all underlying securities issues submitted

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''BX Market Maker'' means a Participant that has registered as a Market Maker on BX pursuant to Chapter VII, Section 2, and must also remain in good standing pursuant to Chapter VII, Section 4.

[4] Market Makers will be required to continue to utilize the Risk Monitor Mechanism in Chapter VI, Section 19, as is the case today.

[5] Pursuant to BX Rules at Chapter VII, Section 5, entitled ''Obligations of Market Makers'', in registering as a market maker, an Options Participant commits himself to various obligations. Transactions of a BX Market Maker must constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and Market Makers should not make bids or offers or enter into transactions that are inconsistent with such course of dealings. Further, all Market Makers are designated as specialists on BX for all purposes under the Act or rules thereunder. *See* Chapter VII, Section 2.

[6] *See* BX Chapter VI, Section 19, ''Risk Monitor Mechanism.''

[7] A trigger is defined as the event which causes the System to automatically remove all quotes in all options series in an underlying issue.

[8] SQF permits the receipt of quotes. SQF Auction Responses and Market Sweeps are also not included.

[9] The System counter is based on trading interest resting on the Exchange book.

[10] *See* proposed new Chapter VII, Section 6(f)(ii).

[11] *Id.*

[12] This would be more than one BX Market Maker, but does not require the aggregation of all of the Participant's Market Makers. A Group would be comprised of BX Market Makers affiliated with one Participant. The Participant would be required to define a Group by providing a list of such affiliated BX Market Makers to the Exchange.

through designated BX protocols, as specified by the Exchange (''Multi-Trigger Threshold''). During a specified time period established by the BX Market Maker not to exceed 15 seconds (''Multi-Trigger Specified Time Period''), the number of times the System automatically removes the BX Market Maker's or Group's quotes in all options series will be based on the number of triggers of the Percentage-Based Threshold, described in proposed (f)(ii), as well as the Volume-Based Threshold described in proposed (f)(ii).[13] For purposes of this rule, a trigger shall be defined as the event which causes the System to automatically remove quotes in all options series in an underlying issue. Once the System determines that the number of triggers equals or exceeds a number established by either the BX Market Maker or Group, during a Multi-Trigger Specified Time Period, the System will automatically remove all quotes in all options series in all underlying issues for that BX Market Maker or Group. A Multi-Trigger Specified Time Period will commence after every trigger of either the Percentage-Based Threshold or the Volume-Based Threshold and will continue until the System removes quotes as described in section (f)(iv) of the proposed rule or the Multi-Trigger Specified Time Period expires. Participants may configure the Multi-Trigger Threshold at the badge level (by BX Market Maker) or by Group (multiple affiliated BX Market Makers), but not both. This is different as compared to the Percentage-Based Threshold in Chapter VI, Section 19 or the newly proposed Volume-Based Thresholds that are configured only on the badge level (by BX Market Maker).[14] The System counts triggers within a Multi-Trigger Specified Time Period across all options for the BX Market Maker or Group. A Multi-Trigger Specified Time Period operates on a rolling basis in that there may be multiple Multi-Trigger Specified Time Periods occurring simultaneously and such Multi-Trigger Specified Time Periods may overlap.

The System will automatically remove quotes in all options in an underlying security when the Volume-Based Threshold has been reached. The System will automatically remove quotes in all options in all underlying securities when the Multi-Trigger Threshold has been reached.[15] The System will send a Purge Notification Message [16] to the BX Market Maker for all affected options when the above thresholds have been reached.

The two thresholds, Volume-Based Threshold and Multi-Trigger Threshold, operate independently of each other. The triggering of the Volume-Based Threshold would occur independently of the Multi-Trigger Threshold. The Multi-Trigger Threshold is somewhat dependent on the Volume-Based Threshold to the extent that the Volume-Based Threshold serves as a trigger for the Multi-Trigger Threshold. Quotes will be automatically executed up to the BX Market Maker's size regardless of whether the quote exceeds the Volume-Based Threshold.[17]

If a BX Market Maker requests the System to remove quotes in all options series in an underlying issue, the System will automatically reset the Volume-Based Specified Time Period(s). The Multi-Trigger Specified Time Period(s) will not automatically reset for the Multi-Trigger Threshold.[18]

When the System removes quotes as a result of the Volume-Based Threshold, the BX Market Maker must send a re-entry indicator to re-enter the System. When the System removes quotes as a result of the Multi-Trigger Threshold, the System will not accept quotes through designated protocols until the BX Market Maker manually requests re-entry.[19] After quotes are removed as a result of the Multi-Trigger Threshold, Exchange staff must set a re-entry indicator in this case to enable re-entry, which will cause the System to send a Reentry Notification Message to the BX Market Maker for all options series in all underlying issues.[20] The BX Market Maker's Clearing Firm will be notified regarding the trigger and re-entry into the System after quotes are removed as a result of the Multi-Trigger Threshold, provided the BX Market Maker's Clearing Firm has requested to receive such notification.[21] The System will then reset all counters to zero and re-entry and continued trading will be permitted. A BX Market Maker is subject to continuous quoting obligations [22] despite the removal of quotes from the System and approval process for re-entry.

Today, the Exchange provides BX Market Makers with the Percentage-Based Threshold in Chapter VI, Section 19 to monitor risk.[23] The Exchange will continue to require BX Market Makers to utilize the Percentage-Based Threshold. The Volume-Based Threshold and the Multi-Trigger Threshold will be optional.

The Exchange reserved subsection (f)(i) for future modifications to this rule.

The Exchange proposes to implement these rule changes within 30 days of the operative day of this rule change.

Example #1 of the Volume-Based Threshold is displayed below. Presume the following Order Book:

Series of underlying XYZ	Size on bid x offer for MM1
100 Strike Call	300x300
100 Strike Put	50x50
110 Strike Call	200x200
110 Strike Put	150x150

In this example, assume the Specified Time Period designated by the Market Maker #1 is 10 seconds and the designated number of contracts permitted for the Volume-Based Threshold is 250 contracts. Assume at 12:00:00, the Market Maker #1 executes all of his offer size, 200 contracts, in the 110 Strike Calls. The System will initiate the Specified Time Period and for 10 seconds the System will count all volume executed in series of underlying XYZ. If at any point during that 10 second period, the Market Maker #1 executes additional contracts in any series of underlying XYZ, those contracts will be added to the initial execution of 200 contracts. To illustrate,

[13] Today, ISE's functionality permits market maker quotes to be removed from the ISE trading system if a specified number of curtailment events occur across both ISE and ISE Gemini, LLC (''ISE Gemini''). ISE and ISE Gemini's trading systems will count the number of times a market maker's pre-set curtailment events occur on each exchange and aggregate them. Once a market maker's specified number of curtailment events across both markets is reached, the trading systems will remove the market maker's quotes in all classes on both ISE and ISE Gemini. ISE will then reject any quotes sent by the market maker after the parameters across both exchanges have been triggered until the market maker notifies the market operations staff of ISE that it is ready to come out of its curtailment. *See* Securities Exchange Release No. 73147 (September 19, 2014), 79 FR 57639 (September 25, 2014) (SR–ISE–2014–09) (Order approving proposed rule change related to market maker risk parameters).

[14] *See* proposed new Chapter VII, Section 6(f)(iii).

[15] The specified time period for the Volume-Based Threshold and the Multi-Trigger Threshold may differ. The specified time period for the Volume-Based Threshold must be the same as the Percentage-Based Threshold in Chapter VI, Section 19.

[16] A message entitled ''Purge Notification Message'' is systemically sent to the BX Marker Maker upon the removal of quotes due to Volume-Based Threshold or Multi-Trigger Threshold.

[17] *See* proposed new Chapter VII, Section 6(f)(iii).

[18] *See* proposed new Chapter VII, Section 6(f)(iv).

[19] In the interest of maintaining fair and orderly markets, the Exchange believes it is important that BX Market Makers communicate their readiness to Exchange staff in a non-automated manner, such as by email or telephone.

[20] *See* proposed new Chapter VII, Section 6(f)(v).

[21] BX Rules at Chapter VI, Section 20 permits the Exchange to share BX MarketMaker designated risk settings in the System with the Clearing Firm.

[22] *See* note 5.

[23] An initial default value is set for each BX Market Maker.

assume at 12:00:05 the Market Maker #1 executes 60 contracts of his offer in the 100 Strike Calls. The total volume executed is now 260 contracts. Since that volume exceeds the Market Maker #1's designated number of contracts for the Volume-Based Threshold (250 contracts), all of his quotes in all series of underlying XYZ over the designated protocols will be removed from the System; no further quotes will be executed until re-entry. The Volume-Based Specified Time Period will be reset for Market Maker #1 in underlying XYZ and Market Maker #1 will need to send a re-entry indicator in order to re-enter quotes in options series for underlying XYZ into the System.

Example #2 of the Volume-Based Threshold: Similar to the example above, assume the Specified Time Period is 10 seconds and the designated number of contracts permitted for the Volume-Based Threshold is 250 contracts. Assume at 12:00:00, Market Maker #1 executes all of his offer size, 200 contracts, in the 110 Strike Calls. The System will initiate the Specified Time Period and for 10 seconds the System will count all volume executed in series of underlying XYZ. If at any point during that 10 second period, Market Maker #1 executes additional contracts in any series of underlying XYZ, those contracts will be added to the initial execution of 200 contracts. Then assume at 12:00:05 Market Maker #1 executes 20 contracts of his offer in the 100 Strike Calls. The total volume executed is 220 contracts which does not exceed the Volume-Based Threshold. This second execution initiates another Specified Time Period so there are two open time periods, the first with 5 seconds remaining and a new 10 second time period. At 12:00:10, the first timer period expires and the initial execution of 200 contracts is no longer counted toward the designated number of contracts permitted for the Volume-Based Threshold. Further assume at 12:00:12, which is outside of the initial time period but still within 10 seconds of the second execution of 20 contracts, another execution occurs with Market Maker #1 executing 230 contracts of his bid in the 100 Strike Calls. This total volume executed toward the Volume-Based Threshold within the Specified Time Period is now 250 contracts which equals the designated number of contracts permitted causing the System to remove all quotes in all series of underlying XYZ over the designated protocols for Market Maker #1 to be removed from the System; no further quotes will be executed until re-entry. The Volume-Based Specified Time Period will be reset for Market Maker #1 in underlying XYZ and Market Maker #1 will need to send a re-entry indicator in order to re-enter quotes in options series for underlying XYZ into the System. This example displays the rolling basis in which the Specified Time Period operates.

Example #3: In order to illustrate the Multi-Trigger Threshold, assume Example #1 and Example #2 provided above occurred in options series of two different underlyings rather than all in options series of underlying XYZ and for two separate Market Makers (MM#1 for Example #1 and MM#2 for Example #2) of the same member organization. Assume a Group is defined by the member organization and is comprised of the MM #1 and MM #2. Further assume the member organization has defined the Multi-Trigger Specified Time Period as 10 seconds and the number of allowable triggers as two. Based on the aforementioned examples, a Multi-Trigger Specified Time Period commences at 12:00:05 when MM#1 triggers the Volume-Based Threshold. This Volume-Based Threshold triggers counts as the first trigger toward the Multi-Trigger Threshold for the Group. Another Multi-Trigger Specified Time Period is initiated at 12:00:12 when MM#2 triggers the Volume-Based Threshold (per Example #2). This Volume-Based Threshold trigger counts as the second trigger toward the Multi-Trigger Threshold for the Group since it is within the Multi-Trigger Specified Time Period of the first trigger. Since the member organization designated two triggers for the number of allowable triggers, the Group, both MM#1 and MM#2, quotes in all option series in all underlying issues for the Group are automatically removed from the System and Purge Notification Messages are sent to the Group; no further quotes will be executed until re-entry. The member organization will need to contact the Exchange to request Exchange staff to enable re-entry into the System.

The Exchange proposes to implement this rule within thirty (30) days of the operative date. The Exchange will issue an Options Trader Alert in advance to inform market participants of such date.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [24] in general, and furthers the objectives of Section 6(b)(5) of the Act [25] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by enhancing the risk protections available to Exchange members. The proposal promotes policy goals of the Commission which has encouraged execution venues, exchange and non-exchange alike, to enhance risk protection tools and other mechanisms to decrease risk and increase stability.

The individual firm benefits of enhanced risk protections flow downstream to counter-parties both within and without the Exchange, thereby increasing systemic protections as well. Additionally, because the Exchange offers these risk tools to BX Market Makers, in order to encourage them to provide as much liquidity as possible and encourage market making generally, the proposal removes impediments to and perfects the mechanism of a free and open market and a national market system and protect investors and the public interest.

With respect to permitting the Multi-Trigger Threshold to be set either to one BX Market Maker or to a number of specified BX Market Makers affiliated with a member, it is important to note that the risk to BX Market Makers is not limited to a single series in an option but to all series in an option. BX Market Makers that quote in multiple series of multiple options have significant exposure, requiring them to offset or hedge their overall positions. The proposed functionality will be useful for BX Market Makers, who are required to continuously quote in assigned options classes on the Exchange. Quoting across many series in an option or multiple options creates the possibility of executions that can create large, unintended principal positions that could expose market makers to unnecessary risk. The Multi-Trigger Threshold functionality is intended to assist BX Market Makers manage that risk at the Group level so that BX Market Makers may provide deep and liquid markets to the benefit of all investors.

The Exchange further represents that its proposal will operate consistently with the firm quote obligations of a broker-dealer pursuant to Rule 602 of Regulation NMS and that the functionality is not mandatory. Specifically, any interest that is executable against a BX Market Maker's

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78(b)(5).

quotes that are received [26] by the Exchange prior to the time either of these functionalities are engaged will be automatically executed at the price up to the BX Market Maker's size, regardless of whether such execution results in executions in excess of the BX Market Maker's pre-set parameters.

With respect to providing risk settings to the BX Market Maker's Clearing Member, each Member that transacts through a Clearing Member on the Exchange executes a Letter of Guarantee wherein the Clearing Member accepts financial responsibility for all Exchange transactions made by the Participant on whose behalf the Clearing Member submits the letter of guarantee. The Exchange believes that because Clearing Members guarantee all transactions on behalf of a Participant, and therefore, bear the risk associated with those transactions, it is appropriate for Clearing Members to have knowledge of what risk settings a BX Market Maker may utilize within the System and receive notice of re-entry into the System after triggering the Multi-Trigger Threshold.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the proposal will not impose a burden on intra-market or inter-market competition, rather it provides BX Market Makers with the opportunity to avail themselves of similar risk tools which are currently available on other exchanges.[27] The proposal does not impose a burden on inter-market competition, because Participants may choose to become market makers on a number of other options exchanges, which may have similar but not identical features.[28] The proposed rule change is meant to protect BX Market Makers from inadvertent exposure to excessive risk. Accordingly, the proposed rule change will have no impact on competition.

Further, the Exchange is proposing this rule change at the request of its BX Market Makers to further reduce their risk in the event the BX Market Maker is suffering from a systems issue or due to the occurrence of unusual or unexpected market activity. The proposed Group parameter for the Multi-Trigger threshold will protect BX Market Makers from inadvertent exposure to excessive risk at the Group level. Reducing such risk will enable BX Market Makers to enter quotations without any fear of inadvertent exposure to excessive risk, which in turn will benefit investors through increased liquidity for the execution of their orders. Such increased liquidity benefits investors because they receive better prices and because it lowers volatility in the options market.

The Exchange believes that requiring BX Market Makers to enter values for the Percentage-Based Threshold is not unreasonably burdensome because BX Market Makers can enter an out-of-range value so that the Exchange-provided risk protections will not be triggered. Reducing risk by utilizing the proposed risk protections will enable BX Market Makers to enter quotations with larger size, which in turn will benefit investors through increased liquidity for the execution of their orders. Such increased liquidity benefits investors because they receive better prices and because it lowers volatility in the options market.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [29] and subparagraph (f)(6) of Rule 19b–4 thereunder.[30] The Exchange has requested that the Commission waive the thirty-day operative delay so that the proposal may become operative immediately. The Exchange states that waiving the thirty-day operative delay will enable Market Makers to enhance their risk controls and risk management processes without additional delay. The Commission believes that waiving the thirty day delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the thirty-day operative delay and designates the proposal effective upon filing.[31]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved. The Exchange has provided the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

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–BX–2015–036 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2015–036. 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

[26] The time of receipt for an order or quote is the time such message is processed by the Exchange book.

[27] *See* Section 8 of the 19b4.

[28] *See* BATS Rule 21.16, BOX Rules 8100 and 8110, C2 Rule 8.12, CBOE Rule 8.18, ISE Rule 804(g), MIAX Rule 612, NYSE MKT Rule 928NY and NYSE Arca Rule 6.40.

[29] 15 U.S.C. 78s(b)(3)(a)(ii).

[30] 17 CFR 240.19b–4(f)(6).

[31] For purposes of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2015–036 and should be submitted on or before August 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17170 Filed 7–13–17; 8:45 am]

BILLING CODE 8011–01–P

[32] 17 CFR 200.30–3(a)(12).

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 Investor Advisory Committee will hold a meeting on Thursday, July 16, 2015, in Multi-Purpose Room LL–006 at the Commission's headquarters, 100 F Street NE., Washington, DC. The meeting will begin at 9:30 a.m. (ET) and will be open to the public. Seating will be on a first-come, first-served basis. Doors will open at 9 a.m. Visitors will be subject to security checks. The meeting will be webcast on the Commission's Web site at *www.sec.gov*.

On June 22, 2015, the Commission issued notice of the Committee meeting (Release No. 33–9851), indicating that the meeting is open to the public (except during that portion of the meeting reserved for an administrative work session during lunch), and inviting the public to submit written comments to the Committee. This Sunshine Act notice is being issued because a quorum of the Commission may attend the meeting.

The agenda for the meeting includes: Remarks from Commissioners; a discussion of background checks as a means to address elder financial abuse (which may include a recommendation); a discussion of the Department of Labor's fiduciary rule proposal; a shareholder rights update panel; a report of the Committee chair regarding Committee matters; an investment management panel discussion on the disclosure of fees and risks in fund products; and a nonpublic administrative work session during lunch.

For further information, please contact the Office of the Secretary at (202) 551–5400.

Dated: July 9, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–17293 Filed 7–10–15; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75277]

Public Availability of the Securities and Exchange Commission's FY 2014 Service Contract Inventory

AGENCY: U.S. Securities and Exchange Commission.

ACTION: Notice.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), SEC is publishing this notice to advise the public of the availability of the FY2014 Service Contract Inventory (SCI) and the FY2013 SCI Analysis. The SCI provides information on FY2014 actions over $25,000 for service contracts. The inventory organizes the information by function to show how SEC distributes contracted resources throughout the agency. SEC developed the inventory per the guidance issued on November 5, 2011 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf.* The Service Contract Inventory Analysis for FY2013 provides information based on the FY 2013 Inventory. The SEC has posted its inventory, a summary of the inventory and the FY2013 analysis on the SEC's homepage at *http://www.sec.gov/about/secreports.shtml* and *http://www.sec.gov/open*.

FOR FURTHER INFORMATION CONTACT: Direct questions regarding the service contract inventory to Vance Cathell, Director Office of Acquisitions 202.551.8385 or *CathellV@sec.gov.*

Dated: June 24, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–17180 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75394; File No. SR–FINRA–2015–017]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Establish the Securities Trader and Securities Trader Principal Registration Categories

July 8, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 29, 2015, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. 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

FINRA is proposing to amend NASD Rule 1032(f) (Limited Representative—Equity Trader) to replace the Equity Trader registration category and qualification examination (Series 55) with a Securities Trader registration category and qualification examination (Series 57). In addition, the proposed rule change amends NASD Rule 1022(a) (General Securities Principal) to establish a Securities Trader Principal registration category. The proposed rule change also makes technical conforming changes to the Form U4 (Uniform Application for Securities Industry Registration or Transfer).

The text of the proposed rule change 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.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA is proposing to replace the current Equity Trader registration category and qualification examination (Series 55) with a Securities Trader registration category and qualification examination (Series 57). FINRA also is proposing to establish a Securities Trader Principal registration category for a principal with supervisory responsibility over securities trading activities.[3] FINRA is expecting the national securities exchanges to file similar proposed rule changes to replace the Proprietary Trader qualification examination (Series 56) with the Securities Trader qualification examination (Series 57) in their respective registration rules relating to securities trading activities. In addition, FINRA is proposing technical conforming changes to the Form U4.

I. Securities Trader Registration Category

As described in greater detail below, FINRA and the national securities exchanges have different qualification standards for individuals engaged in securities trading activities.

Pursuant to NASD Rule 1032(f), each associated person of a member who is included within the definition of ''representative'' in NASD Rule 1031 (Registration Requirements) is required to register with FINRA as an Equity Trader if, with respect to transactions in equity (including equity options), preferred or convertible debt securities effected otherwise than on a securities exchange, such person is engaged in proprietary trading, the execution of transactions on an agency basis or the direct supervision of such activities. There is an exception from the Equity Trader requirement for any associated person of a member whose trading activities are conducted principally on behalf of an investment company that is registered with the SEC pursuant to the Investment Company Act of 1940 and that controls, is controlled by, or is under common control with the member. The Series 55 examination currently qualifies an associated person to function as an Equity Trader. Before registration as an Equity Trader may become effective, the associated person must be registered as either a General Securities Representative (Series 7) or Corporate Securities Representative (Series 62). FINRA does not recognize the Series 56 examination as an acceptable qualification standard for associated persons engaged in securities trading.

In contrast, the exchanges currently use the Series 56 examination as a qualification standard for several registration categories relating to securities trading, including the Proprietary Trader registration category,[4] and most do not recognize the Series 55 examination as an acceptable qualification standard under their respective registration rules.[5] Unlike the Series 55 examination, there is no prerequisite registration requirement for individuals taking the Series 56 examination. The Series 56 examination is administered by FINRA, but, as noted above, it is not recognized by FINRA as an acceptable qualification examination for associated persons engaged in securities trading. Associated persons of FINRA members are required to pass the Series 55 examination to engage in over-the-counter securities trading. Consequently, individuals engaged in trading activities at broker-dealers are subject to varying qualification requirements depending on whether their activities take place on a securities exchange or over-the-counter. Yet, there is significant overlap in the content of the Series 55 and 56 examinations because the examinations test the core knowledge required of individuals engaged in trading activities as well as the self-regulatory organization (SRO) rules, including trading rules, that are common across SROs.

To eliminate duplication and a fragmented qualification standard for individuals engaged in trading activities, FINRA, in consultation with the national securities exchanges, is proposing to amend NASD Rule 1032(f) to replace the Equity Trader registration category and qualification examination with a Securities Trader registration category and qualification examination. As part of the proposed rule change, FINRA is proposing to develop the Securities Trader qualification examination (Series 57), which will be based on the current job functions of securities traders, including elements of the Series 55 and 56 examination programs,[6] and require associated persons to pass the Series 57 examination to register as Securities Traders. FINRA understands that the exchanges also plan to replace the Series 56 examination with the Series 57 examination for those registration categories, such as the Proprietary Trader registration category, where the Series 56 is currently an acceptable qualification standard. To provide consistency with the rules of the national securities exchanges and to develop a more tailored examination, FINRA is proposing to eliminate the current prerequisite registration requirement in NASD Rule 1032(f) (General Securities Representative or Corporate Securities Representative prerequisite registration) and, instead, to include in the Series 57 examination the core knowledge portion of the General Securities Representative examination (Series 7).

Further, FINRA is proposing to amend NASD Rule 1032(f) to provide that an associated person registered as a Securities Trader will not be qualified to function in any other registered capacity, unless he or she is qualified and registered in that other registration category. For instance, a person registered as a Securities Trader will not be able to engage in any retail or institutional sales activities, unless he or she is qualified and registered in the appropriate registration category, such as a General Securities Representative.

A person registered as an Equity Trader in the Central Registration Depository (CRD®) system on the effective date of the proposed rule change will be grandfathered as a Securities Trader without having to take any additional examinations and

[3] The Commission notes that the term ''securities trading activities'' or ''trading activities,'' as used in this filing to describe FINRA's Equity Traders, proposed Securities Traders, and proposed Securities Trader Principals, refers to the securities trading activities described in NASD Rule 1032(f)(1).

[4] For instance, under the rules of the Chicago Board Options Exchange (CBOE), an individual trading permit holder or individual associated person who is engaged in proprietary trading, market-making or effecting transactions on behalf of a broker-dealer is required to register and qualify as a Proprietary Trader. *See* Interpretation and Policy .08(a)(1) to CBOE Rule 3.6A (Qualification and Registration of Trading Permit Holders and Associated Persons). To qualify as a Proprietary Trader under the CBOE rules, an individual must pass the Series 56 examination or be registered as a General Securities Representative. *See* Interpretation and Policy .08(b) to CBOE Rule 3.6A.

[5] NASDAQ recognizes the Series 55 examination. Specifically, NASDAQ members that are FINRA members are also subject to the Equity Trader registration requirement with respect to transactions on NASDAQ, and thus must pass the Series 55 qualification examination to engage in such activities. *See* NASDAQ Rule 1032(f) (Limited Representative—Equity Trader).

[6] The Series 55 examination consists of 100 scored multiple-choice questions and the testing time is 3 hours. The Series 56 examination consists of 100 scored multiple-choice questions and the testing time is 2 hours and 30 minutes. FINRA will develop the Series 57 examination, including the appropriate topics, depth of knowledge, number of questions, time allotted and passing score, and will file the examination with the SEC as part of a separate proposed rule change.

without having to take any other actions. In addition, individuals who were registered as Equity Traders in the CRD system prior to the effective date of the proposed rule change will be eligible to register as Securities Traders without having to take any additional examinations, provided that no more than two years has passed between the date they were last registered as a representative and the date they register as a Securities Trader.[7]

II. Securities Trader Principal Registration Category

FINRA and the national securities exchanges also have different qualification standards for individuals responsible for the supervision of securities trading activities.

Currently, under FINRA rules, an associated person with direct supervisory responsibility over the securities trading activities set forth in NASD Rule 1032(f) is required to qualify and register as an Equity Trader.[8] However, FINRA rules do not expressly require such persons to register in a specific principal registration category.[9] Conversely, most national securities exchanges expressly require that an individual associated with an exchange member with supervisory responsibility over proprietary trading activities qualify and register as a Proprietary Trader Principal.[10]

To harmonize FINRA rules with the rules of the exchanges regarding the registration and qualification of individuals responsible for supervising securities trading activities, FINRA is proposing to amend NASD Rule 1022(a) to establish a Securities Trader Principal registration category and require each associated person of a member who is included within the definition of ''principal'' in NASD Rule 1021 (Registration Requirements) with supervisory responsibility over the securities trading activities described in NASD Rule 1032(f) to qualify and register as a Securities Trader Principal. The proposed rule change will also allow FINRA to more easily track principals with supervisory responsibility over securities trading activities. To qualify for registration as a Securities Trader Principal, an individual must be registered as a Securities Trader and pass the General Securities Principal qualification examination. As stated above, FINRA understands that the exchanges plan to replace the Series 56 examination with the Series 57 examination under their respective registration rules. Therefore, the Series 57 examination will also replace the Series 56 examination for those registration categories, such as the Proprietary Trader Principal registration category, where the Series 56 examination is currently an acceptable prerequisite.

A person registering as a Securities Trader Principal will be required to pass the General Securities Principal examination, but will not be eligible to register as a General Securities Principal unless the person passes the appropriate prerequisite examination for General Securities Principal registration, such as the Series 7 examination. Therefore, FINRA is proposing to amend NASD Rule 1022(a) to clarify that a person qualified and registered as a Securities Trader Principal may only have supervisory responsibility over the activities specified in NASD Rule 1032(f), unless such person is separately qualified and registered in another appropriate principal registration category, such as the General Securities Principal registration category. Conversely, the proposed rule change clarifies that a person registered as a General Securities Principal will not be qualified to supervise the trading activities described in NASD Rule 1032(f), unless he or she qualifies and registers as a Securities Trader (by passing the Series 57 examination) and affirmatively registers as a Securities Trader Principal.

A person registered as a General Securities Principal and an Equity Trader in the CRD system on the effective date of the proposed rule change will be eligible to register as a Securities Trader Principal without having to take any additional examinations. An individual who was registered as a General Securities Principal and an Equity Trader in the CRD system prior to the effective date of the proposed rule change will also be eligible to register as a Securities Trader Principal without having to take any additional examinations, provided that no more than two years has passed between the date they were last registered as a principal and the date they register as a Securities Trader Principal.[11] Members, however, will be required to affirmatively register persons transitioning to the proposed registration category as Securities Trader Principals on or after the effective date of the proposed rule change.

III. Technical Conforming Changes to the Form U4

As part of the proposed rule change, and in anticipation of the national securities exchanges filing similar proposed rule changes to replace the Series 56 examination with the Series 57 examination in their respective registration rules, FINRA is proposing to amend the Form U4 to replace: (1) The Equity Trader registration category with the Securities Trader registration category as well as references to the Series 55 examination with the Series 57 examination; (2) references to the Series 56 examination with the Series 57 examination; and (3) the Proprietary Trader Principal registration category with the Securities Trader Principal registration category.[12]

If the Commission approves the filing, FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 90 days following Commission approval. The effective date will be no later than 270 days following publication of the *Regulatory Notice* announcing Commission approval, but FINRA intends for the effective date to be January 4, 2016.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[13] which requires, among other things, that FINRA rules must 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

[7] *See* NASD Rule 1031(c) (Requirements for Examination on Lapse of Registration).

[8] *See* NASD Rule 1032(f) and FINRA Rule 3110(a) (Supervisory System).

[9] In general, a General Securities Principal with supervisory responsibility over securities trading activities is currently required to qualify and register as an Equity Trader.

[10] For instance, under CBOE rules, an individual trading permit holder or individual associated person who (1) supervises or monitors proprietary trading, market-making or brokerage activities for broker-dealers; (2) supervises or trains those engaged in proprietary trading, market-making or effecting transactions on behalf of a broker-dealer, with respect to those activities; or (3) is an officer, partner or director of a trading permit holder or organization is required to register and qualify as a Proprietary Trader Principal. *See* Interpretation and Policy .08(a)(2) to CBOE Rule 3.6A. To qualify for registration as a Proprietary Trader Principal under the CBOE rules, an individual must be registered as a Proprietary Trader and pass the General Securities Principal qualification examination (Series 24) (passing the General Securities Principal Sales Supervisor Module examination (Series 23), in combination with qualification and registration as a General Securities Sales Supervisor (Series 9/10), is an acceptable qualification alternative to the Series 24 examination). *See* Interpretation and Policy .08(b) to CBOE Rule 3.6A.

[11] *See* NASD Rule 1021(c) (Requirements for Examination on Lapse of Registration).

[12] FINRA will file a separate proposed rule change to amend Section 4(c) of Schedule A to the FINRA By-Laws to establish the fee for the proposed Securities Trader qualification examination.

[13] 15 U.S.C. 78*o*–3(b)(6).

public interest, and Section 15A(g)(3) of the Act,[14] which authorizes FINRA to prescribe standards of training, experience, and competence for persons associated with FINRA members.

FINRA believes that the proposed rule change will streamline, and bring consistency and uniformity to, the qualification and registration requirements for individuals engaged in securities trading activities across different markets and for principals responsible for supervising such activities, which will, in turn, improve members' registration and compliance efforts. Further, the proposed rule change's requirement to affirmatively register principals who have supervisory responsibility over trading activities as Securities Trader Principals will enhance FINRA's ability to more easily identify and, if necessary, contact those principals with supervisory responsibilities over trading activities.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

FINRA believes that the proposed rule change relating to Securities Traders, which FINRA is filing in anticipation of the exchanges filing similar proposed rule changes to replace the Series 56 examination with the Series 57 examination under their respective registration rules, will reduce the burden on associated persons currently required to be registered as traders by harmonizing the registration requirements for representatives engaged in securities trading activities across different markets. The proposed rule change would further reduce the burden on associated persons in terms of the number of qualification examinations that they would be required to take under FINRA rules to be eligible to engage in securities trading activities in the future. Under FINRA rules, an associated person engaged in securities trading activities is currently required to qualify and register as a General Securities Representative (or Corporate Securities Representative) and an Equity Trader. Under the proposed rule change, associated persons would be eligible to engage in securities trading activities by registering as Securities Traders and passing a single comprehensive qualification examination, the Series 57 examination, rather than having to register in multiple categories and pass multiple qualification examinations as currently required under FINRA rules. This will benefit, on an annual basis, the approximately 1,000 associated persons who currently take the Series 55 examination.

Similar to the proposed rule change relating to Securities Traders, FINRA believes that the proposed rule change relating to Securities Trader Principals will reduce the burden on associated persons by harmonizing the registration requirements for principals engaged in securities trading activities across different markets. Further, the proposed rule change will reduce the burden on such principals in terms of the number of qualification examinations that they would be required to take under FINRA rules to be eligible to supervise securities trading activities in the future. Under FINRA rules, a General Securities Principal with supervisory responsibility over securities trading activities is currently required to qualify and register as a General Securities Representative (or Corporate Securities Representative) and an Equity Trader, in addition to qualifying and registering as a General Securities Principal. The proposed rule change would reduce the number of qualification examinations that would be required of a principal to be eligible to supervise securities trading activities under FINRA rules, by requiring such principal to register as a Securities Trader and pass the General Securities Principal qualification examination. The individuals that would benefit from the proposed rule change relating to Securities Trader Principals are a subset of the individuals that would benefit from the proposed rule change relating to Securities Traders.

Further, the proposed rule change does not impose any additional examination burdens on persons who are already registered. There is no obligation to take the proposed Series 57 examination in order to continue in their present duties, so the proposed rule change is not expected to disadvantage current registered persons relative to new entrants in this regard.

Moreover, FINRA does not believe that the proposed requirement to affirmatively register current and new principals who have supervisory responsibility over trading activities as Securities Trader Principals would be unduly burdensome for members, and it believes that the benefits of the proposed requirement, including the enhancement of FINRA's ability to promptly identify and, if necessary, contact those principals with supervisory responsibilities over trading activities, outweigh any additional burden on firms.

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 up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve 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–FINRA–2015–017 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2015–017. 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

[14] 15 U.S.C. 78*o*–3(g)(3).

public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2015–017 and should be submitted on or before August 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17172 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75398; File No. SR–NYSEMKT–2015–46]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 995NY by Deleting the Prohibition on ATP Holders From Entering Customer Limit Orders To Buy and Sell the Same Option Series, for the Account or Accounts of the Same or Related Beneficial Owner

July 8, 2015.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on June 26, 2015, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 995NY by deleting the prohibition on ATP Holders from entering Customer limit orders to buy and sell the same option series, for the account or accounts of the same or related beneficial owner. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, 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, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 995NY—Prohibited Conduct. Specifically, the Exchange is proposing to eliminate subparagraph (b) prohibiting ATP Holders, while acting as agent, from entering Customer limit orders in the same option series, for the account or accounts of the same or related beneficial owner, in such a manner that the Customer or beneficial owner(s) effectively is operating as a market maker by holding itself out as willing to buy and sell such option contract on a regular or continuous basis.

Background

The Exchange adopted Rule 995NY(b) in 2009, when it implemented a new electronic trading platform for NYSE Amex Options (f/k/a American Stock Exchange).[4] Rule 995NY(b) replaced former Rule 934.[5] The Exchange adopted Rule 934 in 2001 to restrict the entry of certain option limit orders.[6] At that time, the Exchange's business model depended on Specialists and registered options traders (collectively ''Market Maker'') for competition and liquidity. Market Makers operated primarily on the trading Floor with limited ability to conduct electronic trading. By contrast, Customers had access to certain benefits such as automatic execution, priority of bids and offers, and firm-quote guarantees, that were not offered to Market Makers. In addition, the Exchange did not distinguish Professional Customers, who are more likely to be able to take advantage of such automated systems, as a separate category of Customer. For these reasons, Rule 934 was designed to prevent Customers from obtaining an unfair advantage by acting in a market maker-like capacity, while having priority over the Specialists and registered traders by virtue of their Customer status.

Proposal

The Exchange proposes to delete Rule 995NY(b) as it is no longer necessary. Specifically, the Exchange believes that the advances in electronic trading that have occurred since 2001, combined with the addition of the Professional Customer designation, have eliminated the need to restrict how Customers enter limit orders at the Exchange.

Specifically, since 2009, the Exchange has operated an electronic trading model that affords all market participants, including both Floor and off-Floor Market Makers, access to automated trading systems. With such access, Market Makers have developed sophisticated trading systems that enable them to compete with the type of automated trading systems that were generally available only to non-Market Makers, including Customers, in 2001.

In addition, in 2010, the Exchange added the Professional Customer designation, which is aimed at differentiating those Customers who engage in computerized or ''high frequency'' trading from the traditional retail investor.[7] Pursuant to Rule 900.2NY(18A), a Professional Customer (i) is not a Broker/Dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). Professional Customers retain the status of Customer, however,

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities and Exchange Act Release No. 59472 (February 27, 2009), 74 FR 9843 (March 6, 2009) (SR–NYSEALTR–2008–14) (Approval Order).

[5] *See* Securities and Exchange Act Release No. 59454 (February 25, 2009). 74 FR 9461 (March 4, 2009) (SR–NYSEAmex–2009–17) (Notice of Filing of Proposal to Delete Certain Rules Governing the Trading of Listed Options).

[6] *See* Securities and Exchange Act Release No. 43948 (February 7, 2001), 66 FR 10539 (February 15, 2001) (SR–Amex–2001–03) (Notice of Filing).

[7] *See* Securities and Exchange Act Release No. 61629 (March 2, 2010), 75 FR 10851 (March 9, 2010) (SR–NYSEAmex–2010–18) (Notice of Filing).

they are treated in the same manner as a Broker Dealer for the purposes of certain Exchange rules, including but not limited to Rule 964NY (Display, Priority and Order Allocation—Trading Systems), Rule 971.1NY (Electronic Cross Transactions), Rule 980NY(b) (Electronic Complex Order Trading), and Rule 995NY(b)(Prohibited Conduct—Limit Orders). By being treated as Broker Dealers, Professional Customers are not entitled to preferential treatment generally afforded to Customers under these rules. Professional Customers were the type of Customer that the Exchange was concerned about in 2001 when adopting Rule 934 (now Rule 995NY(b)). Because Professional Customers are not subject to the rules that Rule 934 (now Rule 995NY(b)) was designed to address, the Exchange believes that the concerns that supported adoption of Rule 934 in 2001 are no longer present.

At least five other options exchanges, including BOX Options Exchange LLC (''BOX''), NASDAQ OMX BX Inc. (''BX''), NASDAQ Stock Market LLC (''NOM''), BATS Exchange Inc. (''BATS'') and NYSE Arca Inc. (''NYSE Arca'') do not have rules prohibiting Customers from entering limit orders to buy and sell the same option series for the account or accounts of the same or related beneficial owner. In addition, each of the aforementioned exchanges has adopted similar rules as NYSE Amex Options governing the treatment of orders entered by Professional Customers. The Exchange notes that NOM and BX, like the Exchange, also afford priority to Customer orders.[8] Accordingly, eliminating the restriction on Customers entering limit orders by deleting Rule 995NY(b) would not be novel. Rather, by deleting the rule, Customers that trade on more than one exchange would be subject to similar rules governing their trading activity.

The Exchange also proposes to delete the reference to Rule 995NY(b) found in Rule 900.2NY(18A), as that rule cite would no longer be necessary with the proposed elimination of the rule.

Implementation

The Exchange proposes to announce the implementation of the proposed rule change via Trader Update, to be published no later than thirty (30) days following the effectiveness of this proposal. The implementation date will be no later than thirty (30) days following publication of the Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5),[10] 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.

First, the limitation on how Customers could enter orders was adopted almost fifteen years ago when the Exchange operated a Floor-based open outcry auction model, with limited access to automated trading systems by Market Makers. Since that time, Market Maker systems have developed into highly efficient sophisticated trading platforms able to compete with market professionals and Customers alike. Second, the adoption of the Professional Customer designation has all but eliminated the ability of high-frequency traders to act like Market Makers, while at the same time realizing the benefits of Customer priority and preferential order allocation. Market Makers are no longer at a competitive disadvantage to Customers when it comes to automated trading, as was the case when the prohibition was first adopted.[11] As such, the Exchange believes the current prohibition is no longer needed, and could even be seen as counter-productive. Accordingly, the Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market by removing a limitation on how Customers enter limit orders that is no longer necessary in today's market structure.

In addition, the Exchange believes that the removal of the limitation on Customer orders will more freely permit the entry of orders by market participants, including retail investors, resulting in more orders on the Exchange and therefore increase liquidity on the Exchange, which would benefit all market participants. Lastly, removing the prohibition is competitive vis-à-vis other options exchanges that do not have similar prohibitions in place to what the Exchange is proposing to delete with this filing. By promoting competition, the proposal may also lead to tighter, more efficient markets to the benefit of market participants, including public investors, that engage in trading and hedging on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, removing the prohibition on order entry found in Rule 995(b) further promotes competition on the Exchange, which should lead to tighter, more efficient markets to the benefit of market participants including public investors that engage in trading and hedging on the Exchange, and thereby make the Exchange a desirable market vis-à-vis other options exchanges. In addition, the Exchange believes that the proposed rule change is pro-competitive because it would align the Exchange's rules with the rules of other markets, including BOX, BX, NOM, BATS and NYSE Arca, thereby enabling Customers that trade on more than one exchange to be subject to similar rules governing their trading activity.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6) thereunder.[15]

At any time within 60 days of the filing of the proposed rule change, the

[8] *See* BX Rule Chapter VI Section 10(1)(C)(1)(a) and 10(1)(C)(2), and NOM Rule Chapter VI Section 10(1)(C)(2)(i) [sic].

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* n.6.

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or 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–NYSEMKT–2015–46 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2015–46. 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 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2015–46 and should be submitted on or before August 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17176 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, Washington, DC 20549–0213.

Extension:

Rule 15c2–8. SEC File No. 270–421, OMB Control No. 3235–0481.

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 (''OMB'') a request for approval of extension of the existing collection of information provided for in the following rule: Rule 15c2–8 (17 CFR 240.15c2–8), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 15c2–8 requires broker-dealers to deliver preliminary and/or final prospectuses to certain people under certain circumstances. In connection with securities offerings generally, including initial public offerings (IPOs), the rule requires broker-dealers to take reasonable steps to distribute copies of the preliminary or final prospectus to anyone who makes a written request, as well as any broker-dealer who is expected to solicit purchases of the security and who makes a request. In connection with IPOs, the rule requires a broker-dealer to send a copy of the preliminary prospectus to any person who is expected to receive a confirmation of sale (generally, this means any person who is expected to actually purchase the security in the offering) at least 48 hours prior to the sending of such confirmation. This requirement is sometimes referred to as the ''48 hour rule.''

Additionally, managing underwriters are required to take reasonable steps to ensure that all broker-dealers participating in the distribution of or trading in the security have sufficient copies of the preliminary or final prospectus, as requested by them, to enable such broker-dealer to satisfy their respective prospectus delivery obligations pursuant to Rule 15c2–8, as well as Section 5 of the Securities Act of 1933.

Rule 15c2–8 implicitly requires that broker-dealers collect information, as such collection facilitates compliance with the rule. There is no requirement to submit collected information to the Commission. In order to comply with the rule, broker-dealers participating in a securities offering must keep accurate records of persons who have indicated interest in an IPO or requested a prospectus, so that they know to whom they must send a prospectus.

The Commission estimates that the time broker-dealers will spend complying with the collection of information required by the rule is 11,900 hours for equity IPOs and 86,460 hours for other offerings. The Commission estimates that the total annualized cost burden (copying and postage costs) is $23,800,000 for IPOs and $3,458,400 for other offerings.

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

The public may view background documentation for this information collection 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) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: July 7, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–17181 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75395; File No. SR–EDGA–2015–25]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Market Data Section of Its Fee Schedule

July 8, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2015, EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the Market Data section of its fee schedule to: (i) Adopt User fees, an Enterprise fee, and a Digital Media Enterprise fee for the EDGA Top and EDGA Last Sale feeds; and (ii) make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, 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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Market Data section of its fee schedule to: (i) adopt User fees, an Enterprise fee, and a Digital Media Enterprise fee for the EDGA Top and EDGA Last Sale feeds; and (ii) make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

EDGA Top and Last Sale Fees

EDGA Top is a market data feed that includes top of book quotations and execution information for all equity securities traded on the Exchange.[5] EDGA Last Sale is a market data feed that includes last sale information for all equity securities traded on Exchange.[6]

The Exchange does not charge fees to either Internal Distributors [7] or External Distributors [8] for receipt of the EDGA Last Sale and EDGA Top feeds. The Exchange also currently does not charge per User [9] fees for either EDGA Last Sale or EDGA Top. Therefore, the Exchange does not currently require an External Distributor of EDGA Last Sale or EDGA Top to count, classify (*e.g.,* professional or non-professional), or report to the Exchange information regarding the customers to which they provide the data. End Users currently do not pay the Exchange for EDGA Last Sale or EDGA Top, nor are End Users required to enter into contracts with the Exchange.

The Exchange now proposes to amend its fee schedule to incorporate fees related to the EDGA Top or EDGA Last Sale feeds.[10] These fees include the following, each of which are described in detail below: (i) Usage Fees for both Professional [11] and Non-Professional [12] Users; [13] (ii) Enterprise Fees; [14] and (iii) a Digital Media Enterprise Fee. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] *See* Exchange Rule 13.8(c).

[6] *See* Exchange Rule 13.8(d).

[7] An ''Internal Distributor'' is defined as ''a Distributor that receives the Exchange Market Data product and then distributes that data to one or more Users within the Distributor's own entity.'' *See* the Exchange Fee Schedule *available at http://batstrading.com/regulation/rule_filings/edga/.* A ''Distributor'' is defined as ''any entity that receives the Exchange Market Data product directly from the Exchange or indirectly through another entity and then distributes it internally or externally to a third party.'' *Id.*

[8] An ''External Distributor'' is defined as ''a Distributor that receives the Exchange Market Data product and then distributes that data to a third party or one or more Users outside the Distributor's own entity.'' *Id.*

[9] A ''User'' is defined as ''a natural person, a proprietorship, corporation, partnership, or entity, or device (computer or other automated service), that is entitled to receive Exchange data.'' *Id.*

[10] The Exchange notes that EDGX Exchange, Inc. (''EDGX''), BATS Y-Exchange, Inc. (''BYX'') and BATS Exchange, Inc. (''BZX'', together with the Exchange, EDGX and BYX, the ''BATS Exchanges'') also filed proposed rule changes with Commission to adopt similar fees for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGX–2015–28, SR–BYX–2015–30, and SR–BATS–2015–48. The Exchange represents that the proposed fees will not cause the combined cost of subscribing to each of the BATS Exchanges' individual Top and Last Sale feeds to be greater than those currently charged to subscribe to the BATS One Feed. *See* Securities Exchange Act Release Nos. 74285 (February 18, 2015), 80 FR 9828 (February 24, 2015) (SR–BATS–2015–11); 74283 (February 18, 2015), 80 FR 9809 (February 24, 2015) (SR–EDGA–2015–09); 74282 (February 17, 2015), 80 FR 9487 (February 23, 2015) (SR–EDGX–2015–09); *and* 74284 (February 18, 2015), 80 FR 9792 (February 24, 2015) (SR–BYX–2015–09) (''Initial BATS One Feed Fee Filings''). In these filings, the Exchange represented that the cost of subscribing to each of the underlying individual feeds necessary to create the BATS One Feed would not be greater than the cost of subscribing to the BATS One Feed. *Id.*

[11] A ''Professional User'' is defined as ''any User other than a Non-Professional User.'' *See* the Exchange Fee Schedule *available at http://batstrading.com/regulation/rule_filings/edga/.*

[12] A ''Non-Professional User'' is defined as ''a natural person who is not: (i) Registered or qualified in any capacity with the Commission, the Commodity Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an ''investment adviser'' as that term is defined in Section [202(a)(11)] of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt.'' *Id.*

[13] The Exchange notes that User fees as well as the distinctions based on professional and non-professional users have been previously filed with or approved by the Commission by the BATS Exchanges and the Nasdaq Stock Market LLC (''Nasdaq''). *See* Securities Exchange Act Release No. 59582 (March 16, 2009), 74 FR 12423 (March 24, 2009) (Order approving SR–Nasdaq–2008–102). *See also* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic].

[14] The Exchange notes that Enterprise fees have been previously filed with or approved by the Commission by the Exchange, EDGA, BYX, BZX, Nasdaq, NYSE, and the CTA/CQ Plans. *See* Nasdaq Rule 7047. Securities Exchange Act Release Nos. 71507 (February 7, 2014), 79 FR 8763 (February 13, 2014) (SR–NASDAQ–2014–011); 70211 (August 15, 2013), 78 FR 51781 (August 21, 2013) (SR–NYSE–2013–58); *and* 70010 (July 19, 2013) (File No. SR–CTA/CQ–2013–04). *See also* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic].

Exchange does not propose to adopt Distributor fees.

User Fees. The Exchange proposes to charge those who receive either EDGA Top or EDGA Last Sale from External Distributors different fees for both their Professional Users and Non-Professional Users. The Exchange will assess a monthly fee for Professional Users of $2.00 per User. Non-Professional Users will be assessed a monthly fee of $0.05 per User.[15] The Exchange does not propose to charge per User fees to Internal Distributors.

External Distributors would be required to count every Professional User and Non-Professional User to which they provide EDGA Top and/or EDGA Last Sale, the requirements for which are identical to that currently in place for the BATS One Feed.[16] Thus, the External Distributor's count will include every person and device that accesses the data regardless of the purpose for which the individual or device uses the data. External Distributors must report all Professional and Non-Professional Users in accordance with the following:

- In connection with an External Distributor's distribution of EDGA Top or EDGA Last Sale, the Distributor should count as one User each unique User that the Distributor has entitled to have access to EDGA Top or EDGA Last Sale. However, where a device is dedicated specifically to a single individual, the Distributor should count only the individual and need not count the device.
- The External Distributor should identify and report each unique User. If a User uses the same unique method to gain access to EDGA Top or EDGA Last Sale, the Distributor should count that as one User. However, if a unique User uses multiple methods to gain access to EDGA Top or EDGA Last Sale (*e.g.,* a single User has multiple passwords and user identifications), the External Distributor should report all of those methods as an individual User.
- External Distributors should report each unique individual person who receives access through multiple devices as one User so long as each device is dedicated specifically to that individual.
- If an External Distributor entitles one or more individuals to use the same device, the External Distributor should include only the individuals, and not the device, in the count.

Enterprise Fee. The Exchange also proposes to establish a $10,000 per month Enterprise Fee that will permit a recipient firm who receives EDGA Top or EDGA Last Sale from an External Distributor to receive the data for an unlimited number of Professional and Non-Professional Users.[17] For example, if a recipient firm had 15,000 Professional Users who each receive EDGA Top or EDGA Last Sale at $2.00 per month, then that recipient firm will pay $30,000 per month in Professional Users fees. Under the proposed Enterprise Fee, the recipient firm will pay a flat fee of $10,000 for an unlimited number of Professional and Non-Professional Users for EDGA Top or EDGA Last Sale. A recipient firm must pay a separate Enterprise Fee for each External Distributor that controls display of EDGA Top or EDGA Last Sale if it wishes such User to be covered by an Enterprise Fee rather than by per User fees. A recipient firm that pays the Enterprise Fee will not have to report its number of such Users on a monthly basis. However, every six months, a recipient firm must provide the Exchange with a count of the total number of natural person users of each product, including both Professional and Non-Professional Users.

Digital Media Enterprise Fee. The Exchange proposes to adopt a Digital Media Enterprise Fee of $2,500 per month for EDGA Top and EDGA Last Sale.[18] As an alternative to proposed User fees discussed above, a recipient firm may purchase a monthly Digital Media Enterprise license to receive EDGA Top and EDGA Last Sale from an External Distributor to distribute to an unlimited number of Professional and Non-Professional Users for viewing via television, Web sites, and mobile devices for informational and non-trading purposes only without having to account for the extent of access to the data or the report the number of Users to the Exchange.

Non-Substantive, Corrective Changes

The Exchange proposes to make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

First, the proposed change to the description of the BATS One Feed[19]

[15] The Exchange notes that EDGX, BYX and BZX also filed proposed rule changes with Commission to adopt User fees for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGX–2015–28, SR–BYX–2015–30, and SR–BATS–2015–48 (proposing a monthly fee of $2.00 per Professional User and of $0.05 per Non-Professional User for EDGX and BYX and a monthly fee of $4.00 per Professional User and of $0.10 per Non-Professional User for BZX). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total of $10.00 per month per Professional User and $0.25 per month per Non-Professional User. This amount is equal to, and not greater than the User Fees charged for the BATS One Summary Feed. *Id.* (adopting fees of $10.00 per month per Professional User and $0.25 per month per Non-Professional User as well as a separate $1,000 per month Data Consolidation Fee for the BATS One Summary Feed).

[16] *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic].

[17] The Exchange notes that EDGA [sic], BYX and BZX also filed proposed rule changes with Commission to adopt Enterprise Fees for their respective Top and Last Sale market data product. File Nos. SR–EDGA–2015–25 [sic], SR–BYX–2015–30, and SR–BATS–2015–48 (proposing a monthly Enterprise Fee of $10,000 for BYX Top and BYX Last Sale and $15,000 for EDGX Top and Last Sale as well as BZX Top and Last Sale). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total monthly Enterprise Fee of $50,000. This amount is equal to, and not greater than the Enterprise Fee charged for the BATS One Summary Feed. *Id.* (adopting a monthly Enterprise Fee of $50,000 as well as a separate $1,000 per month Data Consolidation Fee for the BATS One Summary Feed).

[18] The Exchange notes that EDGX, BYX and BZX also filed proposed rule changes with Commission to adopt a Digital Media Enterprise Fee for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGX–2015–28, SR–BYX–2015–30, and SR–BATS–2015–48 (proposing a monthly Digital Media Enterprise Fee of $2,500 for their respective Top and Last Sale feeds). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total monthly Digital Media Enterprise Fee of $10,000. This amount is less than the Digital Media Enterprise Fee charged for the BATS One Summary Feed. *See* Securities Exchange Act Release Nos. 74598 (March 27, 2015), 80 FR 17791 (April 2, 2015) (SR–BATS–2015–24); 74599 (March 27, 2015), 80 FR 17812 (April 2, 2015) (SR–BYX–2015–19); 74600 (March 27, 2014), 80 FR 17797 (April 2, 2015) (SR–EDGA–2015–14); *and* 74601 (March 27, 2015), 80 FR 17804 (April 2, 2015) (SR–EDGX–2015–14) (adopting a monthly Digital Media Enterprise Fee of $15,000 for the BATS One Summary Feed).

[19] In sum, the BATS One Feed is a data feed that disseminates, on a real-time basis, the aggregate best bid and offer (''BBO'') of all displayed orders for securities traded on EDGA and its affiliated exchanges and for which the BATS Exchanges report quotes under the Consolidated Tape Association (''CTA'') Plan or the Nasdaq/UTP Plan. The BATS One Feed also contains the individual last sale information for the BATS Exchanges (collectively with the aggregate BBO, the ''BATS One Summary Feed''). In addition, the BATS One Feed contains optional functionality which enables recipients to receive aggregated two-sided quotations from the BATS Exchanges for up to five (5) price levels (''BATS One Premium Feed''). *See* Securities Exchange Act Release No. 73918 (December 23, 2014), 79 FR 78920 (December 31, 2014) (File Nos. SR–EDGX–2014–25; SR–EDGA–2014–25; SR–BATS–2014–055; SR–BYX–2014–030)

Continued

Enterprise Fee is intended to align with the descriptions of the Enterprise Fees for EDGA Top and EDGA Last Sale proposed above. The fee schedule currently states that:

[a]s an alternative to User fees, a recipient firm may purchase a monthly Enterprise license to receive the BATS One Feed from an External Distributor to an unlimited number of Professional and Non-Professional Users. A recipient firm must pay a separate Enterprise Fee for each External Distributor that controls the display of the BATS One Feed if it wishes such User to be covered by the Enterprise Fee. The Enterprise Fee is in addition to the Distributor Fee.

The Exchange proposes to delete the last sentence of the above description stating that the Enterprise Fee is in addition to the Distributor Fee. The original purpose of this sentence was to clarify that the Distributor Fee and Enterprise Fee were separate fees. However, the Exchange understands that this sentence has led to confusion because the Exchange does not currently charge Distributor fees. Deleting this sentence does not alter the manner in which the Enterprise Fee is charged. Rather, it is intended to avoid confusion and align the description with that of the proposed Enterprise Fees for EDGA Top and EDGA Last Sale described above.

Second, the Exchange proposes to correct a cross-reference within the definition of ''Non-Professional User''. In part, a ''Non-Professional User'' is currently defined as ''a natural person who is not: . . . engaged as an ''investment adviser'' as that term is defined in Section 201(11) of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act) . . .'' The definition incorrectly states that the term ''investment adviser is defined under Section 201(11) of the Investment Advisers Act of 1940, when it is, in fact, defined under Section 202(a)(11) of the Investment Advisers Act of 1940. Therefore, the Exchange proposes to replace the reference to Section 201(11) with Section 202(a)(11) within the definition of Non-Professional User.

Implementation Date

The Exchange proposes to implement the proposed change to its fee schedule on July 1, 2015.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[20] in general, and furthers the objectives of Section 6(b)(4),[21] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all recipients of Exchange data. The Exchange believes the proposed fees are competitive with those charged by other venues and, therefore, reasonable and equitably allocated to recipients. Lastly, the Exchange also believes that the proposed fees are reasonable and non-discriminatory because they will apply uniformly to all recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act[22] in that it supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Furthermore, the proposed rule change is consistent with Rule 603 of Regulation NMS,[23] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory. In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data.

In addition, the proposed fees would not permit unfair discrimination because all of the Exchange's customers and market data vendors will be subject to the proposed fees on an equivalent basis. EDGA Last Sale and EDGA Top are distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Accordingly, Distributors and Users can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Firms have a wide variety of alternative market data products from which to choose, such as similar proprietary data products offered by other exchanges and consolidated data. Moreover, the Exchange is not required to make any proprietary data products available or to offer any specific pricing alternatives to any customers.

In addition, the fees that are the subject of this rule filing are constrained by competition. As explained below in the Exchange's Statement on Burden on Competition, the existence of alternatives to EDGA Top and EDGA Last Sale further ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect such alternatives. That is, the Exchange competes with other exchanges (and their affiliates) that provide similar market data products. If another exchange (or its affiliate) were to charge less to consolidate and distribute its similar product than the Exchange charges to consolidate and distribute EDGA Top or EDGA Last Sale, prospective Users likely would not subscribe to, or would cease subscribing to, the EDGA Top or EDGA Last Sale.

The Exchange notes that the Commission is not required to undertake a cost-of-service or rate-making approach. The Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for non-core market data would be so complicated that it could not be done practically.[24]

(Notice of Amendments No. 2 and Order Granting Accelerated Approval to Proposed Rule Changes, as Modified by Amendments Nos. 1 and 2, to Establish a New Market Data Product called the BATS One Feed) (''BATS One Approval Order'').

[20] 15 U.S.C. 78f.

[21] 15 U.S.C. 78f(b)(4).

[22] 15 U.S.C. 78k–1.

[23] *See* 17 CFR 242.603.

[24] The Exchange believes that cost-based pricing would be impractical because it would create enormous administrative burdens for all parties, including the Commission, to cost-regulate a large number of participants and standardize and analyze extraordinary amounts of information, accounts, and reports. In addition, it is impossible to regulate market data prices in isolation from prices charged by markets for other services that are joint products. Cost-based rate regulation would also lead to litigation and may distort incentives, including those to minimize costs and to innovate, leading to further waste. Under cost-based pricing, the Commission would be burdened with determining a fair rate of return, and the industry could experience frequent rate increases based on escalating expense levels. Even in industries historically subject to utility regulation, cost-based ratemaking has been discredited. As such, the Exchange believes that cost-based ratemaking would be inappropriate for proprietary market data and inconsistent with Congress's direction that the Commission use its authority to foster the development of the national market system, and that market forces will continue to provide appropriate pricing discipline. *See* Appendix C to NYSE's comments to the Commission's 2000 Concept Release on the Regulation of Market Information Fees and Revenues, which can be found on the Commission's Web site at *http://www.sec.gov/rules/concept/s72899/buck1.htm. See also* Securities Exchange Act Release No. 73816

User Fees. The Exchange believes that implementing the Professional and Non-Professional User fees for EDGA Top and EDGA Last Sale is equitable and reasonable because it will result in greater availability to Professional and Non-Professional Users. Moreover, introducing a modest Non-Professional User fee for EDGA Top and EDGA Last Sale is reasonable because it provides an additional method for retail investors to access EDGA Top and EDGA Last Sale data by providing the same data that is available to Professional Users. The Exchange believes that the proposed fees are equitable and not unfairly discriminatory because they will be charged uniformly to recipient firms and Users. The fee structure of differentiated Professional and Non-Professional fees is utilized by the Exchange for the BATS One Feed and has long been used by other exchanges for their proprietary data products, and by the Nasdaq UTP and the CTA and CQ Plans in order to reduce the price of data to retail investors and make it more broadly available.[25] Offering EDGA Top and EDGA Last Sale to Non-Professional Users with the same data available to Professional Users results in greater equity among data recipients.

In addition, the proposed fees are reasonable when compared to similar fees for comparable products offered by the NYSE. Specifically, NYSE offers NYSE BBO, which includes best bid and offer for NYSE traded securities, for a monthly fee of $4.00 per professional subscriber and $0.20 per non-professional subscriber.[26] NYSE also offers NYSE Trades, which is a data feed that provides the last sale information for NYSE traded securities, for the same price as NYSE BBO. The Exchange's proposed per User Fees for EDGA Top and EDGA Last Sale are less than the NYSE's fees for NYSE Trades and NYSE BBO.

Enterprise Fee. The proposed Enterprise Fee for EDGA Top and EDGA Last Sale are equitable and reasonable as the fees proposed are less than the enterprise fees currently charged for NYSE Trades and NYSE BBO. The NYSE charges a separate enterprise fee of $190,000 per month for NYSE Trades and NYSE BBO.[27] In addition, the Enterprise Fee proposed by the Exchange could result in a fee reduction for recipient firms with a large number of Professional and Non-Professional Users. If a recipient firm has a smaller number of Professional Users of EDGA Top or EDGA Last Sale, then it may continue using the per User structure and benefit from the per User Fee reductions. By reducing prices for recipient firms with a large number of Professional and Non-Professional Users, the Exchange believes that more firms may choose to receive and to distribute the EDGA Top or EDGA Last Sale, thereby expanding the distribution of this market data for the benefit of investors.

The Exchange further believes that the proposed Enterprise Fee is reasonable because it will simplify reporting for certain recipients that have large numbers of Professional and Non-Professional Users. Firms that pay the proposed Enterprise Fee will not have to report the number of Users on a monthly basis as they currently do, but rather will only have to count natural person users every six months, which is a significant reduction in administrative burden. Finally, the Exchange believes that it is equitable and not unfairly discriminatory to establish an Enterprise Fee because it reduces the Exchange's costs and the Distributor's administrative burdens in tracking and auditing large numbers of Users.

Digital Media Enterprise Fee. The Exchange believes that the proposed Digital Media Enterprise Fee for EDGA Top and EDGA Last Sale provides for an equitable allocation of reasonable fees among recipients of the data and is not designed to permit unfair discrimination among customers, brokers, or dealers. In establishing the Digital Media Enterprise Fee, the Exchange recognizes that there is demand for a more seamless and easier-to-administer data distribution model that takes into account the expanded variety of media and communication devices that investors utilize today. The Exchange believes the Digital Media Enterprise Fee will be easy to administer because data recipients that purchase it would not be required to differentiate between Professional and Non-Professional Users, account for the extent of access to the data, or report the number of Users. This is a significant reduction on a recipient firm's administrative burdens and is a significant value to investors. For example, a television broadcaster could display EDGA Top and/or EDGA Last Sale data during market-related programming and on its Web site or allow viewers to view the data via their mobile devices, creating a more seamless distribution model that will allow investors more choice in how they receive and view market data, all without having to account for and/or measure who accesses the data and how often they do so.

The proposed Digital Media Enterprise Fee is equitable and reasonable because it will also enable recipient firms to more widely distribute data from EDGA Top and EDGA Last Sale to investors for informational purposes at a lower cost than is available today. For example, a recipient firm may purchase an Enterprise license in the amount of $10,000 per month for to receive EDGA Top and/or EDGA Last Sale from an External Distributor for an unlimited number of Professional and Non-Professional Users, which is greater than the proposed Digital Media Enterprise Fee. The Exchange also believes the amount of the Digital Media Enterprise Fee is reasonable as compared to the existing enterprise fees discussed above because the distribution of EDGA Top and EDGA Last Sale data is limited to television, Web sites, and mobile devices for informational purposes only, while distribution of EDGA Top and EDGA Last Sale data pursuant to an Enterprise license contains no such limitation. The Exchange also believes that the proposed Digital Media Enterprise Fee is equitable and reasonable because it is less than similar fees charged by other exchanges.[28]

Non-Substantive, Corrective Changes. The Exchange believes that the proposed non-substantive, corrective changes are consistent with Section 6(b) of the Act,[29] in general, and Section 6(b)(4) of the Act,[30] in particular, in that they provide for an equitable allocation of reasonable fees among recipients of the data and is not designed to permit unfair discrimination among customers, brokers, or dealers. These proposed changes are equitable and reasonable because the changes are designed to clarify the fee schedule and avoid potential investor confusion. The amendment to the BATS One Enterprise Fee is also intended to align the

(December 11, 2014), 79 FR 75200 (December 17, 2014) (SR–NYSE–2014–64) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Establish an Access Fee for the NYSE Best Quote and Trades Data Feed, Operative December 1, 2014).

[25] *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. *See also, e.g.,* Securities Exchange Act Release No. 20002, File No. S7–433 (July 22, 1983) (establishing nonprofessional fees for CTA data); Nasdaq Rules 7023(b), 7047.

[26] *See* NYSE Market Data Pricing dated May 2015 *available at http://www.nyxdata.com/.*

[27] *Id.*

[28] The Nasdaq Stock Market offers proprietary data products for distribution over the internet and television under alternative fee schedules that are subject to maximum fee of $50,000 per month. *See* Nasdaq Rule 7039(b). The NYSE charges a Digit Media Enterprise fee of $40,000 per month for the NYSE Trade Digital Media product. *See* Securities Exchange Act Release No. 69272 (April 2, 2013), 78 FR 20983 (April 8, 2013) (SR–NYSE–2013–23).

[29] 15 U.S.C. 78f.

[30] 15 U.S.C. 78f(b)(4).

description with that of the proposed Enterprise Fees for EDGA Top and EDGA Last Sale described above. The proposed changes are also non-discriminatory as they would apply to all recipient firms uniformly.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

EDGA Top and EDGA Last Sale

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The Exchange's ability to price EDGA Last Sale and EDGA Top are constrained by: (i) Competition among exchanges, other trading platforms, and Trade Reporting Facilities (''TRF'') that compete with each other in a variety of dimensions; (ii) the existence of inexpensive real-time consolidated data and market-specific data and free delayed data; and (iii) the inherent contestability of the market for proprietary data.

The Exchange and its market data products are subject to significant competitive forces and the proposed fees represent responses to that competition. To start, the Exchange competes intensely for order flow. It competes with the other national securities exchanges that currently trade equities, with electronic communication networks, with quotes posted in FINRA's Alternative Display Facility, with alternative trading systems, and with securities firms that primarily trade as principal with their customer order flow.

In addition, EDGA Last Sale and EDGA Top compete with a number of alternative products. For instance, EDGA Last Sale and EDGA Top do not provide a complete picture of all trading activity in a security. Rather, the other national securities exchanges, the several TRFs of FINRA, and Electronic Communication Networks (''ECN'') that produce proprietary data all produce trades and trade reports. Each is currently permitted to produce last sale information products, and many currently do, including Nasdaq and NYSE. In addition, market participants can gain access to EDGA last sale prices and top-of-book quotations, though integrated with the prices of other markets, on feeds made available through the SIPs.

In sum, the availability of a variety of alternative sources of information imposes significant competitive pressures on Exchange data products and the Exchange's compelling need to attract order flow imposes significant competitive pressure on the Exchange to act equitably, fairly, and reasonably in setting the proposed data product fees. The proposed data product fees are, in part, responses to that pressure. The Exchange believes that the proposed fees would reflect an equitable allocation of its overall costs to users of its facilities.

In addition, when establishing the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish fair, reasonable, and not unreasonably discriminatory fees and an equitable allocation of fees among all Users. The existence of alternatives to EDGA Last Sale and EDGA Top, including existing similar feeds by other exchanges, consolidated data, and proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if its cost to purchase is not justified by the returns any particular vendor or subscriber would achieve through the purchase.

Non-Substantive, Corrective Changes

The proposed non-substantive, corrective changes to the fee schedule will not have any impact on completion. The proposed changes are designed to clarify the fee schedule and avoid potential investor confusion.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [31] and paragraph (f) of Rule 19b–4 thereunder.[32] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EDGA–2015–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGA–2015–25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGA–

[31] 15 U.S.C. 78s(b)(3)(A).

[32] 17 CFR 240.19b–4(f).

2015–25, and should be submitted on or before August 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17173 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75393; File No. SR–EDGX–2015–29]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees for Use of EDGX Exchange, Inc.

July 8, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2015, EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to EDGX Rules 15.1(a) and (c). Changes to the fee schedule pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, 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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to: (i) Modify its fees for physical connectivity; and (ii) delete the MidPoint Match Volume Tier under footnote 3.

Physical Connectivity

A physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently maintains a presence in two third-party data centers: (i) The primary data center where the Exchange's business is primarily conducted on a daily basis, and (ii) a secondary data center, which is predominantly maintained for business continuity purposes. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $500 per physical port that connects to the System[6] via 1 gigabyte copper circuit; $1,000 per physical port that connects to the System via 1 gigabyte fiber circuit; and $2,000 per physical port that connects to the System via 10 gigabyte fiber circuit.

The Exchange now proposes to amend its physical connectivity fees to align the Exchange's fees with its affiliates.[7] First, the Exchange proposes to amend its Fee Schedule to no longer distinguish between fiber and copper circuits. Therefore, it proposes to delete the charge of $500 per month per physical port that connects to the System via 1 gigabyte copper circuit and to assess a monthly fee of $2,000 per physical port that connects to the System via 1 gigabyte circuit regardless of the type of connection. Second, the Exchange proposes to increase the fee per physical port that connects to the System via 10 gigabyte circuit from $2,000 per month to $4,000 per month. The Exchange also proposes to replace the reference to ''fiber'' with ''physical port'' within the description of the 1 gigabyte and 10 gigabyte physical connectivity fees as it proposes to no longer distinguish between fiber and copper circuits within its Fee Schedule.

Lastly, to further align its physical connectivity fees with its affiliates, the Exchange proposes to pass through in full any hardware costs or connectivity fees incurred that are directly related to completing a cross-connect where the expense to the Exchange billed by a third party exceeds $1,000.[8] The Exchange proposes to pass through the expense as an alternative to the flat installation fees charged by the Exchange's primary competitors. The Exchange does not anticipate that passing through these expenses will affect many of the Exchange's constituents, because the majority of cross-connect completions cost less than $1,000. For this reason, the Exchange proposes to pass-through the charges associated with cross-connect completions that cost more than $1,000 rather than to charge an installation fee for all completions regardless of their cost.

MidPoint Match Volume Tier

The Exchange proposes to delete the MidPoint Match Volume Tier under footnote 3 of its Fee Schedule. Under fee code MM, a Member is currently charged a fee of $0.00120 per share for orders that add liquidity at midpoint of NBBO using: (1) A MidPoint Match[9] order; (2) an order with a Hide Not Slide[10] instruction; or (3) an order with a Non-Displayed[11] instruction. However, under the MidPoint Match Volume Tier, a Member would pay no

[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

[6] The term ''System'' is defined as ''the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.'' *See* Exchange Rule 1.5(cc).

[7] The Exchange's affiliates are EDGA Exchange, Inc. (''EDGA''), BATS Y-Exchange, Inc. (''BYX'') and BATS Exchange, Inc. (''BZX'', together with the Exchange, EDGA and BYX, the ''BATS Exchanges''). The Exchange notes that each of its affiliates will also file proposed rule changes with Commission to adopt similar physical connectivity fees to be effective July 1, 2015.

[8] *See* BZX fee schedule *available at http://batstrading.com/support/fee_schedule/bzx/a and* the BYX fee schedule *available at http://batstrading.com/support/fee_schedule/byx/.*

[9] *See* Exchange Rule 11.8(d).

[10] *See* Exchange Rule 11.6(l)(1)(B).

[11] *See* Exchange Rule 11.6(e)(2).

fee for its orders that yielded fee code MM where that Member added or removed a combined ADV [12] of at least 2,500,000 shares yielding fee codes AA, AM, MM, or MT. Currently, no Member satisfies the tier's criteria. Therefore, the Exchange proposes to delete the MidPoint Match Volume Tier.

The Exchange also notes that the MidPoint Match Volume Tier would no longer be necessary as of July 6, 2015. The Exchange intends to file with the Commission a separate proposal to amend it Fee Schedule for July 6, 2015 effectiveness to, among other things: (i) Delete fee codes AA, AM, and MT; and (ii) amend fee code MM to (a) only apply to orders that add liquidity at the midpoint of the NBBO using MidPoint Peg orders; (b) delete references to MidPoint Match orders, orders utilizing the Hide Not Slide instruction, and orders with a Non-Displayed instruction. These changes are a result of proposed rule change to be filed with the Commission to align certain Exchange functionality with BZX.[13] Therefore, removing the MidPoint Match Volume Tier as of July 1, 2015 would avoid Members confusion and prevent them from attempting to achieve the tier's criteria as the functionality necessary to achieve the tier may be discontinued before the end of July 2015.

Lastly, as a result of the above, the Exchange also proposes to remove a reference to footnote 3 from fee code MM under the Fee Codes and Associated Fee table within its Fee Schedule.

Implementation Date

The Exchange proposes to implement these amendments to its Fee Schedule on July 1, 2015.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[14] in general, and furthers the objectives of Section 6(b)(4),[15] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

Physical Connectivity

The Exchange believes that the proposed physical connectivity fees represent an equitable allocation of reasonable dues, fees, and other charges as its fees for physical connectivity are reasonably constrained by competitive alternatives. If a particular exchange charges excessive fees for connectivity, affected Members and non-Members may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

Furthermore, the proposed rule change is also an equitable allocation of reasonable dues, fees, and other charges as the Exchange believes that the increased fees obtained will enable it to cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems. The additional revenue from the increased fees will also enable the Exchange to continue to maintain and improve its market technology and services. The Exchange believes that the proposed fees for 1 gigabyte circuit of $2,000 per month and for 10 gigabyte circuit of $4,000 per month are reasonable in that they are less than analogous fees charged by the Nasdaq Stock Market LLC (''Nasdaq''), which are $2,500 per month for 1 gigabyte connectivity and range from $10,000–$15,000 per month for 10 gigabyte circuits.[16] In addition, the Exchange proposed physical connectivity fees are designed to align the Exchange's fees with its affiliates.[17]

The Exchange also believes that passing through the cross-connect related expenses in excess of $1,000 as an alternative to the flat installation fees is equitable and reasonable. The proposed pass through would be in lieu of the flat installation fees charged by the Exchange's primary competitors. The Exchange does not anticipate that passing through these expenses will affect many of the Exchange's constituents, because the majority of cross-connect completions cost less than $1,000.

Finally, the Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members and non-Members. Members and non-Members will continue to choose whether they want more than one physical port and choose the method of connectivity based on their specific needs. All Exchange Members that voluntarily select various service options will be charged the same amount for the same services. As is true of all physical connectivity, all Members and non-Members have the option to select any connectivity option, and there is no differentiation with regard to the fees charged for the service.

MidPoint Match Volume Tier

The Exchange believes that the proposal to delete the MidPoint Match Volume Tier represents an equitable allocation of reasonable dues, fees, and other charges as it would avoid confusion by removing a tier from its Fee Schedule for which no Member currently qualifies. It is also reasonable as it would prevent a Member from attempting to achieve the tier's criteria as the functionality necessary to achieve the tier is to be discontinued in the near future. Furthermore, removing the MidPoint Match Volume Tier as of July 1, 2015 would prevent Members attempting to achieve the tier's criteria when they will be unable to do so because the functionality necessary to achieve the tier will be discontinued before the end of July 2015, thereby avoiding Member or investor confusion. Lastly, the Exchange believes that removal of the MidPoint Match Volume Tier is equitable and non-discriminatory in that they apply uniformly to all Members.

[12] ''ADV'' is defined in the Exchange Fee Schedule *available at http://batstrading.com/support/fee_schedule/edgx/.*

[13] A description of the changes proposed in this filing may be found in *BATS EDGX Exchange Modifications, Effective July 6, 2015, available at http://cdn.batstrading.com/resources/release_notes/2015/BATS–EDGX-Exchange-Modifications-Effective-July-6-2015.pdf.*

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(4).

[16] *See* Nasdaq Rule 7034(b).

[17] *See supra* notes 7 and 8.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Physical Connectivity

As discussed above, the Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. Further, excessive fees for connectivity, including port fee access, would serve to impair an exchange's ability to compete for order flow rather than burdening competition. The proposal to increase the fees for physical connectivity would bring the fees charged by the Exchange closer to similar fees charged for physical connectivity by other exchanges.[18] In addition, the proposal to pass through cross-connect installation related expenses serves as an alternative to the flat installation fees charged by the Exchange's primary competitors.

Lastly, the proposed rule change does not impose any burden on intramarket competition as the fees are uniform for all Members and non-Members. The Exchange notes that Members and non-Members also have the ability to obtain access to these services without the need for an independent physical port connection, such as through alternative means of financial extranets and service bureaus that act as a conduit for orders entered by Members and non-Members.

MidPoint Match Volume Tier

The Exchange does not believe that its proposal to delete the MidPoint Match Tier will impose any burden on competition. As stated above, no Member currently satisfies the tier's criteria and the Exchange is proposing to remove it to avoid investor confusion as the functionality necessary to achieve the tier is to be discontinued before the end of July 2015. Therefore, the Exchange believes deleting the MidPoint Match Tier will have no impact on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

[18] *See supra* note 16.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [19] and paragraph (f) of Rule 19b–4 thereunder.[20] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EDGX–2015–29 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGX–2015–29. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGX–2015–29 and should be submitted on or before August 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17171 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75389; File No. SR-NASDAQ–2015–071]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to the Designated Liquidity Provider Program Under Rule 7018(i)

July 8, 2015.

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 July 1, 2015, 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 prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Designated Liquidity Provider (''DLP'') program under Rule 7018(i).

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to make the following changes to the DLP program under Rule 7018(i): (1) Move the program rules from Rule 7018 to Rule 7014; (2) change the name of the program to the Lead Market Maker program; (3) add clarifying rule text; (4) shorten the notice period required before a market maker may withdraw as a DLP; and (5) provide additional flexibility to NASDAQ on the application of the minimum performance measurements under subparagraph (2) of the rule. The DLP program provides fees and credits for execution of a Qualified Security by one of its DLPs. Rule 7018(i)(1) defines Qualified Security as an exchange-traded fund or index-linked security listed on NASDAQ pursuant to NASDAQ Rules 5705, 5710, or 5720 that has at least one DLP. As defined in Rule 7018(i)(2), a DLP is a registered NASDAQ market maker for a Qualified Security that has committed to maintain specified minimum performance standards. The rule provides that a DLP shall be selected by NASDAQ based on factors including, but not limited to, experience with making markets in exchange-traded funds and index-linked securities, adequacy of capital, willingness to promote NASDAQ as a marketplace, issuer preference, operational capacity, support personnel, and history of adherence to NASDAQ rules and securities laws. Moreover, the rule permits NASDAQ to limit the number of DLPs in a security, or modify a previously established limit, upon prior written notice to members.

NASDAQ is proposing to move the rule from Rule 7018, which concerns fees and credits for execution and routing of orders entered on NASDAQ, to Rule 7014, which concerns NASDAQ's market quality incentive programs. NASDAQ adopted the DLP program as a pricing incentive program for market makers in certain exchange traded products. The DLP program is designed to improve market quality in Qualified Securities by providing credits to market makers in return for providing certain levels of market-improving quoting in those securities. As such, the Exchange believes that it is more appropriate to locate the rules relating to the program under Rule 7014, along with other market quality incentive programs.

The Exchange is also proposing to amend Rule 7018(i)(2) to provide NASDAQ additional flexibility in the application of the four performance measurements under the rule. Rule 7018(i)(2) sets forth four minimum performance measurements that a market maker must achieve to be considered a DLP, which are applied to market makers at the conclusion of each month to determine if their contribution to market quality in an individual Qualified Security meets or exceeds the minimum performance measurements. The minimum performance measurements may be determined from time to time by NASDAQ and may vary depending on the price, liquidity, and volatility of the Qualified Security in which the DLP is registered. Under the rule, the performance standards must include the percent of time at the national best bid (best offer) (''NBBO''), the percent of executions better than the NBBO, the average displayed size, and the average quoted spread. NASDAQ has flexibility to modify the specific levels of the performance measurements in an individual Qualified Security in response to changes in the market in price, volatility and liquidity, or NASDAQ may set a uniform level for a particular minimum performance measurement applied to all Qualified Securities. The Exchange is proposing to amend Rule 7018(i)(2) so that it is no longer required to consider all four factors in its minimum performance criteria, but rather provide the Exchange flexibility to apply one or more of the factors. NASDAQ notes that such additional flexibility will enable the Exchange to further tailor eligibility for the incentive program based on overall market conditions, applying only the criteria needed to improve market quality. In this regard, NASDAQ notes that the desired improvement in market quality may be achieved in certain instances by applying fewer than all four of the minimum performance measurements. In some cases, applying all four minimum performance measurements may require setting one or more of the measures so low as to allow all market makers to qualify under those measures, thus rendering those measures superfluous.

The Exchange is adding new language to make it clear that it will provide written notice of the criteria to market participants. This notice will describe the specific criteria applicable under the program for the upcoming month so market participants can understand how to qualify for credits. The description will include not only the criteria applicable but also the standard under each criteria or combination of criteria. Such clarifying language will help market participants understand how changes to the minimum performance measurements will be communicated, thereby providing further transparency into the operation of the program.

NASDAQ will also use the specific criteria described in the notice to measure performance under the program, and to make changes to improve that performance. For example, if after studying performance under a given set of criteria, NASDAQ determines that performance greatly exceeds the criteria, NASDAQ will have a solid basis for increasing the requirements. Alternatively, if this review reveals that a criteria is yielding no improvement to performance, NASDAQ will then have a basis to select an alternative criteria and to so notify market makers of the change.

The Exchange is also shortening the amount of prior written notice that a DMM must provide to NASDAQ when it wishes to withdraw its registration in a Qualified Security from 30 days to 5 days. Historically, the Exchange needed at least 30 days to process the de-registration of a DMM in a Qualified Security. Improvements to the Exchange's systems and processes have now made it possible for the Exchange to process such de-registrations with 5 days' notice.

Lastly, NASDAQ is changing the name of the program to the ''Lead Market Maker program'' and is, accordingly, changing references to ''Designated Liquidity Providers'' and ''DLPs'' to ''Lead Market Makers'' and ''LMMs,'' respectively. NASDAQ believes that the term Lead Market Maker is more descriptive of who is eligible for the program (*i.e.,* market makers), as opposed to a Designated Liquidity Provider, which could lead a market participant to believe that any market participant is eligible to qualify for the program. NASDAQ notes that the proposed change in terminology does not impact the operation of the program, but rather merely clarifies and

harmonizes the terminology used with the terminology used for similar programs of other exchanges. For example, The BATS Exchange, Inc. has a Lead Market Maker program, which provides its market makers with lower fees for removing liquidity and higher credits for providing liquidity if they meet certain performance standards in certain exchange-traded products.[3] NASDAQ believes that harmonizing the terminology with that of other exchanges will promote clarity in its rules and may help to avoid potential market participant confusion over the differing terminology.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[4] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[5] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which NASDAQ operates or controls, and 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change in the terminology applied to the program further perfects the mechanism of a free and open market and a national market system, and, in general, to promotes public interest because it harmonizes NASDAQ's program's terminology with the terminology of other markets that offer similar programs to their market participants. NASDAQ believes that the proposed new terminology is more reflective of who is eligible to participate in the program. As such, the Exchange believes that the proposed change will avoid potential market participant confusion over the scope and nature of the program. Similarly, the Exchange believes that moving the rules of the program to the rule section that contains other market improvement programs will avoid potential market participant confusion and helps NASDAQ further refine its rulebook to make it more understandable and accessible to all market participants. The Exchange believes that adding clarifying language concerning notice of changes to the minimum performance measurements is consistent with the Act because it will promote transparency in the operation and requirements of the program. The Exchange believes that reducing the notice requirement is consistent with further perfecting the mechanism of a free and open market and a national market system because it lessens the time that a DLP must remain registered in a Qualified Security once it makes the determination to de-register.

The proposed change providing NASDAQ additional flexibility in applying the minimum performance measurements will allow NASDAQ to more closely tailor eligibility for the beneficial fees and credits of the program based on the level of improvement to the market NASDAQ determines is desired. In this regard, in certain instances the desired improvement in market quality may be achieved by applying fewer than all four of the minimum performance measurements, including applying just one, two or three of them. Accordingly, allowing the Exchange to apply less than all four of the minimum performance measurements will not negatively impact the public interest or investor protection. The Exchange notes that the minimum standards that NASDAQ sets for a Qualified Security apply to all market makers registered in the security, and therefore, all such market makers that elect to provide the level of market-improving behavior required by the program will receive the credit. The Exchange also believes that the proposed additional flexibility in applying the minimum performance measurements will not permit unfair discrimination among market makers, as the measurements are set based on the Exchange's determination of what beneficial activity, and the amount thereof, in a Qualified Security is needed to achieve the desired improvement to market quality.

The Exchange believes that the proposed change to provide NASDAQ with additional flexibility in applying the four minimum performance measurements is consistent with an equitable allocation of a reasonable fee because NASDAQ will always apply at least one factor, which will require a market maker to improve the market over other market makers in a Qualified Security in order to receive reduced fees and increased credits. In addition, whatever combination of criteria NASDAQ imposes will applied equally to all market markers. It is NASDAQ's belief that the revised program will promote competition among market maker to provide the best markets for investors, even where that competition focuses on just one of the four criteria. NASDAQ believes that as it gains experience with the program, it will be able to apply each criteria and combination of criteria to maximize this competition and benefit to investors. Moreover, credit eligibility is not discretionary under the program. Any market maker that meets the specified criteria will receive the credit.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Specifically, the changes are designed to promote clarity in the application of NASDAQ's rules and to provide NASDAQ flexibility in the application of the qualification requirements of an incentive program, which is designed to improve the market in Qualified Securities on NASDAQ. Such changes do not place a burden on competition between market participants as the changes are applied consistently to all participants. Lastly, the proposed change to provide NASDAQ with greater flexibility in applying the four minimum performance measures may actually promote competition among exchanges to the extent the additional flexibility results in improved market quality on NASDAQ.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[6] and

[3] BATS Rule 11.8(e).

[4] 15 U.S.C. 78f.

[5] 15 U.S.C. 78f(b)(4) and (5).

[6] 15 U.S.C. 78s(b)(3)(a)(iii).

subparagraph (f)(6) of Rule 19b–4 thereunder.[7] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or 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–2015–071 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2015–071. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2015–071 and should be submitted on or before August 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17167 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

[7] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[8] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14330 and #14331]

OKLAHOMA Disaster Number OK–00092

AGENCY: U.S. Small Business Administration

ACTION: Amendment 6.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of OKLAHOMA (FEMA–4222–DR), dated 05/26/2015.

Incident: Severe Storms, Tornadoes, Straight Line Winds, and Flooding.

Incident Period: 05/05/2015 through 06/04/2015.

DATES: *Effective Date:* 07/02/2015.

Physical Loan Application Deadline Date: 07/27/2015.

EIDL Loan Application Deadline Date: 02/26/2016.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416

SUPPLEMENTARY INFORMATION: The notice of the Presidential disaster declaration for the State of OKLAHOMA, dated 05/26/2015 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: (Physical Damage and Economic Injury Loans): Carter, Jefferson, Latimer, Mayes, Okfuskee, Okmulgee, Pushmataha, Stephens, Tulsa

Contiguous Counties: (Economic Injury Loans Only):

Oklahoma: Creek, Delaware, Osage, Pawnee

Texas: Montague

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2015–17107 Filed 7–13–15; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[License No. 01/01–0422]

New Canaan Funding Mezzanine V SBIC, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that New Canaan Funding Mezzanine V SBIC, L.P., 21 Locust Avenue, Suite 1C, New Canaan, CT 06840, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concerns, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). New Canaan Funding Mezzanine V SBIC, L.P. is proposing to provide financing to Safemark, Inc., 2101 Park Center Drive, Suite 125, Orlando, FL 32835. The financing will be used, in part, for working capital, to pay the seller, to pay off existing debt, and to pay fees and expenses.

The proposed transaction is brought within the purview of § 107.730 of the Regulations because Safemark, Inc. will be using financing proceeds from New Canaan Funding Mezzanine V SBIC, L.P. in part to discharge obligations to Corporate Mezzanine IV, L.P. and Trafalgar Business Solutions Ltd., which are Associates of New Canaan Funding Mezzanine V SBIC, L.P. as defined at § 107.50 due to common management.

Therefore, the proposed transaction is considered self-deal pursuant to 13 CFR 107.730 and requires a regulatory exemption. Notice is hereby given that any interested person may submit written comments on the transaction within fifteen days of the date of this publication to Associate Administrator

for Investment, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Dated: July 2, 2015.

Javier Saade,

Associate Administrator for Investment and Innovation.

[FR Doc. 2015–17184 Filed 7–13–15; 8:45 am]

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SMALL BUSINESS ADMINISTRATION

Notice of Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration (''SBA'') under Section 309 of the Small Business Investment Act of 1958, as amended, and Section 107.1900 of the Small Business Administration Rules and Regulations, SBA by this notice declares null and void the license to function as a small business investment company under the Small Business Investment Company License No. 04/74–0290 issued to North Carolina Economic Opportunities Funds, L.P.

United States Small Business Administration.

Dated: July 7, 2015.

Javier E. Saade,

Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2015–17185 Filed 7–13–15; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 9188]

Culturally Significant Objects Imported for Exhibition Determinations: ''Made in the Americas: The New World Discovers Asia'' Exhibition

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), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 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 ''Made in the Americas: The New World Discovers Asia,'' 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 Museum of Fine Arts, Boston, Boston, Massachusetts, from on or about August 18, 2015, until on or about February 15, 2016, at the Winterthur Museum, Garden and Library, Winterthur, Delaware, from on or about March 26, 2016, until on or about January 8, 2017, 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 imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: July 1, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–17229 Filed 7–13–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 9189]

Advisory Committee on International Postal and Delivery Services August 2015 Meeting

SUMMARY: As required by the Federal Advisory Committee Act, Public Law 92–463, the Department of State gives notice of a meeting of the Advisory Committee on International Postal and Delivery Services. This Committee will meet on Thursday August 6, 2015, from 2:00 p.m. to 5:00 p.m. Eastern Time at the American Institute of Architects, Board Room, 1735 New York Avenue NW., Washington, DC 20006.

Any member of the public interested in providing input to the meeting should contact Ms. Shereece Robinson, whose contact information is listed below (see the ''for further information'' section of this notice). Each individual providing oral input is requested to limit his or her comments to five minutes. Requests to be added to the speakers list must be received in writing (letter or email) prior to the close of business on Thursday July 30, 2015; written comments from members of the public for distribution at this meeting must reach Ms. Robinson by letter or email this same date. A member of the public requesting reasonable accommodation should also make their request to Ms. Robinson by July 30. Requests received after that date will be considered but might not be able to be fulfilled.

The agenda of the meeting will include: Consideration of postal terminal dues, customs treatment of mail, and developments in the Universal Postal Union.

FOR FURTHER INFORMATION CONTACT: Please contact Ms. Shereece Robinson of the Office of Specialized and Technical Agencies (IO/STA), Bureau of International Organization Affairs, U.S. Department of State, at tel. (202) 663–2649, by email at *RobinsonSA2@state.gov,* or by mail at IO/STA, Suite L–409 SA–1; U.S. Department of State; Washington, DC 20522.

Dated: June 30, 2015.

Joseph P. Murphy,

Designated Federal Officer, Advisory Committee on International Postal and Delivery Services, Office of Specialized and Technical Agencies, Bureau of International Organization Affairs, Department of State.

[FR Doc. 2015–17228 Filed 7–13–15; 8:45 am]

BILLING CODE 4710–19–P

DEPARTMENT OF STATE

[Public Notice: 9190]

Privacy Act; System of Records: Records Maintained by the Office of Civil Rights, State-09

SUMMARY: Notice is hereby given that the Department of State proposes to amend an existing system of records, Records Maintained by the Office of Civil Rights, State-09, pursuant to the provisions of the Privacy Act of 1974, as amended (5 U.S.C. 552a) and Office of Management and Budget Circular No. A–130, Appendix I.

DATES: This system of records will be effective on August 24, 2015, unless we receive comments that will result in a contrary determination.

ADDRESSES: Any persons interested in commenting on the amended system of records may do so by submitting comments by writing to the Director; Office of Information Programs and Services, A/GIS/IPS; Department of State, SA–2; 515 22nd Street; Washington, DC 20522–8001.

FOR FURTHER INFORMATION CONTACT: John Hackett, Acting Director; Office of Information Programs and Services, A/GIS/IPS; Department of State, SA–2; 515 22nd Street NW; Washington, DC 20522–8100, or at *Privacy@state.gov*.

SUPPLEMENTARY INFORMATION: The Department of State proposes that the current system amend its name from ''Equal Employment Opportunity Records'' (previously published at 75 FR 70342) to ''Records Maintained by the Office of Civil Rights''. The purpose of this system is to contain records for the investigation, processing and resolution of informal and formal complaints of discrimination filed against the Department of State in accordance with 29 CFR part 1614 and the Department's internal procedures for addressing Equal Employment Opportunity (EEO) complaints; for the investigation, processing and resolution of complaints of discrimination under 42 U.S.C. 2000d; and for the investigation, processing and resolution of complaints under 20 U.S.C. 1681, 29 U.S.C. 794 and 794d, 42 U.S.C. 6101, and 36 CFR chapter XI.

The proposed system will include modifications to the following sections: Title, Categories of Individuals Covered by the System, Authority for Maintenance of the System, Purposes, Routine Uses, Safeguards, and System Exempted From Certain Provisions of the Act as well as other administrative updates.

The Department's report was filed with the Office of Management and Budget. The amended system description, ''Records Maintained by the Office of Civil Rights, State-09,'' will read as set forth below.

Joyce A. Barr,

Assistant Secretary for Administration, U.S. Department of State.

STATE–09

SYSTEM NAME:

Records Maintained by the Office of Civil Rights.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Department of State, 2201 C Street NW., Washington, DC 20520.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees and applicants for employment who have filed formal or informal complaints that allege discrimination; employees and members of the public who have filed a complaint under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title IX of the Educational Amendments of 1972 as amended (20 U.S.C. 1681), Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e), Sections 504 or 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794 and 794d), the Equal Pay Act of 1963 (29 U.S.C. 206(d)), the Age Discrimination in Employment Act of 1967 (29 U.S.C. 621), the Genetic Information Nondiscrimination Act of 2008 (42 U.S.C. chapter 21F), Executive Order 11478, as amended, or the Age Discrimination Act of 1975 (42 U.S.C. chapter 76).

CATEGORIES OF RECORDS IN THE SYSTEM:

Investigative reports; employment applications; biographic information to include race, color, national origin, sex, sexual orientation, religion, age, disability, genetic information; and employment histories.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

20 U.S.C. 1681; 29 U.S.C. 794 and 794d; 42 U.S.C. 2000d *et seq.;* 29 U.S.C. 206(d); 42 U.S.C. 2000e *et seq.;* Executive Order 11478, as amended; 42 U.S.C. chapter 21F; 29 U.S.C. 621; and 42 U.S.C. chapter 76.

PURPOSE(S):

For the investigation, information collected is used for the processing and resolution of informal and formal complaints of discrimination filed against the Department of State in accordance with 29 CFR part 1614 and the Department's internal procedures for addressing Equal Employment Opportunity (EEO) complaints; and for the investigation, processing and resolution of complaints of discrimination under 42 U.S.C. 2000d and complaints under 20 U.S.C. 1681, 29 U.S.C. 794 and 794d, 42 U.S.C. 6101, 29 U.S.C. 621, and 36 CFR chapter XI.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Records from this system will be disclosed to the U.S. Equal Employment Opportunity Commission and other federal agencies for purposes of investigating, processing, adjudicating, resolving and litigating complaints involving more than one agency, or in situations where the Department of State has requested that another federal agency provide investigative support for a complaint.

The Department of State periodically publishes in the **Federal Register** its standard routine uses that apply to all of its Privacy Act systems of records. These notices appear in the form of a Prefatory Statement. These standard routine uses apply to the Records Maintained by the Office of Civil Rights, State-09.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Hard copy and electronic.

RETRIEVABILITY:

By individual name and Employee Identification Number (EID).

SAFEGUARDS:

All users are given cyber security awareness training which covers the procedures for handling Sensitive but Unclassified information, including personally identifiable information (PII). Annual refresher training is mandatory. In addition, all Foreign Service and Civil Service employees and those Locally Employed Staff who handle PII are required to take the Foreign Service Institute distance learning course instructing employees on privacy and security requirements, including the rules of behavior for handling PII and the potential consequences if it is handled improperly. Before being granted access to Records Maintained by the Office of Civil Rights, a user must first be granted access to the Department of State computer system.

Remote access to the Department of State network from non-Department owned systems is authorized only to unclassified systems and only through a Department-approved access program. Remote access to the network is configured with the Office of Management and Budget Memorandum M–07–16 security requirements, which include but are not limited to two-factor authentication and time out function.

All Department of State employees and contractors with authorized access have undergone a thorough background security investigation. Access to the Department of State, its annexes and posts abroad is controlled by security guards and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. All paper records containing personal information are maintained in secured file cabinets in restricted areas, access to which is limited to authorized personnel only. Access to computerized files is password-protected and under the direct supervision of the system manager. The system manager has the capability of printing audit trails of access from the computer media, thereby permitting regular and ad hoc monitoring of computer usage. When it is determined that a user no longer needs access, the user account is disabled.

RETENTION AND DISPOSAL:

Records are retired or destroyed in accordance with published records disposition schedules of the Department of State and as approved by the National Archives and Records Administration (NARA). More specific information may be obtained by writing the Director, Office of Information Programs and Services, Department of State, SA–2, 515 22nd Street NW., Washington, DC 20522–8001.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Civil Rights, Room 7428, Department of State, 2201 C Street NW., Washington, DC 20520.

NOTIFICATION PROCEDURES:

Individuals who have cause to believe that the Office of Civil Rights might have records pertaining to them should write to the Director, Office of Information Programs and Services, Department of State, SA–2, 515 22nd Street NW., Washington, DC 20522–8001. The individual must specify that he/she wishes the Records Maintained by the Office of Civil Rights to be checked. At a minimum, the individual must include: Name; date and place of birth; current mailing address and zip code; signature; and the approximate date upon which the individual filed a formal or informal complaint alleging discrimination or requested other services from the Office of Civil Rights.

RECORD ACCESS AND AMENDMENT PROCEDURES:

Individuals who wish to gain access to or amend records pertaining to themselves should write to the Director, Office of Information Programs and Services (address above).

CONTESTING RECORD PROCEDURES:

(See above).

RECORD SOURCE CATEGORIES:

The individual; supervisors of the individual; EEO counselors; EEO personnel; and other employees or individuals having knowledge of the facts involved in the complaint.

SYSTEM EXEMPTED FROM CERTAIN PROVISION OF THE ACT:

Certain records contained within this system of records are exempted from 5 U.S.C. 552a(k)(5) and (k)(6). See 22 CFR part 171.

[FR Doc. 2015–17226 Filed 7–13–15; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by the California Department of Transportation (Caltrans), pursuant to 23 U.S.C. 327, and the United States Fish and Wildlife Service (USFWS).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans and USFWS that are final within the meaning of 23 U.S.C. 139(*l*)(1). The actions relate to a proposed highway project on State Route 152 near the City of Gilroy in Santa Clara County in the State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 11, 2015. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Eric DeNardo, Associate Environmental Planner, 111 Grand Ave. MS–8B Oakland, CA 94612, 7:30 a.m.–5:15 p.m., (510) 286–5645, *eric.denardo@dot.ca.gov.* For USFWS: Jerry Roe, Caltrans Liaison, U.S. Fish and Wildlife Service, 28000 Cottage Way Sacramento, CA 95825, (916) 414–6600, *jerry_roe@fws.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that Caltrans, and USFWS have taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the State Route (SR) 152 Shoulder Widening project in the State of California. The project would improve roadway safety along SR 152 from 0.6 miles west of Prunedale Avenue to 0.24 miles east of Prunedale Avenue east of the City of Gilroy, in unincorporated Santa Clara County. All shoulders less than 8 feet wide would be widened to standard 8-foot shoulders, with rumble strip placement within both shoulders and median. The existing drainage ditch on the westbound shoulder of SR 152 would be improved by relocating it further from the roadway and reconstructing it to have less steep slopes. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Environmental Assessment (EA) for the project, approved on June 24, 2015 in the FHWA Findings of No Significant Impact (FONSI) issued on June 24, 2015, and in other documents in Caltrans' project records. The EA, FONSI, and other project records are available by contacting Caltrans at the addresses provided above. The Caltrans EA and FONSI can be viewed and downloaded from the project Web site at *http://www.dot.ca.gov/dist4/envdocs.htm*, or viewed at public libraries in the project area. The USFWS decision and Biological Opinion are available by contacting USFWS at the address provided above. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. Council on Environmental Quality Regulations
2. National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4321 *et seq.*
3. Federal-Aid Highway Act of 1970, *23 U.S.C. 109*
4. MAP–21, the Moving Ahead for Progress in the 21st Century Act
5. Clean Air Act Amendments of 1990 (CAAA)
6. Clean Water Act of 1977 and 1987
7. Federal Water Pollution Control Act of 1972 (see Clean Water Act of 1977 & 1987)
8. Federal Land Policy and Management Act of 1976 (Paleontological Resources)
9. Noise Control Act of 1972
10. Safe Drinking Water Act of 1944, as amended
11. Endangered Species Act of 1973
12. Executive Order 11990, Protection of Wetlands
13. Executive Order 13112, Invasive Species
14. Executive Order 13186, Migratory Birds
15. Fish and Wildlife Coordination Act of 1934, as amended
16. Migratory Bird Treaty Act
17. Water Bank Act Wetlands Mitigation Banks, ISTEA 1991, Sections 1006–1007
18. Wildflowers, Surface Transportation and Uniform Relocation Act of 1987 Section 130

19. Coastal Zone Management Act of 1972
20. Coastal Zone Management Act Reauthorization Amendments Of 1990
21. Executive Order 11988, Floodplain Management
22. Department of Transportation (DOT) Executive Order 5650.2—Floodplain Management and Protection (April 23, 1979)
23. Rivers and Harbors Appropriation Act of 1899, Sections 9 and 10
24. Title VI of the Civil Rights Act of 1964, as amended
25. *Executive Order 12898,* Federal Actions to Address Environmental Justice and Low-Income Populations

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing E. O. 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Matthew Schmitz,

Director, Project Delivery, Federal Highway Administration, Sacramento, California.

[FR Doc. 2015–17237 Filed 7–13–15; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORATION

Federal Transit Administration

Notice of Meeting of the Transit Advisory Committee for Safety (TRACS)

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Transit Advisory Committee for Safety (TRACS). TRACS is a Federal Advisory Committee established by the Secretary of Transportation in accordance with the Federal Advisory Committee Act to provide information, advice, and recommendations to the Secretary of Transportation and the Administrator of the Federal Transit Administration (FTA) on matters relating to public transportation safety.

DATES: The TRACS meeting will be held on July 28, 2015, from 9:00 a.m. to 5:00 p.m., and July 29, 2015, from 9:00 a.m. to 12:00 p.m. Contact Bridget Zamperini (see contact information below) by July 14, 2015, if you wish to be added to the visitor's list for access to the meeting.

ADDRESSES: The meeting will be held at the National Association of Home Builders, 1201 15th Street NW., Washington, DC 20005. Attendees who are on the visitor's list may access the building by presenting a current state issued driver's license, state issued identification card, or other valid photo identification issued by the Federal government. Although this meeting is open to the public, all attendees should pre-register with the FTA.

SUPPLEMENTARY INFORMATION: This notice is provided in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 2). As noted above, TRACS is a Federal Advisory Committee established to provide information, advice, and recommendations to the Secretary of Transportation and the Administrator of the FTA on matters relating to the safety of public transportation systems. TRACS is currently composed of 28 members representing a broad base of expertise necessary to discharge its responsibilities. The first meeting of TRACS was held on September 9–10, 2010.

For more information on TRACS meetings and other TRACS information, please visit the TRACS Web site at: *http://www.fta.dot.gov/13099.html.* The tentative agenda for the July 2015 TRACS meeting is set forth below:

Agenda

(1) Welcome Remarks/Introductions
(2) Facility Use/Safety Briefing
(3) Review of Draft Report about Establishing a Fatigue Management Program
(4) Review of Draft Report about Preventing and Mitigating Transit Worker Assaults
(5) Public Comments
(6) Future TRACS Activities
(7) Summary of Deliverables/Concluding Remarks

As previously noted, this meeting will be open to the public. However, persons wishing to attend must contact Bridget Zamperini, Office of Transit Safety and Oversight, Federal Transit Administration, (202) 366–0306; or at *TRACS@dot.gov* by close of business July 14, 2015, to have your name added to the participant list. Members of the public who wish to make an oral statement at the meeting or seeking special accommodations are also directed to make a request to Bridget Zamperini, Office of Transit Safety and Oversight, Federal Transit Administration (202) 366–0306; or at *TRACS@dot.gov* on or before the close of business July 14, 2015. Provisions will be made to include oral statements on the agenda, if needed. Members of the public may submit written comments or suggestions concerning the activities of TRACS any time before or after the meeting at *TRACS@dot.gov,* or to the U.S. Department of Transportation, Federal Transit Administration, Office of Transit Safety and Oversight, Attention: Bridget Zamperini, Room E45–310, 1200 New Jersey Avenue SE., Washington, DC 20590. Information from the meeting will be posted on FTA's public Web site at *http://www.fta.dot.gov.* Written comments submitted to TRACS will also be posted at the above web address.

Issued in Washington, DC, this 8th day of July, 2015.

Therese W. McMillan,

Acting Administrator.

[FR Doc. 2015–17182 Filed 7–13–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, August 20, 2015.

FOR FURTHER INFORMATION CONTACT: Susan Jimerson at 1–888–912–1227 or (206) 946–3009.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Thursday, August 20, 2015, at 3 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Susan Jimerson. For more information please contact: Susan Jimerson at 1–888–912–1227 or 206 946–3009, or write TAP Office, 915 2nd Avenue, MS W–406, Seattle, WA 98174, or post comments to the Web site: *http://www.improveirs.org.*

The committee will be discussing various issues related to Taxpayer

Communications and public input is welcome.

Dated: July 1, 2015.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2015–17002 Filed 7–13–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8902

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8902, Alternative Tax on Qualifying Shipping Activities.

DATES: Written comments should be received on or before September 14, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie A. Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Alternative Tax on Qualified Shipping Activities.

OMB Number: 1545–1968.

Form Number: Form 8902.

Abstract: Form 8902 is used to elect the alternative tax on national income from qualifying shipping activities and to figure the alternative tax.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit institutions.

Estimated Number of Respondents: 200.

Estimated Time per Respondent: 15 hr., 17 min.

Estimated Total Annual Burden Hours: 3,056.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 6, 2015.

Christie A. Preston,

IRS Reports Clearance Officer.

[FR Doc. 2015–17314 Filed 7–13–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 990 and Related Schedules

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 990, Return of Organization Exempt From Income Tax Under Section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except black lung benefit trust or private foundation), Schedule A, Organization Exempt Under Section 501(c)(3) (Except Private Foundation), and Section 501(e), 501(f), 501(k), 501(n), or Section 4947(a)(1) Nonexempt Charitable Trust, and Schedule B, Schedule of Contributors.

DATES: Written comments should be received on or before September 14, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms and instructions should be directed to LaNita Van Dyke at Internal Revenue Service, Room 6517, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Return of Organization Exempt From Income Tax Under Section 501(c), 527, 4947(a)(1) of the Internal Revenue Code (except black lung benefit trust or private foundation) (Form 990), Organization Exempt Under Section 501(c)(3) (Except Private Foundation), and Section 501(e), 501(f), 501(k), 501(n), or Section 4947(a)(1) Nonexempt Charitable Trust (Schedule A), and Schedule of Contributors (Schedule B).

OMB Number: 1545–0047.

Form Number: 990, and related schedules.

Abstract: Form 990 is needed to determine that Code section 501(a) tax-exempt organizations fulfill the operating conditions of their tax exemption. Schedule A (Form 990) is used to elicit special information from section 501(c)(3) organizations. Schedule B is used by tax-exempt organizations to list contributors and allows the IRS to distinguish and make public disclosure of the contributors list within the requirements of Code section 527. IRS uses the information from these forms to determine if the filers are operating within the rules of their exemption.

Current Actions: There are no changes being made to the forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Not-for-profit institutions.

Estimated Number of Respondents: 403,068.

Estimated Time per Respondent: 63 hrs., 47 min.

Estimated Total Annual Burden Hours: 25,710,979.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collectionof information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 8, 2015,

Christie Preston,

IRS Reports Clearance Officer.

[FR Doc. 2015–17312 Filed 7–13–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Health Services Research and Development Service, Scientific Merit Review Board; Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Health Services Research and Development Service Scientific Merit Review Board will conduct in-person and teleconference meetings of its seven Health Services Research (HSR) subcommittees on the dates below from 8:00 a.m. to approximately 5:00 p.m. (unless otherwise listed) at the Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, VA, 22314:

- HSR 1—Health Care and Clinical Management on August 25–26, 2015;
- HSR 2—Behavioral, Social, and Cultural Determinants of Health and Care on August 25–26, 2015;
- HSR 4—Mental and Behavioral Health on August 25–26, 2015;
- HSR 5—Health Care System Organization and Delivery on August 25–26, 2015;
- HSR 3—Healthcare Informatics from 12:00 p.m. to 5:00 p.m. on August 26, 2015, and 8:00 a.m. to 5:00 p.m. on August 27, 2015;
- HSR 6—Post-acute and Long-term Care on August 27, 2015; and
- Nursing Research Initiative (NRI) from 8:00 a.m. to 12:00 p.m. on August 27, 2015.

The purpose of the Board is to review health services research and development applications involving: The measurement and evaluation of health care services; the testing of new methods of health care delivery and management; and nursing research. Applications are reviewed for scientific and technical merit, mission relevance, and the protection of human and animal subjects. Recommendations regarding funding are submitted to the Chief Research and Development Officer.

Each subcommittee meeting of the Board will be open to the public the first day for approximately one half-hour at the start of the meeting on August 25–26 (HSR 1, 2, 3, 4, and 5) and on August 27 (HSR 6 and NRI), to cover administrative matters and to discuss the general status of the program. Members of the public who wish to attend the open portion of the subcommittee meetings may dial 1–800–767–1750, participant code 10443.

The remaining portion of each subcommittee meeting will be closed for the discussion, examination, reference to, and oral review of the intramural research proposals and critiques. During the closed portion of each subcommittee meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

No oral or written comments will be accepted from the public for either portion of the meetings. Those who plan to participate during the open portion of a subcommittee meeting should contact Ms. Liza Catucci, Administrative Officer, Department of Veterans Affairs, Health Services Research and Development Service (10P9H), 810 Vermont Avenue NW., Washington, DC 20420, or by email at *Liza.Catucci@va.gov.* For further information, please call Ms. Catucci at (202) 443–5797.

Dated: July 8, 2015.

Rebecca Schiller,

Advisory Committee Management Officer.

[FR Doc. 2015–17178 Filed 7–13–15; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 80 Tuesday,

No. 134 July 14, 2015

Part II

Securities and Exchange Commission

17 CFR Parts 229, 240, 249, et al.

Listing Standards for Recovery of Erroneously Awarded Compensation; Proposed Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 229, 240, 249, and 274

[RELEASE NOS. 33–9861; 34–75342; IC–31702; File No. S7–12–15]

RIN 3235–AK99

Listing Standards for Recovery of Erroneously Awarded Compensation

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: We are proposing a new rule and rule and form amendments to implement the provisions of Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, which added Section 10D to the Securities Exchange Act of 1934. Section 10D requires the Commission to adopt rules directing the national securities exchanges and national securities associations to prohibit the listing of any security of an issuer that is not in compliance with Section 10D's requirements for disclosure of the issuer's policy on incentive-based compensation and recovery of incentive-based compensation that is received in excess of what would have been received under an accounting restatement. The proposed rule and rule amendments would direct the national securities exchanges and national securities associations to establish listing standards that would require each issuer to develop and implement a policy providing for the recovery, under certain circumstances, of incentive-based compensation based on financial information required to be reported under the securities laws that is received by current or former executive officers, and require the disclosure of the policy. A listed issuer would be required to file the policy as an exhibit to its annual report.

DATES: Comments should be received on or before September 14, 2015.

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;* or
- Use the Federal Rulemaking ePortal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments to Brent J. Fields, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–12–15. 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, on official business days between the hours of 10:00 a.m. and 3:00 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.

Studies, memoranda, or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on the SEC's Web site. To ensure direct electronic receipt of such notifications, sign up through the ''Stay Connected'' option at *www.sec.gov* to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Anne Krauskopf, Senior Special Counsel, or Carolyn Sherman, Special Counsel at (202) 551–3500, in the Office of Chief Counsel, Division of Corporation Finance, or Joel K. Levine, Associate Chief Accountant at (202) 551–3400, in the Office of Chief Accountant, Division of Corporation Finance, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: We are proposing to add new Rule 10D–1 [1] under the Securities Exchange Act of 1934.[2] We also are proposing amendments to Items 402,[3] 404 [4] and 601 [5] of Regulation S–K,[6] Item 22 of Schedule 14A,[7] Exchange Act Forms 20–F [8] and 40–F,[9] and Form N–CSR [10] under the Exchange Act and the Investment Company Act of 1940.[11]

Table of Contents

I. Background and Summary 7
II. Discussion of the Proposals 10
A. Issuers and Securities Subject to Proposed Exchange Act Rule 10D–1 11
1. General 11
2. Securities Futures Products and Standardized Options 17
3. Registered Investment Companies 20
B. Restatements 23
1. Restatements Triggering Application of Recovery Policy 23
2. Date the Issuer Is Required to Prepare an Accounting Restatement 28
C. Application of Recovery Policy 33
1. Executive Officers Subject to Recovery Policy 33
2. Incentive-Based Compensation 39
a. Incentive-Based Compensation Subject to Recovery Policy 39
b. Time Period Covered by Recovery Policy 51
c. When Incentive-Based Compensation Is ''Received'' 54
3. Recovery Process 58
a. Determination of Excess Compensation 58
b. Board Discretion Regarding Whether to Seek Recovery 67
c. Board Discretion Regarding Manner of Recovery 73
i. Amount to Be Recovered 74
ii. Means of Recovery 75

[1] 17 CFR 240.10D–1.
[2] 15 U.S.C. 78a *et seq.*
[3] 17 CFR 229.402.
[4] 17 CFR 229.404.
[5] 17 CFR 229.601.
[6] 17 CFR 229.10 *et seq.*
[7] 17 CFR 240.14a–101.
[8] 17 CFR 249.220f.
[9] 17 CFR 249.240f.
[10] 17 CFR 249.331 and 274.128.
[11] 15 U.S.C. 80a–1 *et seq.*

4. Compliance with Recovery Policy ... 79
D. Disclosure of Issuer Policy on Incentive-Based Compensation ... 80
1. Listed U.S. Issuers ... 83
2. Listed Foreign Issuers ... 88
E. Indemnification and Insurance ... 95
F. Transition and Timing ... 99
III. Economic Analysis ... 103
A. Baseline ... 105
B. Analysis of Potential Economic Effects ... 114
1. Potential Effects on Financial Reporting ... 115
2. Potential Effects on Executive Compensation ... 122
3. Additional Potential Effects on Listed Issuers ... 133
4. Potential Effects on U.S. Exchanges ... 140
5. Indemnification and Insurance ... 142
C. Alternatives ... 144
1. Exemptions for Certain Categories of Issuers ... 144
2. Excluding Incentive-Based Compensation Tied to Stock Price ... 145
3. Other Alternatives Considered ... 147
D. Request for Comment ... 149
IV. Paperwork Reduction Act ... 151
A. Background ... 151
B. Summary of Proposed Rule and Rule Amendments ... 153
C. Paperwork Reduction Act Burden Estimates ... 156
D. Solicitation of Comments ... 161
V. Small Business Regulatory Enforcement Fairness Act ... 162
VI. Initial Regulatory Flexibility Act Analysis ... 163
A. Reasons for, and Objectives of, the Proposed Action ... 163
B. Legal Basis ... 164
C. Small Entities Subject to the Proposed Action ... 164
D. Reporting, Recordkeeping, and other Compliance Requirements ... 166
E. Duplicative, Overlapping or Conflicting Federal Rules ... 169
F. Significant Alternatives ... 169
G. Solicitation of Comments ... 171
VII. Statutory Authority and Text of the Proposed Amendments ... 172

I. Background and Summary

We are proposing a new rule, and rule and form amendments to implement the provisions of Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the ''Act''),[12] which added Section 10D to the Securities Exchange Act of 1934 (the ''Exchange Act''). Specifically, Section 10D(a) of the Exchange Act requires the Commission to adopt rules directing the national securities exchanges [13] (the ''exchanges'') and the national securities associations [14] (the ''associations'') to prohibit the listing of any security of an issuer that is not in compliance with the requirements of Section 10D(b). Section 10D(b) requires the Commission to adopt rules directing the exchanges to establish listing standards to require each issuer to develop and implement a policy providing:

(1) For the disclosure of the issuer's policy on incentive-based compensation that is based on financial information required to be reported under the securities laws; and

(2) that, in the event that the issuer is required to prepare an accounting restatement due to the issuer's material noncompliance with any financial reporting requirement under the securities laws, the issuer will recover from any of the issuer's current or former executive officers who received incentive-based compensation (including stock options awarded as compensation) during the three-year period preceding the date the issuer is required to prepare the accounting restatement, based on the erroneous data, in excess of what would have been paid to the executive officer under the accounting restatement.

Other statutes and rules currently administered by the Commission also address the recovery of executive compensation:

- Section 304 of the Sarbanes-Oxley Act of 2002 (''SOX'') [15] provides that if an issuer is required to prepare an accounting restatement due to the material noncompliance of the issuer, as a result of misconduct,[16] with any financial reporting requirements under the securities laws, the chief executive officer and chief financial officer of the issuer shall reimburse the issuer for any bonus or other incentive-based or equity-based compensation received by

[12] Public Law 111–203, 124 Stat. 1900 (2010).

[13] A ''national securities exchange'' is an exchange registered as such under Section 6 of the Exchange Act [15 U.S.C. 78f]. There are currently eighteen exchanges registered under Section 6(a) of the Exchange Act: BATS Exchange, BATS Y-Exchange, BOX Options Exchange, C2 Options Exchange, Chicago Board Options Exchange, Chicago Stock Exchange, EDGA Exchange, EDGX Exchange, International Securities Exchange (''ISE''), ISE Gemini, Miami International Securities Exchange, NASDAQ OMX BX, NASDAQ OMX PHLX, The NASDAQ Stock Market, National Stock Exchange, New York Stock Exchange (''NYSE''), NYSE Arca and NYSE MKT. Certain exchanges are registered with the Commission through a notice filing under Section 6(g) of the Exchange Act for the purpose of trading security futures. As discussed in Section II.A.2, below, we propose to exempt security futures products and standardized options from the scope of the proposed rule. To the extent that our final rule exempts the listing of security futures products and standardized options from its scope, any registered national securities exchange that lists and trades only security futures products or standardized options would not be required to file a rule change in order to comply.

[14] A ''national securities association'' is an association of brokers and dealers registered as such under Section 15A of the Exchange Act [15 U.S.C. 78o–3]. The Financial Industry Regulatory Authority (''FINRA'') is the only association registered with the Commission under section 15A(a) of the Exchange Act. Because FINRA does not list securities, generally we refer only to the exchanges in this release. However, if any associations were to list securities, the rule proposals would apply to them also.

In addition, Section 15A(k) of the Exchange Act (15 U.S.C. 78o–3(k) provides that a futures association registered under Section 17 of the Commodity Exchange Act (7 U.S.C. 21) shall be registered as an association for the limited purpose of regulating the activities of members who are registered as broker-dealers in security futures products pursuant to Section 15(b)(11) of the Exchange Act (15 U.S.C. 78o(b)(11)).

[15] 15 U.S.C. 7243.

[16] The CEO or CFO need not personally engage in misconduct for recovery to be required under Section 304. See *SEC* v. *Jenkins,* 718 F.Supp. 2d 1070, 1074–75 (D. Ariz. 2010) (''[T]he misconduct of the issuer is the misconduct that triggers the reimbursement obligation of the CEO and the CFO.''); *SEC* v. *Baker,* 2012 U.S. Dist. LEXIS 161784 (W.D. Tex 2012).

that person from the issuer during the 12-month period following the first public issuance or filing with the Commission (whichever first occurs) of the financial document embodying such financial reporting requirement; and any profits realized from the sale of securities of the issuer during that 12-month period; and

• Item 402(b) of Regulation S–K includes, as an example of the kind of information that should be addressed, if material, in the company's Compensation Discussion and Analysis (''CD&A''), company policies and decisions regarding the adjustment or recovery of awards or payments to named executive officers [17] if the relevant company performance measures upon which they are based are restated or otherwise adjusted in a manner that would reduce the size of an award or payment.[18]

The proposed rule and rule amendments would supplement these existing provisions by directing the exchanges to establish listing standards that require listed issuers to:

• Adopt and comply with written policies for recovery of incentive-based compensation based on financial information required to be reported under the securities laws, applicable to the listed issuers' executive officers, over a period of three years; and

• disclose those recovery policies in accordance with Commission rules.

To assure that issuers listed on different exchanges are subject to the same disclosure requirements regarding compensation recovery policies, we are proposing amendments to the disclosure rules that would require all issuers listed on any exchange to file their written recovery policy as an exhibit to their annual reports and, if they have taken actions pursuant to that policy, to disclose those actions.

Under the proposed rule and rule amendments, an issuer would be subject to delisting if it does not:

• Adopt a compensation recovery policy that complies with the applicable listing standard;

• disclose the policy in accordance with Commission rules, including providing the information in tagged data format; or

• comply with the policy's recovery provisions.

Listed issuers could, of course, adopt policies more extensive than those called for by the listing standards, so long as those policies at a minimum satisfied the listing standards, and exchanges and associations could adopt listing standards with requirements that are more extensive than those of proposed Rule 10D–1.

II. Discussion of the Proposals

We are proposing new Exchange Act Rule 10D–1 to set forth the listing requirements that exchanges would be directed to establish pursuant to Section 10D of the Exchange Act. We also are proposing rule amendments to Regulation S–K, to the forms by which foreign private issuers file their Exchange Act annual reports, and for certain investment companies, to Form N–CSR and Schedule 14A. These amendments would require disclosure of the listed issuer's policy on recovery of incentive-based compensation and information about actions taken pursuant to such recovery policy. In developing these proposals, we considered the comment letters we received on Section 10D pursuant to our initiative to receive advance public comment in implementing the Act.[19]

A. Issuers and Securities Subject to Proposed Exchange Act Rule 10D–1

1. General

Section 10D of the Exchange Act provides that the Commission shall, by rule, direct the exchanges ''to prohibit the listing of any security of an issuer that does not comply with the requirements of [Section 10D].'' Commenters raised questions as to whether the rule should apply to all issuers with listed securities, such as foreign private issuers [20] and issuers of listed debt whose stock is not also listed.[21]

For the reasons discussed below, the rule and rule amendments we propose would require exchanges to apply the disclosure and recovery policy requirements to all listed issuers, with only limited exceptions. As a preliminary matter, we read the language of Section 10D as generally calling for a broad application of the mandated listing standards. Section 10D does not distinguish among issuers or types of securities, and does not specifically instruct the Commission to exempt any particular types of issuers or securities or direct the Commission to permit the exchanges to provide such exemptions in listing them.[22] We recognize, however, that we could use our general exemptive authority under the Exchange Act [23] to exempt specific categories of issuers or securities to the extent that doing so would be necessary or appropriate in the public interest and consistent with the protection of investors. In evaluating whether to exempt specific categories of issuers and securities, though, we have considered whether providing exemptions from the requirements of Section 10D would be

[17] As defined in Item 402(a)(3) of Regulation S–K, ''named executive officers'' are all individuals serving as the company's principal executive officer during the last completed fiscal year, all individuals serving as the company's principal financial officer during that fiscal year, the company's three other most highly compensated executive officers who were serving as executive officers at the end of that year, and up to two additional individuals who would have been among the three most highly compensated but for not serving as executive officers at the end of that year.

[18] Item 402(b)(2)(viii). Item 402(b) contains the requirements for CD&A, which is intended to be a narrative overview that puts into context the executive compensation disclosure provided in response to the other requirements of Item 402. The CD&A disclosure requirement is principles-based, in that it identifies the disclosure concept and provides several non-exclusive examples. Under Item 402(b)(1), companies must explain all material elements of their named executive officers' compensation by addressing mandatory principles-based topics in CD&A. Item 402(b)(2) sets forth nonexclusive examples of the kind of information that should be addressed in CD&A, if material.

[19] In connection with all of the Dodd-Frank Act rulemakings, we sought comment from the public prior to the issuance of a proposing release. Comments related to the executive compensation provisions of the Dodd-Frank Act are available at *http://www.sec.gov/comments/df-title-ix/executive-compensation/executive-compensation.shtml.* Regarding Section 10D, we received pre-proposal letters from AFL–CIO, Americans for Financial Reform, As You Sow, Center for Effective Government, Demos, Institute for Policy Studies/Global Economy Project, International Brotherhood of Teamsters, Other98.org, Public Citizen and Service Employees International Union (''AFL–CIO Joint Letter''); American Benefits Council; Baker, Donelson, Bearman, Caldwell & Berkowitz, PC; Brian Foley & Company, Inc.; Center on Executive Compensation; Clark Consulting, LLC; Committee on Federal Regulation of Securities of the Section of Business Law of the American Bar Association (''ABA Business Law Section''); Compensia, Inc.; Davis Polk & Wardwell LLP; Frederic W. Cook & Co., Inc.; Mai Datta, Ph.D., Professor of Finance, Wayne State University; Stuart R. Lombardi; Meridian Compensation Partners, LLC; PGGM Investments; Pay Governance LLC; Protective Life Corporation; Robert E. Scully Jr., Member, Stites Harbison, PLLC; Society of Corporate Secretaries and Governance Professionals; Towers Watson; and Sheila Waddell.

[20] *See* letters from ABA Business Law Section (noting that foreign private issuers are not required to comply with the proxy rules or Item 402 executive compensation disclosure, and that home countries may have a greater interest in determining whether companies should have recourse against their executives) and Brian Foley & Company, Inc. (seeking clarification whether Section 954 applies to foreign private issuers).

[21] *See* letter from Brian Foley & Company, Inc.

[22] In this regard, Section 10D differs from the Act's other governance-related provisions, such as Section 951 Shareholder Vote on Executive Compensation Disclosure (amending the Exchange Act to add Section 14A) and Section 952 Compensation Committee Independence (amending the Exchange Act to add Section 10C), which include specific direction for either the Commission or the exchanges to consider exemptions for classes of issuers, or to provide exemptions. Additionally, Section 951 instructs the Commission to take into account whether Section 951's requirements disproportionately burden small issuers.

[23] Section 36(a) of the Exchange Act (15 U.S.C. 78mm(a)).

consistent with what we understand to be the purpose of this statutory provision. In this regard, we note that a report by the Senate Committee on Banking, Housing and Urban Affairs stated that ''[t]his proposal will clarify that all issuers must have a policy in place to recover compensation based on inaccurate accounting so that shareholders do not have to embark on costly legal expenses to recoup their losses or so that executives must return monies that should belong to the shareholders.'' [24] As discussed below, we propose to exempt security futures products, standardized options, and the securities of certain registered investment companies from the proposed listing standards because we believe the compensation structures of issuers of these securities render application of the rule and rule amendments unnecessary.[25] We are not proposing otherwise to exempt categories of listed issuers, such as emerging growth companies,[26] smaller reporting companies,[27] foreign private issuers,[28] and controlled companies,[29] because we believe the objective of recovering excess incentive-based compensation is as relevant for these categories of listed issuers as for any other listed issuer. In reaching this conclusion, we also considered the relative burdens of compliance on these categories of issuers. As discussed more fully in the Economic Analysis, while we recognize that the proposed listing standards could, in certain respects, impose a disproportionate burden on these categories of issuers, there is also reason to believe that these issuers, as well as investors and the markets in general, may derive benefits from being subject to the proposed listing standards.[30]

In our determination of whether to propose exemptions for foreign private issuers we considered the views of commenters that submitted comments before this proposal [31] as well as the incidence of restatements among this category of listed issuers. We are aware of studies that indicate that these issuers, from time to time, restate their financial statements to correct accounting errors.[32] For example, during 2012 and 2013 foreign private issuers, which are approximately 10 percent of all registrants, accounted for over 10 percent of all restatements.[33]

Although some exchange listing standards permit foreign private issuers to follow home country practice in lieu of certain corporate governance requirements,[34] our proposed rule and rule amendments would not permit the exchanges to exempt foreign private issuers from compliance with Section 10D's disclosure and recovery requirements. Consistent with a comment we received,[35] our proposal would, however, allow exchanges to permit foreign private issuers to forgo recovery as impracticable if the recovery of erroneously awarded compensation pursuant to Section 10D would violate the home country's laws so long as certain other conditions are met.[36]

We also considered the incidence of restatements for smaller reporting companies, emerging growth companies and controlled companies in determining not to exclude such companies from these requirements. For example, during 2012 and 2013, U.S. issuers who are not accelerated filers [37] accounted for approximately 55 percent of total U.S. issuer restatements.[38]

We believe that smaller reporting companies constitute a substantial majority of U.S. non-accelerated filers. We also believe that at least some of these categories of issuers use incentive-based compensation arrangements that are based on achievement of financial reporting measures that may be affected by accounting restatements. As a result, we believe that shareholders of these listed issuers would benefit from a policy to recover excess incentive-based compensation and that applying the proposed rule and rule amendments to these issuers will further the statutory goal of assuring that executive officers do not retain incentive-based compensation that they received erroneously. For similar reasons, we are not proposing to grant the exchanges discretion to decide whether additional categories of issuers should be exempted from the proposed listing standards.

Further, Section 10D refers to ''any security'' of an issuer, which would include not only common equity securities, but also debt and preferred

[24] *See* Report of the Senate Committee on Banking, Housing, and Urban Affairs, S.3217, Report No. 111–176 at 135–36 (April 30, 2010) (''Senate Report'').

[25] *See* Sections II.A.2 and 3, below.

[26] Section 2(a)(19) of the Securities Act of 1933 (the ''Securities Act'') and Exchange Act Section 3(a)(80) define ''emerging growth company'' as ''an issuer that had total annual gross revenues of less than $1,000,000,000 . . . during its most recently completed fiscal year.'' An issuer shall continue to be deemed an emerging growth company until the earliest of (1) the last day of the fiscal year during which it had total annual gross revenues of $1 billion; (2) the last day of the fiscal year following the fifth anniversary of the first sale of its common equity securities; (3) the date on which it has issued more than $1 billion in non-convertible date during the previous three years; or (4) the date on which it is deemed a large accelerated filer.

[27] Exchange Act Rule 12b–2 defines ''smaller reporting company'' as ''an issuer that is not an investment company, an asset-backed issuer . . ., or a majority-owned subsidiary of a parent that is not a smaller reporting company and that: (1) Had a public float of less than $75 million as of the last business day of its most recently completed second fiscal quarter, computed by multiplying the aggregate worldwide number of shares of its voting and non-voting common equity held by non-affiliates by the price at which the common equity was last sold, or the average of the bid and asked prices of common equity, in the principal market for the common equity; or (2) in the case of an initial registration statement under the Securities Act or Exchange Act for shares of its common equity, had a public float of less than $75 million as of a date within 30 days of the date of the filing of the registration statement, computed by multiplying the aggregate worldwide number of such shares held by non-affiliates before the registration plus, in the case of a Securities Act registration statement, the number of such shares included in the registration statement by the estimated public offering price of the shares; or (3) in the case of an issuer whose public float as calculated under paragraph (1) or (2) of this definition was zero, had annual revenues of less than $50 million during the most recently completed fiscal year for which audited financial statements are available.'' Whether or not an issuer is a smaller reporting company is determined on an annual basis.

[28] Exchange Act Rule 3b–4(c) defines ''foreign private issuer'' as ''any foreign issuer other than a foreign government except for an issuer meeting the following conditions as of the last business day of its most recently completed second fiscal quarter: (1) More than 50 percent of the issuer's outstanding voting securities are directly or indirectly held of record by residents of the United States; and (2) (i) the majority of the executive officers or directors are United States citizens or residents, (ii) more than 50 percent of the assets of the issuer are located in the United States, or (iii) the business of the issuer is administered principally in the United States.'' Exchange Act Rule 3b–4(b) defines ''foreign issuer'' as ''any issuer which is a foreign government, a national of any foreign country or a corporation or other organization incorporated or organized under the laws of any foreign country.''

[29] Under New York Stock Exchange Rule 303A.00 and NASDAQ Stock Market LLC Rule 5615(c) a ''controlled compan[y]'' is defined as a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company.

[30] *See* Section III, below.

[31] *See* letters from Brian Foley & Company, Inc. (seeking clarification of whether Section 954 would apply to foreign private issuers and listed debt where the issuer's equity is not listed); ABA Business Law Section(recommending the Commission exercise its authority to exempt foreign private issuers from Section 954 rulemaking).

[32] *See* 2013 Financial Restatements: A Thirteen Year Comparison, Audit Analytics (2014) (''A Thirteen Year Comparison'') (addressing accelerated foreign filers, non-accelerated foreign filers, accelerated U.S. filers, and non-accelerated U.S. filers), and Financial Restatement Trends in the United States: 2003–2012, Professor Susan Scholz, University of Kansas, Study Commissioned by the Center for Audit Quality (comparing U.S. and foreign issuers).

[33] *See* A Thirteen Year Comparison.

[34] *See, e.g.,* New York Stock Exchange Rule 303A.00 and NASDAQ Stock Market LLC Rule 5615(a)(3).

[35] *See* letter from ABA Business Law Section.

[36] *See* Section II.C.3.b, below, for a discussion of proposed board discretion in these circumstances.

[37] As defined in Exchange Act Rule 12b–2 [17 CFR 240.12b–2].

[38] *See* A Thirteen Year Comparison.

securities. Accordingly, apart from the proposed exemptions discussed below, we are proposing that the listing standards and other requirements of the proposed rule and rule amendments apply without regard to the type of securities issued, including to issuers of listed debt or preferred securities that do not have listed equity. As described in the Economic Analysis,[39] the potential benefits of a recovery policy would likely accrue to the holders of debt and preferred securities as well as to equity holders. For the same reasons, we do not propose to grant the exchanges discretion to decide whether certain categories of securities should be exempted from the proposed listing standards.

Request for Comment

1. Should the listing standards and other requirements of the proposed rule and rule amendments apply generally to all listed issuers, as proposed? If not, what types of issuers should be exempted, and why? Please explain the rationale that justifies exempting any particular category of issuer.

2. Should we distinguish among listed issuers based on the types of securities listed? Please explain the rationale for any such exemption. For example, do issuers with listed non-convertible debt or preferred stock that do not have listed common equity raise the same concerns as issuers with listed common equity? For listed issuers that do not have listed common equity, do the different residual claims against the cash flows of the issuer warrant a different treatment?

3. Would the proposed listing standards conflict with any home country laws, stock exchange requirements, or corporate governance arrangements that apply to foreign private issuers? If so, please explain the nature of those conflicts. Should the proposed rule and rule amendments allow exchanges to permit foreign private issuers to forego recovery of erroneously awarded compensation if recovery would violate the home country's laws and certain conditions were met, as proposed? Is such an exception necessary or appropriate? If no, why not? If not, are there more appropriate or effective means to address such conflicts?

4. In the event that a foreign private issuer's home country has a law that like Section 10D requires the issuer to disclose its policies on incentive-based compensation and recover erroneously awarded incentive-based compensation from current or former executive officers,[40] should the foreign private issuer be permitted to comply with its home country law instead of complying with the listing standard of the U.S. exchange that lists the foreign private issuer's securities? Please explain why or why not.

5. Should there be a mechanism to determine whether additional categories of issuers and/or securities should be exempted from the proposed listing standards? If so, what mechanism would be appropriate? Should new financial products that may be developed in the future be subject to the proposed requirements? Why or why not? What principles or requirements, if any, should apply to any mechanism? In the absence of a discretionary mechanism for future exemptions, would the proposed rule potentially hinder competition? If so, how?

2. Securities Futures Products and Standardized Options

The Exchange Act's definition of ''equity security'' includes any security future on any stock or similar security.[41] Exchanges registered under Section 6 of the Exchange Act and associations registered under Section 15A(a) of the Exchange Act may trade futures on individual securities and on narrow-based security indexes (''securities futures products'')[42] without such securities being subject to the registration requirements of the Securities Act of 1933 (''Securities Act'') and the Exchange Act so long as they are cleared by a clearing agency that is registered under Section 17A of the Exchange Act or that is exempt from registration under Section 17A(b)(7) of the Exchange Act.[43] In December 2002, we adopted rules to provide comparable regulatory treatment for standardized options.[44]

The role of a clearing agency as the issuer for security futures products and standardized options is fundamentally different from that of other listed issuers.[45] The purchaser of security futures products and standardized options does not, except in the most formal sense, make an investment decision regarding the clearing agency. As a result, information about the clearing agency's business, its officers and directors and their compensation, and its financial statements is less relevant to investors in these securities than information about the issuer of the underlying security.[46] Moreover, the investment risk in security futures products and standardized options is largely determined by the market performance of the underlying security rather than the performance of the clearing agency, which is a self-regulatory organization subject to regulatory oversight.

In recognition of such fundamental differences, the Commission provided exemptions for security futures products and standardized options when it adopted the audit committee listing requirements in Exchange Act Rule10A–3[47] and the compensation committee listing requirements in Exchange Act Rule 10C–1.[48] Specifically, these rules exempt the listing of a security futures

[39] *See* Section III, below.

[40] *See, e.g.,* the UK Corporate Governance Code, September 2014, available at *https://frc.org.uk/Our-Work/Publications/Corporate-Governance/UK-Corporate-Governance-Code-2014.pdf.* Under Section D. of the Corporate Governance Code, a company's remuneration scheme for executive directors for performance-related remuneration should ''include provisions that would enable the company to recover sums paid or withhold the payment of any sum, and specify the circumstances in which it would be appropriate to do so.'' *See also, e.g.,* Directive 2013/36/EU of the European Parliament and of the Council of June 26, 2013, available at *http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0036.* The EU Capital Requirements Directive IV includes specific requirements on compensation, including a bonus cap up to 100% of variable remuneration or, with shareholder approval, 200% of total fixed pay, which must be subject to ''malus or clawback'' arrangements.

[41] Exchange Act Section 3(a)(11).

[42] Exchange Act Section 3(a)(56) [15 U.S.C. 78c(a)(56)], and Commodities Exchange Act Section 1a(32) [7 U.S.C. 1a(32)] define ''security futures product'' as any security future or any put, call, straddle, option or privilege on any security future.

[43] *See* Securities Act Section 3(a)(14) [15 U.S.C. 77c(a)(14)], Exchange Act Section 12(a) [15 U.S.C. 78l(a)], and Exchange Act Rule 12h–1(e) [17 CFR 240.12h–1(e)].

[44] *See* Release No. 33–8171 (Dec. 23, 2002) [68 FR 188]. In that release, we exempted standardized options issued by registered clearing agencies and traded on a registered exchange or on a registered association from all provisions of the Securities Act, other than the antifraud provision of Section 17, as well as the Exchange Act registration provisions. Standardized options are defined in Exchange Act Rule 9b–1(a)(4) [17 CFR 240.9b–1(a)(4)] as option contracts trading on an exchange, an automated quotation system of a registered association, or a foreign securities exchange which relate to option classes the terms of which are limited to specific expiration dates and exercise prices, or such other securities as the Commission may, by order, designate.

[45] *See* Fair Administration and Governance of Self-Regulatory Organizations; Disclosure and Regulatory Reporting by Self-Regulatory Organizations; Recordkeeping Requirements for Self-Regulatory Organizations; Ownership and Voting Limitations for Members of Self-Regulatory Organizations; Ownership Reporting Requirements for Members of Self-Regulatory Organizations; Listing and Trading of Affiliated Securities by a Self-Regulatory Organization, Release No. 34–50699 (Nov. 18, 2004) [69 FR 71126], at n. 260 (''Standardized options and security futures products are issued and guaranteed by a clearing agency.'')

[46] *See Listing Standards for Compensation Committees,* Release No. 33–9199 (Mar. 30, 2011) at Section II.B.2.b.

[47] *See* Exchange Act Rules 10A–3(c)(4) and (5).

[48] *See* Exchange Act Rules 10C–1(b)(5)(iii) and (iv).

product cleared by a clearing agency that is registered pursuant to Section 17A of the Exchange Act or that is exempt from registration pursuant to Section 17A(b)(7)(A) and the listing of a standardized option issued by a clearing agency that is registered pursuant to Section 17A of the Exchange Act. For the reasons that we exempted these securities from Rules 10A–3 and 10C–1, and because any relationship between any incentive-based compensation that the clearing agency pays its executive officers and its financial statements would not be significant to investors in these futures and options, we propose to exempt these securities from the requirements of proposed Rule 10D–1.[49]

Request for Comment

6. Are our proposed exemptions for listing securities futures products and standardized options appropriate? Why or why not?

7. Are there other types of securities that we should consider exempting from Rule 10D–1? If so, please explain which securities we should exempt and why.

3. Registered Investment Companies

In some cases, registered investment companies list their securities on an exchange. These registered investment companies generally include closed-end management investment companies and certain open-end management investment companies and unit investment trusts (''UITs'') that operate as exchange-traded funds (''ETFs'').[50] Listed registered management investment companies, unlike most other issuers, are generally externally managed and often have few, if any, employees that are compensated by the registered management investment companies, (*i.e.,* the issuers). Instead, registered management investment companies typically rely on employees of the investment adviser to manage fund assets and carry out other related business activities. Such employees are typically compensated by the investment adviser of the registered management investment company as opposed to the fund. There are a small number of listed registered management investment companies that are internally managed. Such internally managed registered management investment companies might pay executive officers incentive-based compensation, as defined in proposed Rule 10D–1.

We believe that a listed registered management investment company[51] should be subject to the requirements of proposed Rule 10D–1 only to the extent that it pays executive officers incentive-based compensation. Accordingly, we propose to exempt the listing of any security issued by a registered management investment company if such management company has not awarded incentive-based compensation to any executive officer of the registered management investment company in any of the last three fiscal years or, in the case of a company that has been listed for less than three fiscal years, since the initial listing.[52] Management investment companies that have paid incentive-based compensation in that time period, however, would be subject to the rule and rule amendments and be required to have implemented a compensation recovery policy like other listed issuers. The conditional exemption would avoid causing management investment companies that do not pay incentive-based compensation to develop recovery policies they may never use.

We are also proposing to exempt the listing of any security issued by a UIT from the requirements of proposed Rule 10D–1.[53] Unlike management investment companies, UITs are pooled investment entities without a board of directors, corporate officers, or an investment adviser to render investment advice during the life of the UIT. In addition, because the investment portfolio of a UIT is generally fixed, UITs are not actively managed. Also, unlike registered management investment companies, UITs do not file a certified shareholder report. Accordingly, we believe that due to their particular structure and characteristics, the requirements of proposed Rule 10D–1 would be inapplicable to UITs.[54]

We are also proposing to amend Form N–CSR to redesignate Item 12 as Item 13[55] and to add new paragraph (a)(3) to that Item. The new paragraph would require any registered management investment company that would be subject to the requirements of proposed Rule 10D–1 to include as an exhibit to its annual report on Form N–CSR its policy on recovery of incentive-based compensation.

We are also proposing to add new Item 12 to Form N–CSR as well as to amend Item 22 of Schedule 14A of the Exchange Act. Both amendments would require registered management investment companies that would be subject to proposed Rule 10D–1 to provide information that would mirror the disclosure requirements of Item 402(w) of Regulation S–K.[56]

Request for Comment

8. Are the exemptions for registered management investment companies and UITs as described above appropriate? Why or why not?

9. Should we conditionally exempt business development companies from the proposed listing standards, to the same extent as we propose to do with registered management investment companies? If so, please explain why.

10. Should we unconditionally exempt registered management investment companies from the proposed listing standards, as we propose to do with UITs? Should we unconditionally exempt registered open-end management investment companies that list their securities on an exchange, and only apply the conditional exemption to closed-end management investment companies? Please explain why.

11. Should we require listed registered management investment companies to disclose in annual reports on Form N–CSR or elsewhere whether or not the registered management investment company has in fact

[49] For these same reasons, we believe exempting such securities from Rule 10D–1 would be in the public interest and consistent with the protection of investors. See Exchange Act Section 36(a).

[50] See Investment Company Act Sections 5(a)(1) (definition of open-end management investment company) and 5(a)(2) (definition of closed-end management investment company) [15 U.S.C. 80a–5(a)]. See also Investment Company Act Section 4(2) (definition of UIT). ETFs are open-end management investment companies or UITs that offer redeemable securities that are listed and trade on an exchange. Since the investment portfolio of a UIT is generally fixed, UITs are not management investment companies. See text following note 48 below.

[51] We note that, as proposed, business development companies, which are a category of closed-end management investment company that are not registered under the Investment Company Act, would be subject to proposed Rule 10D–1. [15 U.S.C. 80a–2(a)(48) and 80a–53–64]. The purpose of business development companies is to fund small and developing businesses. In discussing the amendments to the Investment Company Act that established business development companies, the House Report noted such companies' special purpose and specifically recognized the need for such companies to be able to offer incentive-based compensation to their officers. *See* H.R. Rep. No. 1341, 96th Cong., 2d Sess. 21 (1980). We therefore see no reason to exempt business development companies that list their securities for trading on an exchange from the general requirements of the proposed rule.

[52] Proposed Rule 10D–1(b)(2)(iv). We expect that each exchange and association would adopt the necessary listing standards to ensure that those registered management investment companies that qualify for the exemption have complied with the proposed rule's exemption requirements.

[53] Proposed Rule 10D–1(b)(2)(iii).

[54] For similar reasons, the Commission exempted UITs when it adopted the audit committee listing requirements in Exchange Act Rule 10A–3. *See* Exchange Act Rules 10A–3(c)(6).

[55] We are also proposing a conforming amendment to General Instruction D to Form N–CSR to refer to redesignated Item 13(a)(1).

[56] *See* Section II.D.1, below.

awarded incentive-based compensation to executive officers in the last three fiscal years, or in the case of a registered management investment company that has been listed for less than three fiscal years, since the listing of the registered management investment company? Should a similar disclosure requirement apply to UITs?

B. Restatements

1. Restatements Triggering Application of Recovery Policy

Sections 10D(a) and 10D(b)(2) require exchanges and associations to adopt listing standards that require issuers to adopt and comply with policies that require recovery ''in the event that the issuer is required to prepare an accounting restatement due to the material noncompliance of the issuer with any financial reporting requirement under the securities laws.'' The Senate Report indicated that Section 10D was intended to result in ''public companies [adopting policies] to recover money that they erroneously paid in incentive compensation to executives as a result of material noncompliance with accounting rules. This is money that the executive would not have received if the accounting was done properly.'' [57] Commenters equested guidance regarding the definition of material noncompliance generally.[58] One commenter recommended that the Commission either identify the circumstances that would constitute material noncompliance with financial reporting requirements or, at a minimum, provide examples of such circumstances as a guide for making such a determination, since the determination of whether or not any noncompliance is material would be based on the facts and circumstances of each situation.[59] In addressing who must make the material noncompliance determination, one commenter noted that Section 10D was unclear as to who must make this determination [60] and others recommended that the determination be left to the issuer.[61]

Two commenters noted that because a restatement would have to be the result of material noncompliance with financial reporting requirements, Congress recognized that not all accounting restatements would require recovery.[62] Several commenters recommended that the Commission exclude restatements based on changes in generally accepted accounting principles from the types of restatements that trigger recovery.[63] Another commenter observed that a change in accounting standards would appear not to trigger recovery, but a change in how an auditor interprets accounting standards may trigger recovery, even absent issues regarding whether the issuer had adequate controls in place over its financial reporting system.[64]

We believe that an error that is material to previously issued financial statements constitutes ''material noncompliance'' by the issuer with a financial reporting requirement under the securities laws, as contemplated by Section 10D. Accordingly, proposed Rule 10D–1 would provide that issuers adopt and comply with a written policy providing that in the event the issuer is required to prepare a restatement [65] to correct an error [66] that is material to previously issued financial statements,[67] the obligation to prepare the restatement would trigger application of the recovery policy.[68] In connection with this, proposed Rule 10D–1 would define an accounting restatement as the result of the process of revising previously issued financial statements to reflect the correction of one or more errors that are material to those financial statements.[69] We do not propose to describe any type or characteristic of an error that would be considered material for purposes of the listing standards required by proposed Rule 10D–1 because materiality is a determination that must be analyzed in the context of particular facts and circumstances. Moreover, materiality has received extensive and comprehensive judicial and regulatory attention.[70] We note that issuers should consider whether a series of immaterial error corrections, whether or not they resulted in filing amendments to previously filed financial statements, could be considered a material error when viewed in the aggregate.

As indicated in the accounting standards, the following types of changes to an issuer's financial statements do not represent error corrections, and therefore would not trigger application of the issuer's recovery policy under the proposed listing standards:

- Retrospective application of a change in accounting principle; [71]
- Retrospective revision to reportable segment information due to a change in

[57] Senate Report at 135.

[58] *See* letters from Frederic W. Cook & Co., Inc., Towers Watson, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC and Compensia, Inc.

[59] *See* letter from Compensia, Inc.

[60] *See* letter from Compensia, Inc.

[61] *See* letters from Baker, Donelson, Bearman, Caldwell & Berkowitz, PC and Davis Polk & Wardwell LLP.

[62] *See* letters from Towers Watson and Baker, Donelson, Bearman, Caldwell & Berkowitz, PC.

[63] *See* letters from Center on Executive Compensation, Frederic W. Cook & Co., Inc. and Protective Life Corporation.

[64] *See* letter from Towers Watson.

[65] Under U.S. Generally Accepted Accounting Principles (''GAAP''), a restatement is ''the process of revising previously issued financial statements to reflect the correction of an error in those financial statements.'' *See* FASB ASC Topic 250, *Accounting Changes and Error Corrections* (formerly SFAS No. 154, *Accounting Changes and Error Corrections*) (''ASC Topic 250''). Under International Financial Reporting Standards as issued by the International Accounting Standards Board (''IFRS''), a retrospective restatement is ''correcting the recognition, measurement and disclosure of amounts of elements of financial statements as if a prior period error had never occurred.'' *See* IAS 8, *Accounting Policies, Changes in Accounting Estimates and Errors,* paragraph 5.

[66] Under GAAP, an error in previously issued financial statements is ''[a]n error in recognition, measurement, presentation, or disclosure in financial statements resulting from mathematical mistakes, mistakes in the application of generally accepted accounting principles (GAAP), or oversight or misuse of facts that existed at the time the financial statements were prepared. A change from an accounting principle that is not generally accepted to one that is generally accepted is a correction of an error.'' *See* ASC Topic 250. Under IFRS, prior period errors are ''omissions from, and misstatements in, the entity's financial statements for one or more prior periods arising from a failure to use, or misuse of, reliable information that: (a) Was available when financial statements for those periods were authorised for issue; and (b) could reasonably be expected to have been obtained and taken into account in the preparation and presentation of those financial statements. Such errors include the effects of mathematical mistakes, mistakes in applying accounting policies, oversights or misinterpretations of facts, and fraud.'' *See* IAS 8, *Accounting Policies, Changes in Accounting Estimates and Errors,* paragraph 5.

[67] When we refer to financial statements, we mean the statement of financial position (balance sheet), income statement, statement of comprehensive income, statement of cash flows, statement of owners' equity, and accompanying footnotes, as required by Commission regulations. When we refer to financial statements for registered investment companies and business development companies, we mean the statement of assets and liabilities (balance sheet) or statement of net assets, statement of operations, statement of changes in net assets, statement of cash flows, schedules required by Rule 6–10 of Regulation S–X, financial highlights, and accompanying footnotes, as required by Commission regulations.

[68] Proposed Rule 10D–1(c)(5).

[69] Proposed Rule 10D–1(c)(1)

[70] *See, e.g., TSC Industries, Inc.* v. *Northway,* 426 U.S. 438 (1976); *Basic* v. *Levinson,* 485 U.S. 224 (1988).

[71] A change in accounting principle is ''[a] change from one generally accepted accounting principle to another generally accepted accounting principle when there are two or more generally accepted accounting principles that apply or when the accounting principle formerly used is no longer generally accepted. A change in the method of applying an accounting principle also is considered a change in accounting principle.'' *See* ASC Topic 250. IAS 8 has similar guidance. A change from an accounting principle that is not generally accepted to one that is generally accepted, however, would be a correction of an error.

the structure of an issuer's internal organization;[72]

- Retrospective reclassification due to a discontinued operation;[73]
- Retrospective application of a change in reporting entity, such as from a reorganization of entities under common control;[74]
- Retrospective adjustment to provisional amounts in connection with a prior business combination;[75] and
- Retrospective revision for stock splits.

Request for Comment

12. For purposes of proposed Rule 10D–1, an accounting restatement would be defined as the result of the process of revising previously issued financial statements to correct errors that are material to those financial statements. Rather than including this definition in our proposed rule, should we refer to the definition of ''restatement'' in GAAP?[76] If we do not refer to the definition in GAAP, is it appropriate to include in the proposed definition the phrase ''errors that are material'' or might it be confusing or redundant? Is our proposed approach the appropriate means to implement Section 10D, including its ''material noncompliance'' provision?

13. If an issuer evaluates whether certain errors are material, and concludes that such errors are immaterial or are not the result of material noncompliance, should the issuer disclose its evaluation? If so, what should be disclosed and where should such disclosure be required?

14. Should any revision to previously issued financial statements that results in a reduction in incentive-based compensation received by an executive officer always trigger application of an issuer's recovery policy under the proposed listing standards? Why or why not?

15. As noted above, certain changes to the financial statements would not trigger recovery because they do not represent error corrections under the accounting standards. Are there any other types of changes to an issuer's financial statements that should not be deemed to trigger application of the issuer's recovery policy?

16. Should the proposed listing standards contain any anti-evasion language regarding the circumstances in which recovery would be triggered? If so, what should the language provide?

2. Date the Issuer Is Required To Prepare an Accounting Restatement

Section 10D(b)(2) requires exchanges and associations to adopt listing standards that require issuers to adopt and comply with policies that require the recovery of excess incentive-based compensation ''during the 3-year period preceding the date on which the issuer is required to prepare an accounting restatement.'' Section 10D does not specify when a listed issuer is ''required to prepare an accounting restatement'' for purposes of this recovery provision.

Several commenters requested clarification on how to determine the date on which the issuer is ''required to prepare an accounting restatement'' and provided suggestions in this regard.[77] One commenter asked whether a restatement would be ''required'' for purposes of Section 10D as of the date the financial statements are stated incorrectly.[78] Another commenter expressed the view that the date of the erroneous statement should be the date on which a new statement must be prepared.[79] Other commenters recommended that the recovery trigger should be the date the issuer files an accounting restatement due to the issuer's material noncompliance with a financial reporting requirement under the securities laws.[80] A different commenter suggested using the date the decision to undertake the restatement is made, providing as examples the date an issuer's board of directors authorizes the preparation of an accounting restatement or the date a court or regulatory authority orders or requires an issuer to prepare an accounting restatement.[81] Another commenter recommended that the issuer be deemed ''required to prepare an accounting restatement'' when a Current Report on Form 8–K is filed disclosing non-reliance on the issuer's financial statements, or, if no Form 8–K is required, the date that either the board of directors or management determines that a restatement is required.[82]

We considered the alternatives identified by commenters for when an issuer is ''required to prepare an accounting restatement'' for purposes of the proposed listing standards, and are concerned that some of these alternatives would not operate effectively with the three-year look-back period for recovery prescribed by Section 10D. While the issuer has an obligation to file materially complete and accurate financial statements, which could support using the date the erroneous financial statements were filed as the triggering date for Section 10D, we believe this approach would not fully effectuate Section 10D's purpose. If the date of filing of the erroneous financial statements were used as the starting point for the look-back period, recovery would not apply to any incentive-based compensation received after that date, even when the amount was affected by the erroneous financial statements. For example, if 2014 net income was materially misstated, and a 2014–2016 long-term incentive plan had a performance measure of three-year cumulative net income, a look-back period that covered only the three years before the erroneous filing would not capture the compensation earned under that plan. While the date of the erroneous filing is easily discernible, using this date may result in listed issuers recovering only incentive-based compensation that was received during the fiscal year preceding the filing date of the financial statements that included the subsequently restated financial reporting measure. We believe this result would be inconsistent with the three-year look-back period that the statute specifies.

We also considered using the date the issuer files the accounting restatement for triggering the three-year look-back period. However, we believe this approach also would not appropriately implement Section 10D because the issuer necessarily would have been required to prepare an accounting restatement at some point before it actually filed the restatement.[83] Moreover, an issuer might improperly delay filing a restatement after determining that restatement was necessary, and by doing so could affect

[72] If an issuer changes the structure of its internal organization in a manner that causes the composition of its reportable segments to change, the corresponding information for earlier periods, including interim periods, should be revised unless it is impracticable to do so. *See* ASC Topic 280–10–50–34. IFRS 8 has similar guidance.

[73] *See* ASC Topic 205–20. IFRS 5 has similar guidance.

[74] *See* ASC Topic 250–10–45–21. IFRS does not have specific guidance addressing this reporting matter.

[75] *See* ASC Topic 805–10–25–13. IFRS 3 has similar guidance.

[76] *See* n.65, above.

[77] *See* letters from Center on Executive Compensation, Compensia, Inc., Davis Polk & Wardwell LLP, Meridian Compensation Partners, LLC, and Towers Watson.

[78] *See* letter from Towers Watson.

[79] *See* AFL–CIO Joint Letter.

[80] *See* letters from Center on Executive Compensation and Protective Life Corporation.

[81] *See* letter from Compensia, Inc.

[82] *See* letter from Davis Polk & Wardwell LLP.

[83] As noted in Section II.C.2.b, below, the three-year look-back period is not meant to limit or designate the reporting periods for which an accounting restatement is required, or to limit which restated financial statements may be filed with the Commission.

the amounts of compensation subject to recovery.

In considering how best to craft a trigger for recovery under the proposed listing standards, we have sought to define the date on which an accounting restatement is required in a way that provides reasonable certainty for issuers, shareholders and exchanges while not permitting issuers to avoid recovery when a material error has occurred. To that end, we are proposing a definition that would be triggered by the occurrence of certain issuer or third-party determinations about the need for a restatement. Specifically, under the proposed listing standards, the proposed rule would state that the date on which an issuer is required to prepare an accounting restatement is the earlier to occur of:

- The date the issuer's board of directors, a committee of the board of directors, or the officer or officers of the issuer authorized to take such action if board action is not required, concludes, or reasonably should have concluded, that the issuer's previously issued financial statements contain a material error; or
- The date a court, regulator or other legally authorized body directs the issuer to restate its previously issued financial statements to correct a material error.[84]

A note to the proposed rule would indicate that the first proposed date generally is expected to coincide with the occurrence of the event described in Item 4.02(a) of Exchange Act Form 8–K, although neither proposed date is predicated on a Form 8–K having been filed.[85] For the first proposed date to occur, the issuer merely needs to have concluded that previously issued financial statements contain a material error, which we expect may occur before the precise amount of the error has been determined. While we recognize that listed issuers must apply judgment before concluding that previously issued financial statements contain a material error, we believe this judgment should be applied on an objective basis, which is when a reasonable issuer, based on the facts available, would have concluded that the previously issued financial statements contain a material error. In this regard, while not dispositive, we believe that an issuer would have to consider carefully any notice received from its independent auditor that previously issued financial statements contain a material error.

We recognize that the second proposed date on which an issuer would be required to prepare a restatement for purposes of Section 10D may occur earlier than the board's determination if a court or other legally authorized body, such as a regulator, directs the issuer to restate.

We believe a definition that incorporates the proposed triggering events rather than leaving the determination solely to the discretion of the issuer would better realize the objectives of Section 10D while providing clarity about when a recovery policy, and specifically the determination of the three-year look-back period, will be triggered for purposes of the proposed listing standards. In this regard, we note that the proposed rule also states that an issuer's obligation to recover excess incentive-based compensation is not dependent on if or when the restated financial statements are filed. Further, we note that issuers that knowingly, recklessly or negligently misreport materially false or misleading financial information would be subject to liability under existing antifraud provisions.[86]

Request for Comment

17. Is it appropriate to treat the earlier of the two proposed dates as ''the date on which an issuer is required to prepare an accounting restatement'' for purposes of triggering the Section 10D recovery obligation? If not, why not? Would using these dates provide sufficient certainty and transparency for issuers, investors and exchanges to determine when recovery would be triggered for purposes of compliance with the proposed listing standards? Are there additional triggers we should consider including?

18. Should receipt of a notice from a company's independent auditor that previously issued financial statements contain a material error constitute a date when the issuer ''reasonably should have concluded'' that such statements contain a material error? Why or why not? What if the issuer disagrees with the auditor's conclusion?

19. Are there other means of defining the date on which an issuer is required to prepare an accounting restatement that would provide clear benchmarks that do not inject subjectivity into when recovery would be triggered? If so, how should the date on which the issuer is required to prepare a restatement be defined?

C. Application of Recovery Policy

1. Executive Officers Subject to Recovery Policy

Section 10D(b)(2) requires exchanges and associations to adopt listing standards that require issuers to adopt and comply with policies that provide for recovery of excess incentive-based compensation from ''any current or former executive officer of the issuer who received incentive-based compensation.'' Section 10D does not define ''executive officer'' for purposes of the recovery policy.[87]

Several commenters requested guidance on the definition of executive officer.[88] One commenter[89] indicated that the Section 10D's reference to executive officer appears to use the executive officer definition in Exchange Act Rule 3b–7.[90] Another commenter[91] questioned whether the recovery policy would cover officers subject to Exchange Act Section 16[92] or only the

[84] Proposed Rule 10D–1(c)(2).

[85] Note to proposed Rule 10D–1(c)(2). For example, if a listed issuer files an Item 4.02(b) Form 8–K because it is advised by, or receives notice from, its independent accountant that disclosure should be made or action should be taken to prevent future reliance on a previously issued audit report or completed interim review related to previously issued financial statements that contain a material error, the triggering event for the recovery policy occurs when the listed issuer decides to restate its financial statements even if it subsequently neglects to file an Item 4.02(a) Form 8–K to report that decision.

[86] *See* Securities Act Section 17(a) [15 U.S.C. 77q(a)], Exchange Act Section 10(b) [15 U.S.C. 78j(b)] and Exchange Act Rule 10b–5 [17 CFR 240.10b–5].

[87] The Senate Committee on Banking, Housing, and Urban Affairs noted that ''[t]his policy is required to apply to executive officers, a very limited number of employees, and is not required to apply to other employees.'' Senate Report at 136.

[88] *See* letters from Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, Towers Watson and Robert E. Scully Jr.

[89] *See* letter from Towers Watson.

[90] Exchange Act Rule 3b–7 provides that ''[t]he term executive officer, when used with reference to a registrant, means its president, any vice president of the registrant in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the registrant.'' Executive officers of subsidiaries may be deemed executive officers of the registrant if they perform such policy making functions for the registrant.'' 17 CFR 240.3b–7.

[91] *See* letter from Baker, Donelson, Bearman, Caldwell & Berkowitz, PC.

[92] 15 U.S.C. 78p. As defined in Exchange Act Rule 16a–1(f) [17 CFR 240.16a–1(f)], the term ''officer'' means ''an issuer's president, principal financial officer, principal accounting officer (or, if there is no such accounting officer, the controller), any vice-president of the issuer in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the issuer. Officers of the issuer's parent(s) or subsidiaries shall be deemed officers of the issuer if they perform such policy-making functions for the issuer.'' The rule also contains specific provisions with respect to limited partnerships and trusts, and a note providing that ''policy-making function'' is not intended to include policy making functions that are not

named executive officers.[93] Another specifically recommended using the Section 16 definition of ''officer,'' and stated that executive officers of subsidiaries should be included in the definition.[94] A different commenter requested guidance regarding how the recovery policy should apply to persons who are executive officers during only a portion of the recovery period.[95]

We believe that Section 10D's mandatory recovery policy was intended to apply, at a minimum, to all executive officers of the issuer, rather than a more limited category such as the named executive officers for whom executive compensation disclosure is required under Item 402 of Regulation S–K. The Senate Report accompanying the statute indicates that ''[t]his policy is required to apply to executive officers[.]'' [96] Moreover, we believe applying the recovery policy to all executive officers would more effectively realize the statutory goal of Section 10D because officers with policy making functions and important roles in the preparation of financial statements set the tone for and manage the issuer. In this regard, we do not believe that a listed issuer should be unable to recover unearned compensation from an executive officer simply because he or she was not one of the individuals identified for purposes of Item 402's disclosure requirements.

The proposed listing standards would include a definition of ''executive officer'' in Rule 10D–1 that is modeled on the definition of ''officer'' in Rule 16a–1(f). For purposes of Section 10D, an ''executive officer'' would be the issuer's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the issuer in charge of a principal business unit, division or function (such as sales administration or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the issuer. Executive officers of the issuer's parents or subsidiaries would be deemed executive officers of the issuer if they perform such policy making functions for the issuer.[97]

In particular, the proposed definition would expressly include the principal financial officer and the principal accounting officer (or if there is no such accounting officer, the controller) among the officers specified. We believe that their responsibility for financial information justifies their inclusion in the definition of ''executive officer'' for this purpose, just as these officers were specifically included in the Rule 16a–1(f) definition of ''officer.[98] Although the compensation recovery provisions of Section 10D apply without regard to an executive officer's responsibility for preparing the issuer's financial statements, we believe that it is clearly appropriate for officers with an important role in financial reporting to be subject to the recovery policy. The proposed definition, like Rule 16a–1(f), provides that executive officers of the issuer's parents or subsidiaries may be deemed executive officers of the issuer if they perform policy making functions for the issuer. As is the case for Section 16 officer determination, if pursuant to Item 401(b) of Regulation S–K the issuer identifies a person as an ''executive officer,'' it would be presumed that the board of directors has made that judgment and the persons so identified are executive officers for purposes of proposed Rule 10D–1.[99]

Section 10D(b)(2) calls for the recovery policy to apply to ''any current or former executive officer of the issuer who received incentive-based compensation [during the three-year look-back period].'' We believe that the statute was designed to require recovery of excess incentive-based compensation provided for service as an executive officer. Accordingly, the rule and rule amendments we propose would require recovery of excess incentive-based compensation received by an individual who served as an executive officer of the listed issuer at any time during the performance period for that incentive-based compensation.[100] This would include incentive-based compensation derived from an award authorized before the individual becomes an executive officer, and inducement awards granted in new hire situations, as long as the individual served as an executive officer of the listed issuer at any time during the award's performance period. As proposed, recovery would not apply to an individual who is an executive officer at the time recovery is required if that individual had not been an executive officer at any time during the performance period for the incentive-based compensation subject to recovery.

Request for Comment

20. Consistent with the Rule 16a–1(f) definition of ''officer'', should we define ''executive officers'' to expressly include the principal financial officer and the principal accounting officer (or if there is no such accounting officer, the controller), as proposed?

21. Are there any other officers, such as the chief legal officer, chief information officer, or such other officer, who by virtue of their position should be specifically named as executive officers subject to the issuer's recovery policy? If so, which additional officers should be subject to the issuer's recovery policy and why?

22. Are there any other officers who should be included in the group of executive officers subject to the issuer's recovery policy, but who may not fall within the proposed definition? Is the definition of executive officer appropriate? If not, how else should executive officer be defined?

23. Alternatively, is the proposed definition of ''executive officer'' too broad? Should we instead limit the recovery policy to ''named executive officers,'' as defined in Items 402(a)(3) and 402(m)(2) of Regulation S–K or otherwise define a more narrow set of officers subject to recovery?

24. Will the scope of the term ''executive officer'' for purposes of Section 10D affect issuers' practices in

significant and that persons identified as ''executive officers'' pursuant to Item 401(b) of Regulation S–K [17 CFR 229.401(b)] are presumed to be officers for purposes of Section 16, as are other persons enumerated in Rule 16a–1(f) but not in Item 401(b). 15 U.S.C. 78p.

[93] *See* Item 402(a)(3) of Regulation S–K. For smaller reporting companies and emerging growth companies, named executive officers include the following: all individuals serving as the issuer's principal executive officer or acting in similar capacities during the last completed fiscal year, regardless of compensation level; the issuer's two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at the end of the last completed fiscal year; and up to two additional individuals for whom disclosure would have been provided based on highest compensation but for the fact that the individual was not serving as an executive officer of the issuer at the end of the last completed fiscal year. *See* Item 402(m)(2) of Regulation S–K and Section 102(c) of the Jumpstart Our Business Startups Act (''JOBS Act'').

[94] *See* AFL–CIO Joint Letter.

[95] *See* letter from Baker, Donelson, Bearman, Caldwell & Berkowitz, PC.

[96] *See* Senate Report.

[97] Proposed Rule 10D–1(c)(3), which also would specify who would be executive officers if the issuer is a limited partnership or trust.

[98] 17 CFR 240.16a–1(f). In proposing their inclusion in the Rule 16a–1(f) definition of ''officer,'' the Commission noted that principal financial officers and principal accounting officers are required to sign an issuer's Securities Act registration statements and Exchange Act annual reports on Form 10–K. Release No. 34–27148 (Aug. 18, 1989) [54 FR 35667] at n. 31. Subsequently, Section 302 of SOX required the principal financial officer, as well as the principal executive officer, to certify the information contained in each annual or quarterly report filed under Section 13(a) or 15(d) of the Exchange, and the effectiveness of the issuer's internal controls. Listed companies could, of course, adopt policies that applied to a larger group of employees so long as the policy at a minimum applied to executive officers.

[99] *See* proposed Note to Rule10D–1(c)(3), modeled on the *Note* to Rule 16a–1(f).

[100] Proposed Rule 10D–1(b)(1)(i)(B).

identifying executive officers for other purposes? If so, how, and what if anything should we do to address that? Are there other means of simplifying the identification of ''executive officers'' for purposes of Rule 10D–1 that would promote consistency with identifying executive officers for other purposes, such as Item 401(b) of Regulation S–K? Is there another, more appropriate definition?

25. Is it consistent with the purposes of Section 10D to apply recovery to any incentive-based compensation earned during the three completed fiscal years immediately preceding the date that the issuer is required to prepare a restatement if that person served as an executive officer at any time during the performance period? Alternatively, should an individual be subject to recovery only for incentive-based compensation earned during the portion of the performance period during which the individual was serving as an executive officer? Should an individual who is an executive officer at the time recovery is required be subject to recovery even if that individual did not serve as an executive officer of the issuer at any time during the performance period for the affected incentive-based compensation? If a different standard should govern the circumstances when an executive officer or former executive officer is subject to recovery, what should that standard be, and why should it apply?

2. Incentive-Based Compensation

a. Incentive-Based Compensation Subject to Recovery Policy

Section 10D(b)(2) requires exchanges and associations to adopt listing standards that require issuers to adopt and comply with recovery policies that apply to ''incentive-based compensation (including stock options awarded as compensation)'' that is received, based on the erroneous data, in ''excess of what would have been paid to the executive officer under the accounting restatement.'' Implicit in these statutory requirements is that the amount of such compensation received in the three-year look-back period would have been less if the financial statements originally had been prepared as later restated.

Several commenters recommended that the Commission clarify the types of compensation to which the listing standards' recovery policy would apply.[101] To that end, some commenters suggested potential standards that focused on the compensation being based on or related to publicly reported financial statements.[102] For example, one commenter stated that any form of compensation that is contingent upon the achievement of one or more pre-determined and objective performance goals ''that expressly relate to and are derived from one or more financial or stock price metric set forth in an issuer's financial statements filed with the Commission'' should be incentive-based compensation for purposes of Section 10D.[103] In some cases, commenters suggested we look to the existing definitions of ''incentive plan,'' ''equity incentive plan award'' and ''non-equity incentive plan award'' in Item 402(a)(6)(iii) of Regulation S–K in defining incentive-based compensation subject to recovery.[104]

To identify compensation that is awarded or vests based on financial performance measures, some commenters[105] provided various examples of financial information required to be reported under the securities laws, such as revenue, net income and earnings per share, and examples of related non-GAAP measures, such as EBITDA.[106] Commenters also recommended that awards based solely on satisfaction of non-financial measures—for example, operational measures such as market share and customer satisfaction, subjective measures such as leadership, and strategic measures such as consummation of a merger—should not be subject to an issuer's recovery policy.[107] Generally, commenters who specifically addressed stock price and total shareholder return[108] measures recommended excluding them from recovery policies,[109] or expressed the view that any connection between the erroneous data relating to an accounting restatement and the fluctuating value of the issuer's stock would be tangential and speculative.[110]

One commenter who addressed the statute's inclusion of ''stock options awarded as compensation'' questioned whether recovery should apply to the extent the enhancement in an award's value is solely attributable to increases in the fair market value of the underlying shares.[111] Other commenters recommended excluding from recovery equity awards that are not granted upon achievement of one or more pre-determined and objective financial metrics, and that vest solely upon the passage of time, continued service or satisfaction of non-financial metrics.[112]

Commenters also raised questions whether other forms of compensation, such as discretionary bonuses, future benefits under supplemental retirement benefit plans calculated based on incentive compensation awards and investment returns on incentive-based compensation deferred pursuant to deferred compensation plans, would be incentive-based compensation subject to recovery.[113] In particular, some commenters requested guidance concerning bonuses paid pursuant to ''pool plans,'' where achievement of financial performance measures establishes the overall size of the bonus pool, but discretion is exercised in determining the amount of individual bonuses.[114]

In considering how best to define incentive-based compensation for purposes of the proposed rule,[115] we have considered the statutory language of Section 10D, the views of commenters, and the administrability of any mandatory recovery policy that encompasses such compensation. Rather than identifying each type or form of compensation to which a recovery policy required under the listing standards would apply, for purposes of proposed Rule 10D–1 we propose to define ''incentive-based compensation'' in a principles-based manner, which we believe would enable the rule and rule amendments to operate effectively as new forms of compensation and new measures of

[101] *See, e.g.,* letters from ABA Business Law Section, American Benefits Council, Center on Executive Compensation, Meridian Compensation Partners, LLC, Protective Life Corporation, Robert E. Scully Jr, and Society of Corporate Secretaries and Governance Professionals.

[102] *See, e.g.,* letters from ABA Business Law Section, American Benefits Council, Center on Executive Compensation, David Polk, and Meridian Compensation Partners, LLC.

[103] *See* letter from Meridian Compensation Partners, LLC.

[104] *See* letters from ABA Business Law Section and David Polk.

[105] *See, e.g.,* letters from Center on Executive Compensation, Meridian Compensation Partners, LLC and Protective Life Corporation.

[106] Earnings before interest, taxes, depreciation and amortization.

[107] *See, e.g.,* letters from Center on Executive Compensation, Meridian Compensation Partners, LLC, Protective Life Corporation, and Society of Corporate Secretaries and Governance Professionals.

[108] ''Total shareholder return'' or ''TSR'' is a measure based on the change in stock price plus dividends over a period of time.

[109] *See* letters from Center on Executive Compensation and Protective Life Corporation.

[110] *See* letter from American Benefits Council.

[111] *See* letter from American Benefits Council.

[112] *See* letters from Center on Executive Compensation, Compensia, Meridian Compensation Partners, LLC and Protective Life Corporation.

[113] *See, e.g.,* letter from Robert E. Scully, Jr.

[114] *See* letters from Center on Executive Compensation and Protective Life Corporation.

[115] The proposed definition would be applicable only to recovery of incentive-based compensation under proposed Rule 10D–1, and would not apply to the recovery of incentive-based compensation pursuant to SOX Section 304.

performance upon which compensation is based are developed. As proposed, ''incentive-based compensation'' would be defined as ''any compensation that is granted, earned or vested based wholly or in part upon the attainment of any financial reporting measure.'' [116]

The proposed definition would further provide that ''financial reporting measures'' are measures that are determined and presented in accordance with the accounting principles used in preparing the issuer's financial statements,[117] any measures derived wholly or in part from such financial information,[118] and stock price and total shareholder return. Such measures would be encompassed by the definition of financial reporting measures whether or not included in a filing with the Commission,[119] and may be presented outside the financial statements, such as in Management's Discussion and Analysis of Financial Conditions and Results of Operations (''MD&A'') [120] or the performance graph.[121] Accordingly, examples of financial reporting measures would include, but would not be limited to, the following accounting-based measures (including measures derived therefrom):

- Revenues;
- Net income;
- Operating income;
- Profitability of one or more reportable segments; [122]
- Financial ratios (*e.g.,* accounts receivable turnover and inventory turnover rates);
- Net assets or net asset value per share (for registered investment companies and business development companies that are subject to the rule);
- EBITDA; [123]
- Funds from operations (''FFO'') [124] and adjusted funds from operations (''AFFO'');
- Liquidity measures (*e.g.,* working capital, operating cash flow);
- Return measures (*e.g.,* return on invested capital, return on assets);
- Earnings measures (*e.g.,* earnings per share);
- Sales per square foot or same store sales, where sales is subject to an accounting restatement;
- Revenue per user, or average revenue per user, where revenue is subject to an accounting restatement;
- Cost per employee, where cost is subject to an accounting restatement;
- Any of such financial reporting measures relative to a peer group, where the issuer's financial reporting measure is subject to an accounting restatement; and
- Tax basis income.

In addition to measures that are derived from the financial statements, the proposed definition of financial reporting measures would include performance measures based on stock price or total shareholder return. Section 10D(b) requires disclosure of an issuer's policy with respect to ''incentive-based compensation that is based on financial information required to be reported under the securities laws'' and recovery of compensation awarded ''based on the erroneous data.'' Although the phrase ''financial information required to be reported under the securities laws'' might be interpreted as applying only to accounting-based metrics, we believe that it also includes performance measures such as stock price and total shareholder return that are affected by accounting-related information and that are subject to our disclosure requirements.[125] Further, Congress' direction to include compensation that is *based on* financial information and to recover compensation *based on* the erroneous accounting data suggests that we should include incentive compensation tied to measures such as stock price and total shareholder return to the extent that improper accounting affects such measures, and in turn results in excess compensation. We also recognize that total shareholder return is a frequently used performance metric for executive compensation,[126] and that excluding it might not promote the goals we believe Congress intended. Moreover, we are concerned that not including TSR could incentivize issuers to alter their executive compensation arrangements in ways that would avoid application of the mandatory recovery policy and result in less efficient incentive alignment.[127]

In proposing that the statutory language should be interpreted to encompass incentive-based compensation tied to stock price and total shareholder return, as well as accounting-based metrics, we have considered potential administrative burdens that could be imposed on issuers in determining the amount of compensation to be recovered. In some cases, issuers may need to engage in complex analyses that require significant technical expertise and specialized knowledge, and may involve substantial exercise of judgment in order to determine the stock price impact of a material restatement. Due to the presence of confounding factors, it sometimes may be difficult to establish the relationship between an accounting error and the stock price. We recognize these potential challenges and, as discussed more fully below,[128] are proposing that issuers be permitted to use reasonable estimates when determining the impact of a restatement on stock price and total shareholder return and to require them to disclose the estimates.[129] We believe that being able to use reasonable estimates to assess the effect of the accounting restatement on these performance measures in determining the amount of erroneously awarded compensation should help to mitigate these potential difficulties.

While the definition we are proposing is intended to be applied broadly and flexibly, it does not encompass all forms

[116] *See* proposed Rule 10D–1(c)(4). ''In part,'' is included in the definition to clarify that incentive-based compensation need not be based solely upon attainment of a financial reporting measure. An example of compensation that is based in part upon the attainment of a financial reporting measure would include an award in which 60 percent of the target amount is earned if a certain revenue level is achieved, and 40 percent of the target amount is earned if a certain number of new stores are opened. Similarly, an award for which the amount earned is based on attainment of a financial reporting measure but is subject to subsequent discretion by the compensation committee to either increase or decrease the amount would be based in part upon attainment of the financial reporting measure.

[117] For foreign private issuers whose financial statements are based upon a comprehensive body of accounting principles other than GAAP or IFRS, the restatement would relate to amounts reported using such other accounting principles but not the reconciliation to GAAP. We would not consider the reconciliation to GAAP to be within the meaning of financial reporting measures for purposes of this proposed rule.

[118] The proposed definition is broader than a ''non-GAAP financial measure'' for purposes of Exchange Act Regulation G [17 CFR 244.100 *et seq.*] and Item 10 of Regulation S–K [17 CFR 229.10].

[119] For example, same store sales or regional sales volume may not be disclosed in a filing with the Commission, but nevertheless could be affected by an accounting restatement for revenue recognition.

[120] 17 CFR 229.303. *See also* Item 5, Form 20–F. Examples of this could be accounts receivable turnover, EBITDA, or sales per square foot.

[121] 17 CFR 229.201(e).

[122] As disclosed in a financial statement footnote. *See* ASC Topic 280.

[123] Earnings before interest, taxes, depreciation and amortization.

[124] FFO is a non-GAAP financial measure commonly used in the real estate industry.

[125] In this regard, we note that Item 201 of Regulation S–K requires issuers with common equity the principal market for which is an exchange, to disclose the high and low sales prices ''for each full quarterly period within the two most recent fiscal years and any subsequent interim period for which financial statements are included . . . .'' In addition, Item 201(e) of Regulation S–K requires issuers that are not smaller reporting companies to disclose stock price information and a performance graph comparing the company's cumulative total shareholder return with a performance indicator of the overall stock market and either a published industry index or company-determined peer comparison.

[126] *See* Section III, below.

[127] *See* Section III, below.

[128] *See* Section II.C.3.a, below.

[129] *See* Section II.D.1, below.

of incentive compensation.[130] An incentive plan award that is granted, earned or vested based solely upon the occurrence of certain non-financial events, such as opening a specified number of stores, obtaining regulatory approval of a product, consummating a merger or divestiture, completing a restructuring plan or financing transaction, would not be ''incentive-based compensation'' because these measures of performance are not financial reporting measures. Although these non-financial metrics are not included in the proposed definition, we are soliciting comment below on whether the definition of ''incentive-based compensation'' should include additional performance measures.

The statute further specifies that incentive-based compensation to which recovery should apply under the recovery policy required by the listing standard ''includ[es] stock options awarded as compensation.'' Accordingly, as proposed, ''incentive-based compensation'' would include options and other equity awards whose grant or vesting is based wholly or in part upon the attainment of any measure based upon or derived from financial reporting measures.[131] Applying the proposed Rule 10D–1 definition, compensation that would be subject to the recovery policy required by the proposed listing standards would include, but not be limited to:

- Non-equity incentive plan awards that are earned based wholly or in part on satisfying a financial reporting measure performance goal;
- Bonuses paid from a ''bonus pool,'' the size of which is determined based wholly or in part on satisfying a financial reporting measure performance goal;
- Restricted stock, restricted stock units (''RSUs''), performance share units (''PSUs''), stock options, and stock appreciation rights (''SARs'') that are granted or become vested based wholly or in part on satisfying a financial reporting measure performance goal; and
- Proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based wholly or in part on satisfying a financial reporting measure performance goal.

Examples of compensation that would *not* be ''incentive-based compensation'' for this purpose would include, but not be limited to:

- Salaries;[132]
- Bonuses paid solely at the discretion of the compensation committee or board that are not paid from a ''bonus pool,'' the size of which is determined based wholly or in part on satisfying a financial reporting measure performance goal;
- Bonuses paid solely upon satisfying one or more subjective standards (*e.g.,* demonstrated leadership) and/or completion of a specified employment period;
- Non-equity incentive plan awards earned solely upon satisfying one or more strategic measures (*e.g.,* consummating a merger or divestiture), or operational measures (*e.g.,* opening a specified number of stores, completion of a project, increase in market share); and
- Equity awards for which the grant is not contingent upon achieving any financial reporting measure performance goal and vesting is contingent solely upon completion of a specified employment period and/or attaining one or more non-financial reporting measures.

Request for Comment

26. Is the scope of incentive-based compensation subject to recovery under Section 10D(b) properly defined by reference to compensation that is granted, earned or vested based wholly or in part upon attainment of any measure that is determined or presented in accordance with applicable accounting principles? If not, please explain what other forms of compensation should be covered and why.

27. Is the proposed definition of ''incentive-based compensation'' the best means to capture all forms of compensation that could be subject to reduction if recalculated based on an accounting restatement? If not, please explain what other forms of compensation, which would not be covered by the proposed definition, should be covered.

28. Are there circumstances in which compensation that is received upon completion of a specified employment period or upon the attainment of any other goal that is not covered by our proposed definition should be considered incentive-based compensation subject to recovery? Why or why not? If so, how would an issuer calculate the recoverable amounts in the event of an accounting restatement? Are there any other measures of compensation that should be included in the definition of incentive-based compensation? If so, which ones and why?

29. Should compensation that is based upon stock price performance or total shareholder return be considered incentive-based compensation subject to recovery? If not, please explain why not. If compensation that is based on stock price performance or total shareholder return is included as incentive-based compensation subject to recovery, what calculations would need to be made to determine the recoverable amount? What are the costs and technical expertise required to prepare these calculations? Who would make these calculations for issuers? Would the costs be greater than for calculations tied to other financial reporting measures, which would be subject to mathematical recalculation directly from the information in an accounting restatement? Would the exchanges be able to efficiently assess these calculations for purposes of enforcing compliance with their listing standards? Why or why not? Should we require an independent third party to assess management's calculations?

30. Should incentive-based compensation be defined to include compensation that is based on satisfying one or more subjective standards (such as demonstrated leadership) to the extent that such subjective standards are satisfied in whole or in part by meeting a financial reporting measure performance goal (such as stock price performance or revenue metrics)? If so, how could this approach be implemented? Is it sufficient that the current proposal encompasses ''any compensation that is granted, earned or vested based wholly or in part upon the

[130] In this regard we note that the proposed definition of ''incentive-based compensation'' is narrower in scope than the definition of ''incentive plan,'' in Item 402(a)(6)(iii) of Regulation S–K, which is ''any plan providing compensation intended to serve as an incentive for performance to occur over a specified period, whether such performance is measured by reference to financial performance of the registrant or an affiliate, the registrant's stock price, or any other performance measure.'' Item 402(a)(6)(iii) of Regulation S–K [17 CFR 229.402(a)(6)(iii)]. The proposed Rule 10D–1 definition would not include ''other performance measures'' in light of Section 10D's reference to incentive-based compensation based on financial information required to be reported under the federal securities laws.

[131] This would be the standard for purposes of proposed Rule 10D–1 even though time-vested stock options are generally considered ''performance-based'' for purposes of exclusion from the Internal Revenue Code Section 162(m) $1 million cap on tax-deductible executive compensation if the amount of compensation attributable to the options is based solely on an increase in company stock price, assuming the exercise price is no less than fair market value of the underlying stock on the date of grant. *See* 26 CFR 1.162–27(e)(2)(vi).

[132] However, to the extent that an executive officer receives a salary increase earned wholly or in part based on the attainment of a financial reporting measure, such a salary increase would be subject to recovery as a non-equity incentive plan award for purposes of proposed Rule 10D–1.

attainment of a financial reporting measure''? If not, why not?

31. Should the proposed rule or listing standards contain any anti-evasion language that would treat as incentive-based compensation amounts received purportedly based on one or more subjective standards but that are in fact based on financial information metrics, total shareholder return or stock price performance? If so, what should the language provide?

32. Should the definition of ''incentive-based compensation'' included in Rule 10D–1 be principles-based, as proposed? Alternatively, should the definition specify performance measures that may be affected by an accounting restatement? If so, please explain which examples should be included and why.

33. Regarding the statutory provision that incentive-based compensation subject to recovery ''includ[es] stock options awarded as compensation,'' does the proposed definition provide a basis by which issuers can identify equity awards that would be covered? If not, please explain why not. If all options should be subject to recovery, how should the amount subject to recovery following an accounting restatement be computed for time-vested options that are not granted based on satisfaction of a financial reporting measure performance goal?

34. Regarding bonuses granted from a ''bonus pool,'' the size of which is based wholly or in part upon satisfying a financial reporting measure performance goal, does the proposed definition properly subject this form of compensation to recovery? If not, how should we treat such compensation for purposes of Rule 10D–1?

35. Is further guidance needed as to how the proposed definition would apply to forms of compensation that may be paid out on a deferred basis, such as employee or employer contributions of incentive-based compensation to nonqualified deferred compensation plans and earnings thereon, and future retirement benefits payable under pension plans, such as supplemental retirement benefit plans, that are calculated based on incentive-based compensation? [133] If so, what further guidance should we provide?

b. Time Period Covered by Recovery Policy

Section 10D(b)(2) requires exchanges and associations to adopt listing standards that require issuers to adopt and comply with recovery policies that apply to excess incentive-based compensation received ''during the three-year period preceding the date on which the issuer is required to prepare an accounting restatement'' but does not otherwise specify how this three –year look-back period should be measured. Commenters recommended that the listing standards address this point.[134] One commenter suggested that it be the three fiscal years preceding the date that a Form 8–K is filed disclosing non-reliance on the issuer's financial statements, or, if no Form 8–K is required, preceding the date that either the board of directors or management makes a determination that a restatement is required.[135]

Under proposed Rule 10D–1, the three-year look-back period for the recovery policy required by the listing standards would be the three completed fiscal years immediately preceding the date the issuer is required to prepare an accounting restatement.[136] We believe that basing the look-back period on fiscal years, rather than a preceding 36-month period, is consistent with issuers' general practice of making compensation decisions and awards on a fiscal year basis. Using the proposed recovery period trigger, if a calendar year issuer concludes in November 2018 that a restatement of previously issued financial statements is required and files the restated financial statements in January 2019, the recovery policy would apply to compensation received in 2015, 2016 and 2017. The three-year look-back period is not meant to alter the reporting periods for which an accounting restatement is required or for which restated financial statements are to be filed with the Commission.[137] Moreover, an issuer would not be able to delay or relieve itself from the obligation to recover erroneously awarded incentive-based compensation by delaying or failing to file restated financial statements.

In proposing Rule 10D–1, we considered other approaches, such as a recovery policy that requires issuers to recover incentive-based compensation received during any period of three consecutive years preceding the date on which the issuer is required to prepare an accounting restatement so long as the incentive-based compensation was affected by the error. However, we do not believe that this approach is the most appropriate means to implement Section 10D because it would require additional judgments about which three years' compensation should be subject to recovery, making it less objective and harder for exchanges and listed issuers to apply uniformly.

In situations where an issuer has changed its fiscal year end during the three-year look-back period, we are proposing that the issuer must recover any excess incentive-based compensation received during the transition period occurring during, or immediately following, that three-year period in addition to any excess incentive-based compensation received during the three-year look-back period (*i.e.,* a total of four periods).[138] A transition period refers to the period between the closing date of the issuer's previous fiscal year end and the opening date of its new fiscal year.[139] For example, consider a situation in which, in late 2015, an issuer changes its fiscal closing date from June 30 to December 31, and subsequently reports on the transition period from July 1, 2015 to December 31, 2015. If the issuer's board of directors concludes in May 2017 that it will restate previously issued financial statements due to a material error, the look-back period would consist of the year ended June 30, 2014, the year ended June 30, 2015, the period from July 1, 2015 to December 31, 2015, and the year ended December 31, 2016. However, consistent with Rule 3–06(a) of Regulation S–X, a transition period of nine to 12 months would be considered a full year in applying the three-year look-back period requirement.

Request for Comment

36. Is the proposed approach to determine the three-year look-back period for recovery an appropriate means to implement Section 10D? Does it properly reflect the way in which issuers make their compensation decisions (on a fiscal year by fiscal year basis)? Why or why not?

37. Should a different approach be used to determine the three-year look-back period for recovery? If so, how should the look-back period be determined, and why? For example, should an issuer be permitted to apply

[133] *See* Section II.C.3.a, below, addressing the computation of excess incentive-based compensation for these forms of compensation.

[134] *See* letters from Frederic W. Cook & Co., Inc., ABA Business Law Section and Baker, Donelson, Bearman, Caldwell & Berkowitz, PC.

[135] *See* letter from Davis Polk & Wardwell LLP.

[136] Proposed Rule 10D–1(b)(ii).

[137] For example, assume the three-year look-back period is 2016, 2017 and 2018, and incentive compensation received (as ''received'' would be defined in proposed Rule 10D–1(c)(6), discussed in Section II.C.2.c, below) in 2016 was earned by achieving a certain level of cumulative operating income for the two-year period from 2015 to 2016. In determining the amount of excess compensation received in 2016, the issuer would be required to prepare restated financial statements for 2015 and 2016 even if the issuer does not file one or both of those restated financial statements.

[138] Proposed Rule 10D–1(b)(1)(ii).

[139] 17 CFR 240.13a–10 and 17 CFR 240.15d–10

its recovery policy to any three-year period in which incentive-based compensation received by executive officers was affected by the accounting error?

38. Is the proposed approach regarding transition periods related to a change in fiscal year appropriate? If not, what alternative approach should we consider? Consistent with Rule 3–06(a) of Regulation S–X, should a transition period of nine to 12 months be considered a full year in satisfying the three-year look-back period requirement?

c. When Incentive-Based Compensation Is ''Received''

Section 10D does not specify when an executive officer should be deemed to have received incentive-based compensation for the recovery policy required under the applicable listing standards. One commenter asked the Commission to clarify whether an option or SAR is received when it is granted or when it is exercised or whether restricted stock, RSUs, other stock-based compensation and long-term cash incentives are received when granted, earned, vested or paid out.[140] Another commenter suggested that compensation be deemed received on the earlier of the date the compensation is paid to or earned by the executive officer, construing ''earned'' to mean when an executive officer obtains a non-forfeitable interest in a compensatory award.[141]

As proposed, incentive-based compensation would be deemed received for purposes of triggering the recovery policy under Section 10D in the fiscal period[142] during which the financial reporting measure specified in the incentive-based compensation award is attained, even if the payment or grant occurs after the end of that period.[143] Under this standard, the date of receipt would depend upon the terms of the award. If the grant of an award is based, either wholly or in part, on satisfaction of a financial reporting measure, the award would be deemed received in the fiscal period when that measure was satisfied. If an equity award vests upon satisfaction of a financial reporting measure, the award would be deemed received in the fiscal period when it vests. Similarly, a cash award earned upon satisfaction of a financial reporting measure would be deemed received in the fiscal period when that measure is satisfied.

A particular award may be subject to multiple conditions. We are not proposing that an executive officer must have satisfied all conditions to an award for the incentive-based compensation to be deemed received for purposes of triggering the recovery policy. For example, an issuer could grant an executive officer an RSU award in which the number of RSUs earned is determined at the end of the three-year incentive-based performance period (2015–2017), but the award is subject to service-based vesting for two more years (2018–2019). Although the executive officer does not have a non-forfeitable interest in the RSUs before expiration of the subsequent two-year service-based vesting period, the number of shares in which the RSUs ultimately will be paid will be established at the end of the three-year performance period. In light of Section 10D's purpose to require listed issuers to recover compensation that ''the executive would not have received if the accounting was done properly,''[144] we believe that in this circumstance the executive officer ''receives'' the compensation for purposes of triggering the recovery policy when the relevant financial reporting measure performance goal is attained, even if the executive officer has established only a contingent right to payment at that time. If the issuer's board of directors concludes in 2018 that the issuer will restate previously issued financial statements for 2015 through 2017 (the three-year performance period),[145] the recovery policy should apply to reduce the number of RSUs ultimately payable in stock, even though the executive has not yet satisfied the two-year service-based vesting condition to payment. In this example, if the executive officer were deemed not to receive the RSUs before obtaining a non-forfeitable interest in them, such a restatement of the financial statements that would reduce the number of RSUs ultimately payable in stock would not be subject to recovery because the incentive-based compensation would not have been received during the three-year look-back period. We do not believe such an outcome would appropriately implement the policy underlying Section 10D, because it would mean that the mere passage of time pursuant to a service-based vesting condition or a subsequent performance condition unrelated to a financial reporting measure[146] would preclude the issuer from recovering incentive-based compensation.

Ministerial acts or other conditions necessary to effect issuance or payment, such as calculating the amount earned or obtaining the board of directors' approval of payment, would not affect the determination of the date received. For example, for an equity award deemed received upon grant, receipt would occur in the fiscal year that the relevant financial reporting measure performance goal was satisfied, rather than a subsequent date on which the award was issued.[147] Similarly, a non-equity incentive plan award would be deemed received in the fiscal year that the executive earns the award based on satisfaction of the relevant financial reporting measure performance goal, rather than a subsequent date on which the award was paid.[148]

Under proposed Rule 10D–1, incentive-based compensation would be subject to the issuer's recovery policy to the extent that it is received while the issuer has a class of securities listed on an exchange or an association.[149] An award of incentive-based compensation granted to an executive officer before the issuer lists a class of securities would be subject to the recovery policy, so long as the incentive-based compensation was received by the executive officer while the issuer had a class of listed securities. Incentive-based compensation received by an executive officer before the issuer's securities become listed would not be subject to the recovery policy under our proposed

[140] *See* letter from Brian Foley & Company, Inc.

[141] *See* letter from Meridian Compensation Partners, LLC.

[142] Including a transition period for a change in fiscal year, if applicable.

[143] Proposed Rule 10D–1(c)(6).

[144] *See* Senate Report at 135.

[145] In this example, the three-year performance period coincides with the three-year look-back period covered by the recovery policy. *See* Section II.C.2.b. above regarding the three-year look-back period.

[146] For example, if the subsequent condition in the example above was not service-based vesting but instead called for the issuer to open 100 stores during 2018 and 2019, or required the executive to comply with a non-compete or non-solicitation covenant during those years.

[147] The fiscal year in which an incentive-based equity award is deemed received upon grant in some cases may be a fiscal year preceding the fiscal year in which the ASC Topic 718 grant date occurs and for which it is reported in the Summary Compensation Table and Grants of Plan-Based Awards Table because our requirements for reporting equity awards in the Summary Compensation Table do not utilize a ''performance year'' standard. *See Proxy Disclosure Enhancements,* Release No. 33–9089 (Dec. 16, 2009) [74 FR 68334] at Section II.A.2.c.

[148] This would be the same fiscal year for which the non-equity incentive plan award earnings are reported in the Summary Compensation Table, based on Instruction 1 to Item 402(c)(2)(vii), which provides: ''If the relevant performance measure is satisfied during the fiscal year (including for a single year in a plan with a multi-year performance measure), the earnings are reportable for that fiscal year, even if not payable until a later date, and are not reportable again in the fiscal year when amounts are paid to the named executive officer.''

[149] Proposed Rule 10D–1(b)(1)(i)(A).

rule. As proposed, an exchange would not be permitted to list an issuer that it has delisted or that has been delisted from another exchange for failing to comply with its recovery policy until the issuer comes into compliance with that policy.[150]

Request for Comment

39. Should incentive-based compensation be deemed ''received'' for purposes of triggering the recovery policy under Section 10D in the fiscal year during which attainment of the financial reporting measure specified in the incentive-based compensation award, by its terms, causes the incentive-based compensation to be granted, to be earned or to vest, as proposed? If not, when should incentive-based compensation be deemed ''received'' for purposes of triggering the recovery policy?

40. Should an executive officer be required to obtain a non-forfeitable entitlement to the incentive-based compensation to ''receive'' the compensation? Would such a requirement effectuate the purpose of Section 10D? Should the rule specifically address the treatment of awards subject to multiple vesting conditions, only some of which may be linked to financial reporting measures? If so, what would be the appropriate treatment of such rewards?

41. If following receipt, as proposed to be defined, an executive officer contributes incentive-based compensation to a nonqualified deferred compensation plan, how should deferral affect recovery? [151]

42. Should incentive-based compensation be subject to the issuer's recovery policy only to the extent that it is received while the issuer has a class of securities listed, as proposed? If not, please explain in what circumstances a different standard should apply and why. For example, if a company lists in 2017, and restates the three prior fiscal years in 2018, should its policy require recovery of incentive-based compensation received in 2015 or 2016?

3. Recovery Process

a. Determination of Excess Compensation

Section 10D(2)(b) requires exchanges and associations to adopt listing standards that require issuers to adopt and comply with recovery policies that apply to the amount of incentive-based compensation received ''in excess of what would have been paid to the executive officer under the accounting restatement.''

Commenters recommended that the Commission clarify how excess compensation subject to recovery should be determined.[152] One commenter suggested that the Commission establish a clear set of guidelines as to how issuers should calculate the recoverable amount under a variety of common arrangements, or alternatively, a clear set of principles to be used to make such calculations.[153] In some cases, commenters recommended specific ways to measure excess compensation for particular forms of incentive-based compensation. For example, for cash awards based upon the achievement of erroneous financial metrics, one commenter recommended that the excess incentive-based compensation should be the difference between the cash award that was granted and the cash award that should have been granted using the restated financial metric.[154]

Several commenters sought clarity regarding performance-based equity awards, with some recommending various methods to calculate the recoverable amount for different forms of these awards, taking into account such factors as whether an award is granted or vested based on attaining a financial statement metric, whether or not an option has been exercised, and whether the shares have been sold.[155]

Regarding bonuses paid from ''pool plans,'' two commenters questioned whether determination of the recoverable amount might depend on whether the board or compensation committee had exercised any discretion, either in determining whether to allocate the entire pool to bonus awards or in determining individual bonus amounts.[156] For example, commenters noted that if a restatement reduces the size of the bonus pool, but not below the aggregate amount that the board exercised discretion to pay out as bonuses, there would not appear to be any excess compensation to recover. Alternatively, if a restatement reduces the size of the bonus pool below the aggregate amount paid out, the commenters sought clarification whether each bonus paid would need to be ratably reduced, or if discretion could be exercised in allocating recovery of the excess amount among individual bonuses as long as the aggregate excess amount is recovered. Another commenter questioned, in general, whether the amount of compensation earned should be measured by reference to the target achieved, or the compensation actually provided after the compensation committee exercised discretion to either increase or decrease the amount.[157] A different commenter suggested that where incentive-based compensation is not determined based solely on formulaic measures, but also on qualitative measures, the same percentage recoverable from the formulaic portion based on the restatement also should be recovered from the portion based on qualitative measures.[158] Other commenters noted that executive officers would already have paid personal income taxes on incentive-based compensation they had received.[159]

We propose to define the recoverable amount as ''the amount of incentive-based compensation received by the executive officer or former executive officer that exceeds the amount of incentive-based compensation that otherwise would have been received had it been determined based on the accounting restatement.'' [160] Applying this definition, after an accounting restatement, the issuer would first recalculate the applicable financial reporting measure and the amount of incentive-based compensation based thereon. The issuer would then determine whether, based on that financial reporting measure as calculated relying on the original financial statements and taking into account any discretion that the compensation committee had applied to reduce the amount originally received, the executive officer received a greater amount of incentive-based compensation than would have been received applying the recalculated financial reporting measure.[161] Where

[150] Proposed Rule 10D–1(b)(1)(vi).

[151] *See* Section II.C.3.a, below, addressing the computation of excess incentive-based compensation for this form of compensation.

[152] *See, e.g.,* letters from Center on Executive Compensation, Compensia, Inc., Meridian Compensation Partners, LLC, Pay Governance LLC and Towers Watson.

[153] *See* letter from Compensia, Inc.

[154] *See* letter from Center on Executive Compensation.

[155] *See, e.g.,* letters from Compensia, Inc., and Meridian Compensation Partners, LLC.

[156] *See* letters from Center on Executive Compensation and Protective Life Corporation.

[157] *See* letter from Davis Polk & Wardwell LLP.

[158] *See* AFL-CIO Joint Letter.

[159] *See* letters from Clark Consulting, Davis Polk & Wardwell LLP and Frederic W. Cook & Co, Inc.

[160] Proposed Rule 10D–1(b)(1)(iii).

[161] For example, assume a situation in which, based on the financial reporting measure as originally reported, the amount of the award was $3,000. However, the issuer exercised negative discretion to pay out only $2,000. Following the restatement, the amount of the award based on the corrected financial reporting measure is $1,800. Taking into account the issuer's exercise of negative

Continued

incentive-based compensation is based only in part on the achievement of a financial reporting measure performance goal, the issuer first would determine the portion of the original incentive-based compensation based on or derived from the financial reporting measure that was restated. The issuer would then need to recalculate the affected portion based on the financial reporting measure as restated, and recover the difference between the greater amount based on the original financial statements and the lesser amount that would have been received based on the restatement.[162]

For incentive-based compensation that is based on stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the recoverable amount may be determined based on a reasonable estimate of the effect of the accounting restatement on the applicable measure.[163] To reasonably estimate the effect on the stock price, there are a number of possible methods with different levels of complexity of the estimations and related costs.[164] For these measures, the issuer would be required to maintain documentation of the determination of that reasonable estimate and provide such documentation to the relevant exchange or association.[165]

The recoverable amount would be calculated on a pre-tax basis [166] to ensure that the company recovers the full amount of incentive-based compensation that was erroneously awarded, consistent with the policy underlying Section 10D. Recovery on a pre-tax basis also would permit the company to avoid the burden and administrative costs associated with calculating recoverable amounts based on the particular tax circumstances of individual executive officers, which may vary significantly based on factors independent of the incentive-based compensation.

While we intend for the definition to apply in a principles-based manner, we recognize that applying the principles may not always be simple. Cash awards that are received upon satisfaction of a financial reporting measure should be relatively straightforward. The recoverable amount would be the difference between the amount of the cash award (whether payable as a lump sum or over time) that was received and the amount that should have been received applying the restated financial reporting measure.[167]

For cash awards paid from bonus pools, the size of the aggregate bonus pool from which individual bonuses are paid would be reduced based on applying the restated financial reporting measure. If the reduced bonus pool is less than the aggregate amount of individual bonuses received from it, the excess amount of an individual bonus would be the *pro rata* portion of the deficiency. If the aggregate reduced bonus pool would have been sufficient to cover the individual bonuses received from it, then no recovery would be required.

Equity awards involve different considerations. For equity awards, if the shares, options or SARs are still held at the time of recovery, the recoverable amount would be the number received in excess of the number that should have been received applying the restated financial reporting measure. If the options or SARs have been exercised, but the underlying shares have not been sold, the recoverable amount would be the number of shares underlying the excess options or SARs applying the restated financial measure. If the shares have been sold, the recoverable amount would be the sale proceeds received by the executive officer with respect to the excess number of shares.[168] In any case in which the shares have been obtained upon exercise and payment of an exercise price, the recoverable amount would be reduced to reflect the applicable exercise price paid.[169]

We recognize that there may be circumstances in which both proposed Rule 10D–1 and SOX Section 304 could provide for recovery of the same incentive-based compensation. The proposed rule is not intended to alter or otherwise affect the interpretation of Section 304 or the determination by the Commission or the courts of when reimbursement is required under Section 304. If, however, an executive officer reimburses an issuer pursuant to Section 304, such amounts should be credited to the extent that an issuer's Rule 10D–1 recovery policy requires repayment of the same compensation by that executive officer. Further, recovery under Rule 10D–1 would not preclude recovery under Section 304 to the extent any applicable amounts have not been reimbursed to the issuer.

Request for Comment

43. Do the proposed rule and rule amendments articulate an appropriate standard for calculating the amount of excess incentive-based compensation that listed issuers must recover? Why or why not?

44. For incentive-based compensation based on stock price or total shareholder return, would permitting the recoverable amount to be determined based on a reasonable estimate of the effect of the accounting restatement, as proposed, facilitate administration of the rule by issuers and exchanges? Why or why not? Should we provide additional guidance regarding how such estimates should be calculated? If so, what particular factors should that guidance address?

45. As proposed, should the issuer be required to maintain documentation of the determination of that reasonable estimate and provide such documentation to the relevant exchange? Why or why not? Is the documentation required sufficient for compliance monitoring? If not, what else should be required? Should the rule specify a period of time that an issuer would need to maintain such documentation or what types of documentation should be maintained? If so, what period of time or

discretion, the recoverable amount would be $200 (*i.e.*, $2,000—$1,800).

[162] For example, assume a situation in which, based on the financial reporting measure as originally reported, the amount of the award was $3,000. The issuer exercised positive discretion to increase the amount by $1,000, paying out a total of $4,000. Following the restatement, the amount of the award based on the corrected financial reporting measure is $1,800. Taking into account the issuer's exercise of positive discretion, the recoverable amount would be $1,200, provided that based on the revised measurement, the exercise of positive discretion to increase the amount by $1,000 was still permitted under the terms of the plan.

[163] Proposed Rule 10D–1(b)(1)(iii)(A).

[164] *See* Section III.B.2, below, discussing different methodologies for determining a reasonable estimate of the effect of the accounting restatement on the stock price or total shareholder return.

[165] Proposed Rule 10D–1(b)(1)(iii)(B).

[166] Proposed Rule 10D–1(b)(1)(iii) provides that the erroneously awarded compensation shall be computed without regard to any taxes paid by the executive officer. The pre-tax amount refers to the full amount of incentive-based compensation received by the executive officer, rather than the amount remaining after he or she satisfies his or her personal income tax obligation on it.

[167] Similarly, for nonqualified deferred compensation, the executive officer's account balance or distributions would be reduced by the excess incentive-based compensation contributed to the nonqualified deferred compensation plan and the interest or other earnings accrued thereon under the nonqualified deferred compensation plan. In addition, for retirement benefits under pension plans, the excess incentive-based compensation would be deducted from the benefit formula, and any related distributions would be recoverable.

[168] Where excess shares have been gifted, such as gifts to charities, the recoverable amount would be the gifted shares' fair market value at the date of the gift.

[169] Shares sold can be traced consistent with Treas. Reg. 1.1012–1(c) and Rule 144(d) [17 CFR 230.144(d)].

documentation is appropriate? Should we require that such determination be disclosed, either to the exchange or in Commission filings? What would be the effects of such disclosure?

46. Should the rule and rule amendments alternatively, or in addition, include specific instructions for how to compute the excess amount of specific forms of incentive-based compensation? If so, which ones and why?

47. Is further guidance needed on the application of the proposed standard? If yes, what additional guidance is necessary? Is further guidance required regarding any particular form of compensation? For example:

a. Should we provide guidance on how to determine the recoverable amount of supplemental retirement plan benefits that are calculated based on erroneously awarded incentive-based compensation? If so, what should that guidance be?

b. For equity awards granted based on satisfaction of a financial reporting measure, the guidance above directs listed issuers to recover the excess number of shares or, if no longer held, the proceeds from the sale of the excess shares so that executive officers cannot benefit from future appreciation in shares that were not earned. Instead of recovering the excess number of shares, should listed issuers have the choice to recover the cash value of the excess shares? If so, should the shares be valued at the vesting date, the date the recoverable amount is determined, or some other date?

c. Where the number of excess shares is less than the entire award and some of the shares received were sold and some are still held, should recovery be made first against the remaining shares that are held? Alternatively, should recovery apply first to shares that were sold, so as not to erode company stock holding policies? Should this decision be left to the listed issuer's discretion?

d. Where excess shares have been gifted, such as gifts to charities, should the recoverable amount be the shares' fair market value at the date of the gift? If not, at what other date should the excess shares be valued?

e. Is the guidance above appropriate for determining the recoverable amount where the listed issuer has exercised discretion to reduce or increase the original amount of incentive-based compensation received?

48. Where the issuer chose to increase the original amount of incentive-based compensation, should an amount proportionate to the effect of the restatement on the financial statement measure also be recovered from the discretionary enhancement?

49. One commenter recommended that the Commission require recovery of a proportionate amount of incentive compensation awarded under qualitative standards.[170] Should we require recovery of amounts awarded under qualitative standards that may involve judgement by the board? If so, how would the excess compensation be calculated in those instances?

50. Is further guidance needed regarding circumstances in which both proposed Rule 10D–1 and SOX Section 304 would apply?

b. Board Discretion Regarding Whether To Seek Recovery

Section 10D requires exchanges and associations to adopt listing standards that require issuers to adopt and comply with recovery policies. Specifically, the statute provides that ''the issuer will recover'' incentive-based compensation, and does not address whether there are circumstances in which an issuer's board of directors may exercise discretion not to recover.

Commenters suggested that the Commission's implementing rules should address the issue of board discretion whether to pursue recovery and, if such discretion is permitted, address its scope. Many of these commenters asserted that the Commission should allow for board discretion to determine whether to pursue recovery.[171] Commenters raised concerns about situations where the potential costs of recovery may exceed the excess incentive-based compensation to be recovered [172] and recommended that boards be permitted to evaluate the benefits of recovery against the costs involved.[173] Commenters noted the following factors that may affect this decision: the likelihood of recovery; [174] *de minimis* recovery; [175] the need to pursue litigation to recover; [176] and the possibility that recovery might violate existing statutory or contractual provisions.[177] One commenter asserted that in the absence of discretion, companies will be incentivized to implement compensation arrangements that are not subject to Section 10D recovery provisions.[178] Other commenters recommended the Commission establish a standard similar to the Troubled Asset Relief Program (''TARP'') standard where an issuer is not required to enforce its recovery policy if it would be unreasonable to do so.[179]

In considering this issue, we note that the Emergency Economic Stabilization Act of 2008 (''EESA'') contained an executive compensation recovery provision [180] applicable to any financial institution that sells troubled assets to the Secretary of the United States Department of the Treasury under TARP. In its interim final rule to provide guidance on the EESA's executive compensation and corporate governance provisions applicable to entities receiving financial assistance under TARP, the Department of the Treasury provided that ''[t]he TARP recipient must exercise its clawback rights except to the extent it demonstrates that it is unreasonable to do so, such as, for example, if the expense of enforcing the rights would exceed the amount recovered.'' [181]

We are mindful that allowing discretion whether to recover excess incentive-based compensation could undermine the purpose of Section 10D by permitting an issuer's board of directors to determine that an executive officer may retain incentive-based compensation to which he or she is not entitled. At the same time, we acknowledge that there are circumstances in which pursuing

[170] *See* AFL-CIO Joint Letter.

[171] *See* letters from Davis Polk & Wardwell LLP, Center on Executive Compensation, Meridian Compensation Partners, LLC, American Benefits Council, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, Compensia, Inc., Clark Consulting, LLC, Society of Corporate Secretaries and Governance Professionals, Frederic W. Cook & Co., Inc., Stuart R. Lombardi and Protective Life Corporation.

[172] *See* letters from Clark Consulting, LLC and ABA Business Law Section.

[173] *See* letters from Davis Polk & Wardwell LLP, Meridian Compensation Partners, LLC, American Benefits Council, Compensia, Inc., Clark Consulting, LLC, Society of Corporate Secretaries and Governance Professionals, Stuart R. Lombardi and Protective Life Corporation.

[174] *See* letter from Society of Corporate Secretaries and Governance Professionals.

[175] *See* letters from Center on Executive Compensation, Meridian Compensation Partners, LLC, American Benefits Council, Frederic W. Cook & Co., Inc., and Protective Life Corporation.

[176] *See* letters from Society of Corporate Secretaries and Governance Professionals and Center on Executive Compensation.

[177] *See* letters from Society of Corporate Secretaries and Governance Professionals and Center on Executive Compensation.

[178] *See* letter from Stuart R. Lombardi. To guard against the abuse of discretion, this commenter recommended that following a restatement an issuer either should publicly announce its decision whether to pursue or decline recovery, or should delegate all clawback decision making authority to an independent party.

[179] *See* letters from Baker, Donelson, Bearman, Caldwell & Berkowitz, PC and Compensia, Inc.

[180] Section 111(b)(3)(B) of EESA, Public Law 110–343, 12 U.S.C. 5221, as amended by Title VII of Division B of the American Recovery and Reinvestment Act of 2009 (''ARRA''), Public Law 111–5 [123 STAT. 115] (Feb. 17, 2009).

[181] TARP Standards for Compensation and Corporate Governance, 31 CFR 30.8.

recovery of excess incentive-based compensation may not be in the interest of shareholders and that a standard similar to the TARP standard would permit boards of directors to evaluate whether to pursue recovery of excess incentive-based compensation in particular circumstances.

To address these circumstances, proposed Rule 10D–1 would provide that an issuer must recover erroneously awarded compensation in compliance with its recovery policy except to the extent that pursuit of recovery would be impracticable because it would impose undue costs on the issuer or its shareholders or would violate home country law and certain conditions are met. We believe the unqualified ''no-fault'' recovery mandate of Section 10D intends that the issuer should pursue recovery in most instances. For example, we do not believe the extent to which an individual executive officer may be responsible for the financial statement errors requiring the restatement could be considered in seeking the recovery. Further, we do not view inconsistency between the proposed rule and rule amendments and existing compensation contracts, in itself, as a basis for finding recovery to be impracticable, because issuers can amend those contracts to accommodate recovery.[182]

In our view, the only criteria that should be considered are whether the direct costs of enforcing recovery would exceed the recoverable amounts or whether recovery would violate home country law. Before concluding that it would be impracticable to recover any amount of excess incentive-based compensation based on enforcement costs,[183] the issuer would first need to make a reasonable attempt to recover that incentive-based compensation.[184] The issuer would be required to document its attempts to recover, and provide that documentation to the exchange.[185] As described in Section II.D, below, the issuer also would be required to disclose why it determined not to pursue recovery. We believe that in this circumstance requiring an attempt to recover is both consistent with the no-fault character of Section 10D, and necessary for the issuer to justify concluding that recovery of the amount at issue would be impracticable. Similarly, before concluding that it would be impracticable to recover because doing so would violate home country law, the issuer first would need to obtain an opinion of home country counsel, not unacceptable to the applicable national securities exchange or association, that recovery would result in such a violation.[186] In addition, to minimize any incentive countries may have to change their laws in response to this provision, the relevant home country law must have been adopted in such home country prior to the date of publication in the **Federal Register** of proposed Rule 10D–1.

In either case, to prevent potential conflicts of interest, any determination that recovery would be impracticable would need to be made by the issuer's committee of independent directors that is responsible for executive compensation decisions.[187] In the absence of a compensation committee, the determination would need to be made by a majority of the independent directors serving on the board. Such a determination, as with all determinations under proposed Rule 10D–1, would be subject to review by the listing exchange.[188]

We believe that the proposed issuer discretion is necessary or appropriate in the public interest and consistent with the protection of investors because it would save issuers the expense of pursing recovery in circumstances where the costs of recovery could exceed or be disproportionate to the recoverable amounts, and for foreign private issuers, would avoid such issuers having to choose between potential de-listing or violating home country laws, either of which could be detrimental to shareholders. Further, as discussed below,[189] we propose to require a listed issuer to disclose the reasons why it decided not to pursue recovery in particular instances. We believe that requiring this disclosure will mitigate potential abuse of this discretion.

Request for Comment

51. Is the proposed issuer discretion not to pursue recovery of incentive-based compensation consistent with the purpose of Section 10D? Is the scope of this discretion appropriate? Why or why not?

52. Should the standard for exercising discretion not to recover be limited to the extent to which that recovery is impracticable? Should direct costs of recovery be a basis for exercising discretion not to recover? If so, what specific costs of recovery should be considered? For example, should only direct expenditures to third-parties be considered, as proposed? Should we further define what constitutes ''direct costs''? Should an issuer be permitted to consider indirect costs, such as opportunity costs or reputational costs? Should the issuer disclose the cost estimates in its Exchange Act annual reports? If the cost estimates are not disclosed in the issuer's annual reports, should those costs be independently verified?

53. Should the issuer first be required to make a reasonable attempt to recover that compensation, as proposed? If so, should we specify what steps to recover excess incentive-based compensation should be required or what constitutes a ''reasonable attempt'' to recover such compensation? Should this requirement depend on what financial reporting metric triggers recovery? Should the issuer be required to document its attempts to recover, and provide that documentation to the exchange?

54. Should a listed issuer be permitted to forego recovering incentive-based compensation if doing so would violate home country law? In this circumstance, should the issuer first be required to obtain a legal opinion from home country counsel, as proposed? If not, why not? Are there any other conditions that should be met beyond a legal opinion from home country counsel before an issuer should be permitted to forego recovering incentive-based compensation in these circumstances? Should the proposed accommodation apply only to the extent that recovery would conflict with home country laws in effect before the date of publication of proposed Rule 10D–1 in the **Federal Register**, as proposed? If not, please explain why not. In addition, as proposed, the listed issuer would need to provide such opinion to the

[182] We note that some have suggested that issuers may be able to amend their by-laws to implement their recovery policies. *See, e.g.*, Robert E. Scully Jr, Executive Compensation, the Business Judgment Rule, and the Dodd-Frank Act: Back to the Future for Private Litigation?, The Federal Lawyer, January 2011, pp 39–41.

[183] Only direct costs involving financial expenditures, such as reasonable legal expenses, would be considered for this purpose. Indirect costs relating to concerns such as reputation or the effect on hiring new executive officers would not be taken into account.

[184] Proposed Rule 10D–1(b)(1)(iv).

[185] *Id.*

[186] *Id.* The listed issuer would need to provide such opinion to the exchange or association.

[187] Exchange Act Rule 10C–1 mandated that the exchanges adopt listing standards to require that directors responsible for oversight of executive compensation (whether or not serving as part of a formal compensation committee) be independent. Examples of such listing standards are Section 303A.05 of the NYSE Listed Company Manual and NASDAQ Rule 5605(d), both of which require listed companies, with limited exceptions, to have a compensation committee composed entirely of independent directors. Listed companies were given until the earlier of their first annual meeting of shareholders after January 15, 2014 or October 31, 2014 to comply with the revised NYSE and Nasdaq independence requirements for compensation committee members.

[188] Proposed Rule 10D–1(b)(1)(iv).

[189] *See* Section II.D.1, below.

exchange upon request. Should a copy of this opinion be filed with the Commission as an exhibit? Why or why not?

55. Should the determination that recovery would be impracticable need to be made by the issuer's committee of independent directors responsible for executive compensation decisions, or in the absence of such a committee, by a majority of the independent directors serving on the board? If not, why not, and who should be authorized to make the determination?

56. Are there other circumstances in which a listed issuer should be permitted to not pursue recovery from its former executive officers? If so, please explain the circumstances and what, if any, conditions should apply.

57. Could application of the Section 10D recovery policy to current or former employees cause an issuer to violate any existing statutory or contractual provisions? If so, please specify the applicable provisions, how they might make affect recovery, and how an issuer could address them to implement recovery.

58. Would issuers be able to implement their recovery policies with respect to existing compensation agreements and arrangements through amendments to their by-laws?

c. Board Discretion Regarding Manner of Recovery

Section 10D does not address whether an issuer's board of directors may exercise discretion in the manner in which it recovers excess compensation to comply with the listing standards. Commenters suggested that the Commission's rule and rule amendments should address whether boards may exercise discretion in effecting recovery in two primary areas—the amount to be recovered when discretion was exercised in the original grant, and the means of recovery.

i. Amount To Be Recovered

Commenters requested that boards be able to exercise discretion with regard to the amount to be recovered when discretion was used in determining the original award amount.[190] For example, some issuers use ''pool plans,'' in which the size of the available bonus pool is determined based wholly or in part on satisfying a financial reporting measure performance goal, but specific amounts granted from the pool to individual executives are based on discretion. One commenter recommended that the issuer's board of directors have the discretion to decide how much to recover from each executive officer, as long as the issuer recovers the aggregate erroneously awarded amount.[191] A different commenter stated that the issuer's board should be given the same level of discretion to determine the amount to be recovered from individual executive officers as was used in making the initial compensation decision.[192] This commenter also suggested that the Commission consider situations in which the issuer's board would be permitted to settle for less than the full amount when seeking recovery under its recovery policy.[193]

As proposed, Rule 10D–1 would not limit the amount of compensation the board could seek to recover on any other legal basis. However, under the proposed rule, issuers' boards of directors would not be permitted to pursue differential recovery among executive officers, including in ''pool plans,'' where the board may have exercised discretion as to individual grants in allocating the bonus pool. In this instance, we believe that recovery should be *pro rata* based on the size of the original award rather than discretionary. We believe that permitting discretion in these instances would be inconsistent with Section 10D's no-fault standard and its goal of preventing executive officers from retaining compensation to which they are not entitled under the restated financial reporting measure. Additionally, permitting discretion in these instances could result in issuers selectively applying recovery policies to former executive officers, which we believe also would be inconsistent with Section 10D's purpose.

Moreover, consistent with Section 10D's emphasis on preventing executive officers from retaining compensation that they received and to which they were not entitled under the issuer's restated results, and as described above, we are not proposing that issuers be permitted to settle for less than the full recovery amount unless impracticable from a cost standpoint. In that circumstance, the same conditions would apply as for a determination to forgo recovery.[194]

ii. Means of Recovery

In addition, several commenters recommended that boards of directors be able to exercise discretion on how to accomplish recovery under the recovery policy required by the proposed listing standards.[195] One commenter suggested that boards may decide to recover the excess compensation over time or from future pay,[196] while another commenter recommended that issuers recover erroneously paid compensation first from current compensation owing, and then from executive officers' after-tax funds.[197] One commenter recommended that recovery of an incentive-based compensation award that has been earned but not paid should be accomplished through forfeiture of the award, while recovery in all other cases should be accomplished solely by the executive officer's repayment.[198] Several commenters suggested cancellation of unvested equity and non-equity awards or offsetting against amounts otherwise payable by the issuer to the executive officer, such as deferred compensation, as possible recovery methods.[199]

We recognize that the appropriate means of recovery may vary by issuer and by type of compensation arrangement. Consequently, we believe issuers should be able to exercise discretion in how to accomplish recovery. Nevertheless, in exercising this discretion, we believe that issuers should act in a manner that effectuates the purpose of the statute—to prevent executive officers from retaining compensation that they received and to which they were not entitled under the issuer's restated results. Regardless of the means of recovery utilized, we believe that issuers should recover excess incentive-based compensation reasonably promptly, as undue delay would constitute non-compliance with an issuer's policy as required.

Request for Comment

59. How and under what circumstances, if any, should the board of directors be able to exercise discretion regarding the amount to be recovered? What steps should the board

[190] *See* letters from Davis Polk & Wardwell LLP, Center on Executive Compensation and Society of Corporate Secretaries and Governance Professionals. *See* Section II.C.3.a, above, regarding the amount to be recovered when discretion was used to either increase or decrease the original award amount.

[191] *See* letter from Protective Life Corporation.

[192] *See* letter from Center on Executive Compensation.

[193] *See* letter from Center on Executive Compensation.

[194] *See* Section II.C.3.b, above.

[195] *See* letters from Davis Polk & Wardwell LLP, Center on Executive Compensation, Pay Governance LLC, Society of Corporate Secretaries and Governance Professionals, Stuart R. Lombardi and Protective Life Corporation.

[196] *See* letter from Davis Polk & Wardwell LLP.

[197] *See* letter from Frederic W. Cook & Co., Inc.

[198] *See* letter from Meridian Compensation Partners, LLC.

[199] *See* letters from Center on Executive Compensation, Society of Corporate Secretaries and Governance Professionals and Protective Life Corporation.

of directors be required to take, if any, before exercising any permitted discretion about the amount to be recovered from individual executive officers?

60. Are there any material tax considerations relevant to whether an issuer should be able to exercise discretion as to the amount of recovery? If so, please explain.

61. Would the exercise of discretion by an issuer's board of directors on the amount to be recovered where discretion was used in determining the original award amount (*e.g.,* in a pool plan) be consistent with the purpose of Section 10D? If so, how?

a. If an issuer uses a pool plan in which achievement of a financial reporting measure determines the aggregate amount of the bonus pool and the bonus pool is insufficient after giving effect to the restatement, how should the issuer determine the amount to be recovered? Should this decision be left to the board of directors or compensation committee? Should recovery be on a *pro rata* basis?

62. Should an issuer's board of directors be able to exercise discretion regarding the means of recovery, as proposed? If so, how and under what circumstances should the board be able to exercise discretion regarding the means of recovery? Are there any steps the board should be required to take before it exercises any permitted discretion regarding the means of recovery?

63. Should any of the principles discussed in this section be codified?

64. Should deferred payment arrangements be permitted when an executive officer otherwise is unable to repay excess incentive-based compensation? If so, should the time period over which repayment may be deferred be limited?

65. If recovery does not occur reasonably promptly, this would constitute non-compliance with an issuer's policy. Should there be an explicit window of time within which an issuer must have recovered excess incentive-based compensation from an executive beyond which the failure to recover would not be considered ''reasonably prompt''? Why or why not? If so, what should that time period be?

66. Should an issuer be permitted to recover excess incentive-based compensation by netting incentive-based compensation overpayments with incentive-based compensation underpayments that result from restating financial statements for multiple periods during the three-year recovery period? For example, suppose an issuer's restatement for a material error in revenue recognition results in a shift in revenue from the most recent year to an earlier year in the three-year period, such that an incentive payment in the earlier year would have been greater under the restatement. Should the issuer be permitted to recover the excess incentive-based compensation in the later year by crediting the earlier ''underpayment''? Why or why not? Should the conclusion be different from the situation where the executive officer received incentive-based compensation due to the achievement of a cumulative performance goal for the three-year period based on the financial reporting measure? Why or why not?

67. One commenter suggested that we specifically authorize or approve of the use of a nonqualified deferred compensation plan (*e.g.,* a ''holdback plan'' or ''bonus bank'') to aid in the recovery of erroneously awarded incentive-based compensation.[200] Would these or other mechanisms aid in the recovery of such compensation? Why or why not?

4. Compliance With Recovery Policy

Under the proposed rule and rule amendments, an issuer would be subject to delisting if it does not adopt and comply with its compensation recovery policy.[201] The proposed rule and rule amendments do not specify the time by which the issuer must complete the recovery of excess incentive-based compensation. Rather, under proposed Rule 10D–1, an exchange would determine whether the steps an issuer is taking constitute compliance with its recovery policy. In making this assessment, an exchange would need to determine, among other things, whether the issuer was making a good faith effort to promptly pursue recovery.

Request for Comment

68. Should Rule 10D–1 specify the time by which the issuer must complete the recovery of excess incentive-based compensation required by the listing standards?

69. Should Rule 10D–1 provide an objective standard to determine whether an issuer is complying with its recovery policy? For example, if the issuer has not recovered a certain percentage of excess incentive-based compensation within a certain time period after a restatement that triggers application of the policy, should it be deemed non-compliant? If so, what percentages or time periods should be used, and why?

70. Alternatively, should Rule 10D–1 provide a standard that includes different subjective criteria, or both subjective and objective criteria, to determine whether an issuer is complying with its recovery policy? If so, what standard should be used and why?

71. Are there procedures that should be considered to assess compliance with an issuer's policies and procedures concerning recovery of excess incentive-based compensation? If so, what are they? Should an issuer be required to disclose those policies and procedures? Should there be an independent third-party assessment of an issuer's compliance with those policies and procedures?

72. Could proposed Rule 10D–1 be revised to better ensure compliance with the obligation to recover? If so, how?

D. Disclosure of Issuer Policy on Incentive-Based Compensation

Section 10D(b)(1) requires exchanges and associations to adopt listing standards that call ''for disclosure of the policy of the issuer on incentive-based compensation that is based on financial information required to be reported under the securities laws.'' Sections 10D(a) and (b) require that the Commission adopt rules requiring the exchanges to prohibit the listing of any security of an issuer that does not develop and implement a policy providing for such disclosure.

Commenters noted that Section 10D(b)(1) could be read either to require disclosure about the issuer's policy on incentive-based compensation generally, or, instead, to require disclosure only about the issuer's recovery policy with regard to such compensation. One commenter[202] requested that the Commission address how the disclosure required by Section 10D(b)(1) would relate to the recovery policy disclosure already provided in an issuer's CD&A.[203] Another commenter recommended implementing Section 10D(b)(1)'s disclosure requirement by mandating that CD&A include the type of disclosure currently addressed but not mandated under Item 402(b)(2)(viii) of Regulation S–K, to the extent that such policies relate to financial

[200] *See* letter from Clark Consulting.

[201] Under the proposed rule and rule amendments, it would also be subject to delisting if it does not disclose its compensation recovery policy in accordance with Commission rules.

[202] *See* letter from Baker, Donelson, Bearman, Caldwell & Berkowitz, PC.

[203] Item 402(b)(2)(viii) provides as an example of information that may be material information to be disclosed under CD&A ''[r]egistrant policies and decisions regarding the adjustment or recovery of awards or payments if the relevant registrant performance measures upon which they are based are restated or otherwise adjusted in a manner that would reduce the size of an award or payment.''

information required to be reported under the securities laws.[204]

A different commenter recommended that the Commission not interpret Section 10D(b)(1) as creating a new disclosure requirement for incentive-based compensation or, if the Commission does adopt a separate disclosure requirement, that it allow the requirement to be satisfied by identifying any types of incentive-based compensation that are based on financial information that is required to be reported under the securities laws.[205] This commenter further recommended that the Commission allow an issuer to present any required disclosure on its general corporate Web site in view of the information about incentive-based compensation that is currently required in proxy materials under Item 402 of Regulation S–K.

Other commenters sought disclosure of issuers' clawback decisions. One commenter recommended public disclosure of an issuer's decision whether or not to pursue recovery as a means to prevent abuse of any permitted discretion.[206] A different commenter stated that in addition to disclosing the existence of a clawback policy, listed issuers should be required to disclose whether or not recovery has been initiated and completed, along with details of the sums recovered and identity of executives from whom compensation was recovered, as a prophylactic against firms that restate but do not meet their obligation to recover funds.[207]

In part, because Section 10D(b)(1) comes under the Section 10D(b) heading ''Recovery of Funds,'' we construe its disclosure requirement to mean disclosure of the listed issuer's policy related to recovery of erroneously awarded compensation. This approach would permit an assessment of a listed issuer's compliance with the mandatory recovery policy, while avoiding a potential duplication of the existing disclosure requirements applicable to incentive-based compensation. The proposed disclosure requirements are intended to inform shareholders and the listing exchange as to both the substance of a listed issuer's recovery policy and how the listed issuer implements that policy in practice.

While the specific language of Sections 10D(a) and (b) may be ambiguous, we believe that it is intended to require listed issuers to adopt, comply with, and provide disclosure about their compensation recovery policies. Accordingly, proposed Rule 10D–1 would call for the listing standards to include among the new requirements that listed issuers disclose their recovery policies.[208] Implementing the disclosure requirement as an element of the listing standards would permit exchanges to commence de-listing proceedings for issuers that fail to make the required disclosure, as well as those that fail to adopt recovery policies or fail to comply with their terms.

Further, to provide consistent disclosure across exchanges, proposed Rule 10D–1 would provide that the required disclosure about the issuer's recovery policy must be filed in accordance with the disclosure requirements of the federal securities laws. These requirements would be implemented by the proposed amendments to Regulation S–K and relevant forms described below. Structuring the provision in this manner would assure that, in addition to making the disclosure a condition to listing, it would be subject to Commission oversight to the same extent as other disclosure required in Commission filings.

Finally, to facilitate verification of compliance by the exchanges, the listing standards of each exchange would require that listed issuers record their compensation recovery policies in writing, and these recovery policies would be filed with the Commission, as described immediately below.

1. Listed U.S. Issuers

The first of the proposed disclosure requirements would amend Item 601(b) of Regulation S–K to require that a listed issuer file its recovery policy as an exhibit to its annual report on Form 10–K.[209] For this purpose, an issuer would be ''a listed issuer'' if it had a class of securities listed on an exchange registered pursuant to Section 6 of the Exchange Act or an association registered pursuant to Section 15A of the Exchange Act at any time during its last completed fiscal year. Because the disclosure is keyed to the statutorily mandated listing requirement, we would apply this disclosure requirement to all listed issuers and do not propose to apply it to issuers who do not have a listed class of securities.

Although not specifically required by the Act, to further implement Section 10D(b)(1), we are also using our discretionary authority to propose to amend Item 402 of Regulation S–K to require listed issuers to disclose how they have applied their recovery policies. Proposed Item 402(w) of Regulation S–K would apply if at any time during its last completed fiscal year either a restatement that required recovery of excess incentive-based compensation pursuant to the listed issuer's compensation recovery policy was completed or there was an outstanding balance of excess incentive-based compensation from the application of that policy to a prior restatement. In this circumstance, the listed issuer would be required to provide the following information in its Item 402 disclosure:

- For each restatement, the date on which the listed issuer was required to prepare an accounting restatement, the aggregate dollar amount of excess incentive-based compensation attributable to such accounting restatement and the aggregate dollar amount of excess incentive-based compensation that remains outstanding at the end of its last completed fiscal year;[210]
- The estimates used to determine the excess incentive-based compensation attributable to such accounting restatement, if the financial reporting measure related to a stock price or total shareholder return metric;
- The name of each person subject to recovery of excess incentive-based compensation attributable to an accounting restatement, if any, from whom the listed issuer decided during the last completed fiscal year not to pursue recovery, the amount forgone for each such person, and a brief description of the reason the listed issuer decided in each case not to pursue recovery; and
- The name of, and amount due from, each person from whom, at the end of its last completed fiscal year, excess incentive-based compensation had been outstanding for 180 days or longer since the date the issuer determined the amount the person owed.

As proposed, the disclosure would show a listed issuer's activity to recover excess incentive-based compensation

[204] *See* letter from ABA Business Law Section.

[205] *See* letter from Compensia, Inc.

[206] *See* letter of Stuart R. Lombardi.

[207] *See* AFL–CIO Joint Letter, suggesting that this disclosure be in the Form 8–K.

[208] Proposed Rule 10D–1(b)(1).

[209] Proposed Item 601(b)(96) of Regulation S–K. The Form 20–F Instructions as to Exhibits would be amended correspondingly to add new Instruction 17. Similarly, Form 40–F would be amended to add new paragraph (17(a)) to General Instruction B. Form N–CSR would be amended to renumber Item 12 (Exhibits) as Item 13 and add new paragraph (a)(3) to that item for those registered management investment companies that would be subject to the requirements of proposed Rule 10D–1.

[210] Proposed Instruction 4 to Item 402(w) would provide that if the aggregate dollar amount of excess incentive-based compensation has not yet been determined, the listed issuer would disclose this fact and explain the reasons.

during its last completed fiscal year. We believe this disclosure would inform shareholders' voting and investment decisions and help exchanges ensure compliance with their listing standards. All listed issuers would be subject to Item 402(w) disclosure.[211] The proposed disclosure would be included along with the listed issuer's other Item 402 disclosure in annual reports on Form 10–K and any proxy and consent solicitation materials that require executive compensation disclosure pursuant to Item 402 of Regulation S–K.[212] As proposed, a listed issuer that complies with its Item 402(w) disclosure requirements would not need to disclose any incentive-based compensation recovery pursuant to Item 404(a).[213] With respect to registered management investment companies subject to proposed Rule 10D–1, information mirroring the proposed Item 402(w) disclosure would be included in annual reports on Form N–CSR and in proxy statements and information statements relating to the election of directors.[214]

Since our proposal would apply to *any* current or former executive officer to recovery, rather than only the ''named executive officers'' whose compensation is subject to discussion in CD&A, we propose this disclosure requirement as a separate item rather than as an amendment to CD&A. If the listed issuer is required to provide CD&A under Item 402 of Regulation S–K, however, the listed issuer could choose to include the disclosure required by proposed Item 402(w) in its CD&A discussion of its recovery policies and decisions pursuant to Item 402(b)(2)(viii) of Regulation S–K. Such a practice could benefit investors by disclosing all compensation recovery information in a single location in the filing.

We also considered implementing Section 10D(b)(1)'s disclosure requirement by mandating that CD&A include the type of disclosure currently addressed but not mandated under Item 402(b)(2)(viii) of Regulation S–K, to the extent that such policies relate to financial information required to be reported under the securities laws. This approach, however, would always locate the disclosure in CD&A, a section that requires discussion of the compensation awarded to, earned by, or paid to the smaller group of ''named executive officers.'' Further, smaller reporting companies, emerging growth companies and foreign private issuers are not required to provide CD&A in their filings and proposed Item 402(w) disclosure would be required in some filings that do not require CD&A disclosure.[215] In addition, the disclosure called for by CD&A is not limited to recovery triggered by the restatement of a financial reporting measure, but instead encompasses other adjustments that would reduce the size of an award or payment, including with respect to an award based on a strategic or operational measure.[216]

We are also proposing amendments to the Summary Compensation Table disclosure requirements. A new instruction to the Summary Compensation Table would require that any amounts recovered pursuant to a listed issuer's erroneously awarded compensation recovery policy reduce the amount reported in the applicable column for the fiscal year in which the amount recovered initially was reported, and be identified by footnote.[217] For example, if a listed issuer reported that in 2016 its Principal Executive Officer earned $1 million in non-equity incentive plan award compensation, and in 2017 a restatement of 2016 financial statements resulted in recovery of $300,000 of that incentive-based compensation, the 2017 Summary Compensation Table would revise the 2016 reported amount to $700,000, with footnote disclosure of the $300,000 recovered. The Summary Compensation Table ''total'' column would also be revised the same way. The new instruction would apply in any filing requiring Summary Compensation Table disclosure covering the affected fiscal year, including in Securities Act registration statements.

We are proposing that the disclosure required by proposed Item 402(w) be provided in interactive data format using XBRL using block-text tagging.[218] The interactive data would have to be provided as an exhibit to the definitive proxy or information statement filed with the Commission and as an exhibit to the annual report on Form 10–K.[219] Issuers would be required to prepare their interactive data using the list of tags the Commission specifies and submit them with any supporting files the EDGAR Filer Manual prescribes.[220] This requirement generally would apply to all listed issuers.[221] We believe requiring the data to be tagged would lower the cost to investors of collecting this information, and would permit data to be analyzed more quickly by shareholders, exchanges and other end-users than if the data was provided in a non-machine readable format.

2. Listed Foreign Issuers

Foreign private issuers, including Canadian issuers using the MJDS, would be required to provide the same information called for by Item 402(w) in, and to file their erroneously awarded

[211] *See* proposed Instruction 1 to Item 402(w), defining the term ''listed registrant; and proposed Instruction 2 to Item 402(w) defining the term ''compensation recovery policy.''

[212] Proposed Instruction 5 to Item 402(w).

[213] Proposed Instruction 5.a.iii to Item 404(a) of Regulation S–K. Item 404(a) requires a description of any transaction, since the beginning of the issuer's last fiscal year, or any currently proposed transaction, in which the issuer was or is to be a participant and the amount involved exceeds $120,000, and in which any related person had or will have a direct or indirect material interest. For registered management investment companies, *see* proposed Instruction 1 to Item 22(b)(20) of Schedule 14A (information provided pursuant to Item 22(b)(20) is deemed to satisfy the requirements of paragraphs (b)(8) and (b)(11) of Item 22 with respect to the recovery of erroneously awarded compensation pursuant to Rule 10D–1(b)(1)).

[214] Proposed Item 12 of Form N–CSR; proposed Item 22(b)(20) of Schedule 14A. We are also proposing to amend General Instruction D to Form N–CSR to permit registered management investment companies subject to proposed Rule 10D–1 to answer the information required by proposed Item 12 by incorporating by reference from the company's definitive proxy statement or definitive information statement.

[215] Smaller reporting companies and emerging growth companies are not required to provide CD&A in accordance with the scaled disclosure requirements contained in Item 402 of Regulation S–K. *See* Item 402(*l*) of Regulation S–K and Section 102(c) of the JOBS Act. Foreign private issuers and filers under the multijurisdictional disclosure system (''MJDS'') who file annual reports on Form 20–F or Form 40–F, respectively, are not subject to Item 402 of Regulation S–K and are not required to provide CD&A. *See* Form 20–F and Form 40–F. Similarly, foreign private issuers electing to use U.S. issuer registration and reporting forms are not required to provide CD&A because they will be deemed to comply with Item 402 by providing the information required by Items 6.B and 6.E of Form 20–F, with more detailed information provided if otherwise made publicly available or required to be disclosed by the issuer's home jurisdiction or a market in which its securities are listed or traded. *See* Item 402(a)(1) of Regulation S–K.

In addition, Form N–CSR and Schedule 14A do not require registered investment companies to provide CD&A disclosure. Currently, registered investment companies are not subject to Item 402 disclosure. We are proposing that registered management investment companies subject to proposed Rule 10D–1 would provide information mirroring the proposed Item 402(w) disclosure in annual reports on Form N–CSR pursuant to proposed Item 12 of that form, and in proxy statements and information statements pursuant to proposed Item 22(b)(20) of Schedule 14A.

[216] Item 402(b)(2)(viii) of Regulation S–K: ''Registrant policies and decisions regarding the adjustment or recovery of awards or payments if the relevant registrant performance measures upon which they are based are restated or otherwise adjusted in a manner that would reduce the size of an award or payment.''

[217] Proposed Instruction 5 to Item 402(c), and proposed Instruction 5 to Item 402(n).

[218] Data becomes interactive when it is labeled or ''tagged'' using a computer markup language such as XBRL that software can process for analysis.

[219] Proposed Item 25 of Schedule 14A and proposed Item 601(b)(97) of Regulation S–K.

[220] The EDGAR Filer Manual is available at: *http://www.sec.gov/info/edgar/edmanuals.htm.*

[221] *See* n. 229, below.

compensation policies as an exhibit to, the annual reports they file with the Commission pursuant to Section 13(a) of the Exchange Act.[222] We propose to require foreign private issuers, including MJDS filers, to disclose the information in annual reports they file on Form 20–F, Form 10–K [223] and Form 40–F, as applicable. Because securities registered by these listed issuers are exempt from Section 14(a) of the Exchange Act,[224] they would not be required to disclose the information in any proxy or consent solicitation materials with respect to their securities.

Form 20–F is used as either the registration statement or annual report for foreign private issuers under the Exchange Act.[225] The proposals would amend Item 402(a)(1) to add proposed Item 6.F of Form 20–F to the list of mandatorily required executive compensation disclosures for foreign private issuers.[226] As proposed, Item 6.F would mirror the disclosure requirements of Item 402(w). In addition, a listed foreign private issuer that provides the disclosure required by Item 6.F of Form 20–F would not need to provide Item 7.B [227] disclosure of any individual excess incentive-based compensation recovery transaction otherwise subject to Item 7.B.[228] We are proposing a similar amendment to Form 40–F to add Paragraph (17) of General Instruction B to mirror the disclosure requirements of Item 402(w). As discussed above, listed issuers would generally be required to tag this disclosure in an interactive data format.[229]

Request for Comment

73. Is the proposed approach of having the listing standard require an issuer to disclose its compensation recovery policy an appropriate means to implement Sections 10D(a) and 10D(b)(1)?

74. Would it be preferable to implement the disclosure requirement only through issuer disclosure requirements? Alternatively, would it be preferable to make the disclosure requirement solely a listing standard requirement? If so, please explain why.

75. Should a listed issuer be required, as proposed, to file as an exhibit to its Exchange Act annual report its policy regarding the recovery of incentive-based compensation that is based on or derived from financial information required to be reported under the securities laws? Are there better ways to disclose the policy? Should the policy be included in the text of the Exchange Act annual report?

76. Would proposed Item 402(w) and the proposed amendment to Item 404 elicit the appropriate level of detail about how issuers have applied their recovery policies? Should listed issuers be required to disclose the names of executive officers from whom recovery has been forgone, the amounts forgone and the reason the listed issuer decided not to pursue recovery? Should listed issuers be required to disclose the names of executive officers from whom, as of the end of the last completed fiscal year, excess incentive-based compensation had been outstanding for 180 days or longer since the date the issuer determined the amount the person owed? If not, are there different disclosures that should be required?

77. Should an issuer also be required to disclose the basis of the determination of the amount of excess incentive-based compensation and any critical estimates used in determining the amounts? Should a listed issuer also be required to disclose the process or procedures by which it will seek to recover excess incentive-based compensation for amounts in which it is seeking recovery? Why or why not? If not, what should be disclosed and why?

78. As proposed, Item 402(w) disclosure would be required if at any time during the last completed fiscal year either a restatement was completed that required recovery pursuant to the listed issuer's compensation recovery policy, or there was an outstanding balance of excess incentive-based compensation based on application of that policy to a prior restatement. Should the disclosure proposed in Item 402(w) be required in both these circumstances? If not, please explain why. Will it be clear if a restatement was completed during a fiscal year, such that disclosure would be required? If not, what guidance should we provide? Alternatively, should listed issuers be required to disclose every restatement in Item 402(w)—even if recovery of excess incentive-based compensation is not required?

79. Should Item 402(w) disclosure be required even after an issuer has been delisted if it has not recovered all compensation under the policy?

80. Would the proposed Item 402(w) disclosure properly track any amount of incentive-based compensation subject to recovery through the duration of the recovery obligation until that amount either is recovered or the listed issuer concludes that recovery would be impracticable? If not, how should we revise the disclosure requirement to better track such amounts?

81. Is there any additional information that would be important to investors that should be disclosed?

82. Should the disclosure proposed by Item 402(w) of Regulation S–K be required only in annual reports and proxy and consent solicitations, as proposed? If not, please explain why. Should the disclosure of a listed issuer's application of its recovery policy be implemented by amending the executive compensation disclosure requirements of Item 402, as proposed? Alternatively, should it be implemented

[222] A foreign private issuer required to file annual reports with the Commission pursuant to Section 13(a) or Section 15(d) of the Exchange Act may file on Form 20–F or, if it elects to use the registration and reporting forms that U.S. issuers use, on Form 10–K. MJDS filers are those eligible Canadian reporting issuers that file registration statements and reports with the Commission in accordance with the requirements of the MJDS. MJDS filers file annual reports with the Commission pursuant to Section 13(a) or Section 15(d) of the Exchange Act on Form 40–F.

[223] If a foreign private issuer elects to use the registration and reporting forms that U.S. issuers use and files its annual report on Form 10–K, it is deemed to comply with Item 402 of Regulation S–K, an express form requirement of Form 10–K, by complying with Item 402(a)(1) of Regulation S–K. Therefore, we are also proposing to amend Item 402(a)(1) of Regulation S–K to include proposed Item 6.F of Form 20–F, which calls for the same disclosure as proposed Item 402(w).

[224] *See* Exchange Act Rule 3a12–3 (stating that securities registered by a foreign private issuer, as defined in Rule 3b–4, shall be exempt from sections 14(a), 14(b), 14(c), 14(f) and 16 of the Exchange Act).

[225] Form 20–F also sets forth disclosure requirements for registration statements filed by foreign private issuers under the Securities Act. Effective in 2000, the Commission incorporated in Form 20–F the International Equity Disclosure Standards, which were published by the International Organization of Securities Commissions (IOSCO). Release No. 33–7745 (Sept. 28, 1999) [64 FR 53900]. The disclosure requirements for related party transactions are set forth in Item 7.B of Form 20–F.

[226] The amendment would require a foreign private issuer that elects to provide domestic Item 402 disclosure to provide Item 402(w) disclosure in its annual report.

[227] Item 7.B requires a description of related party transactions for foreign private issuers.

[228] Proposed Instruction 4 to Item 7.B of Form 20–F.

[229] In general, foreign private issuers are required to submit Interactive Data Files, as defined in Rule 11 of Regulation S–T, to the Commission with their financial statements; however, those foreign private issuers that prepare their financial statements in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board are not required to submit Interactive Data Files until the Commission specifies on its Web site a taxonomy for use by such foreign private issuers in preparing their Interactive Data Files. *See Interactive Data to Improve Financial Reporting,* Release No. 33–9002 (Jan. 30, 2009) at n. 94 *http://www.sec.gov/rules/final/2009/33-9002.pdf. See also* Letter to the Center for Audit Quality (Apr. 8, 2011) at *http://www.sec.gov/divisions/corpfin/cf-noaction/2011/caq040811.htm.* We anticipate that foreign private issuers that do not yet submit a data file with their financial statements would have a similar accommodation for submitting proposed Item 6.F disclosure in a tagged format.

by amending the Item 407 corporate governance disclosure requirements, or by adopting a new Item of Regulation S–K? If so, please explain why.

83. Should a listed issuer only be required to provide the disclosure proposed by Item 402(w) in a report to its listing exchange or association, rather than in its annual reports and proxy and consent solicitations? If detailed notification is provided to its exchange or association, what type of disclosure, if any, should be made in a listed issuer's Commission filings? Alternatively, should a listed issuer be required to provide the proposed Item 402(w) disclosure and, in addition, be required to make a separate notification to its exchange or association?

84. How would the proposed Item 402(w) disclosure be used by institutional and retail investors, investment advisers, and proxy advisory firms in making voting decisions and recommendations on matters such as director elections and executive compensation?

85. Should we require that the disclosure required by proposed Item 402(w) be tagged in XBRL format, as proposed? Should we require a different format, such as, for example, eXtensible Markup Language (XML)? Would tagging these disclosures enhance the ability of shareholders and exchanges to assess issuers' compliance with their recovery policies? Alternatively, instead of requiring that either of these disclosures be tagged, should tagging this disclosure be optional?

86. Is the burden to implement the proposed tagging requirements comparatively greater for smaller reporting companies and emerging growth companies than for other issuers, such that we should exempt them or provide them a phase-in period for this requirement? If so, please explain the differential burden and how long a phase-in period it would justify.

87. We anticipate that foreign private issuers would not be required to submit an electronic data file with proposed Item 6.F disclosure until they submit financial statement information in an electronic data file. Is there a reason to require this information to be tagged before financial statement information is available in an electronic data file? What would the relative costs and benefits be of filing this information for the first time together or filing them separately?

88. Is the proposed instruction to Item 404(a), which would exclude a transaction involving recovery of excess incentive-based compensation that is disclosed pursuant to Item 402(w) from disclosure as a related party transaction, appropriate? Why or why not?

89. In the Summary Compensation Table, should any amount recovered pursuant to a listed issuer's recovery policy reduce the amount reported in the applicable column for the fiscal year in which the amount recovered initially was reported, as proposed? For example, with respect to equity awards, should the then-probable grant date fair value reported be reduced by the portion of that grant date fair value attributable to the number of shares or options recovered? Should this disclosure be required in any filing containing Summary Compensation Table disclosure? Should we require similar reductions in amounts reported in compensation tables required for registered management investment companies? Why or why not? Are there any special considerations relating to registered management investment companies that make disclosing this information more or less useful than similar disclosure by operating companies? If so, please describe.

90. Our rules permit emerging growth companies and smaller reporting companies to provide scaled disclosure of certain requirements. Should the proposed disclosure rules for incentive-based compensation recovery policies be scaled for these companies? If so, please explain why and in what manner.

91. Is the disclosure proposed to be included in annual reports on Form N–CSR and proxy statements and information statements that mirrors the proposed disclosure in Item 402(w) appropriate for registered management investment companies subject to the rule? Should it be modified and, if so, how? Is it appropriate to include disclosure in both Form N–CSR reports and proxy statements and information statements? Should we, as proposed, amend General Instruction D to permit registered management investment companies to answer proposed Item 12 of Form N–CSR by incorporating by reference information from definitive proxy statements and definitive information statements? Why or why not? Should the proposed disclosure appear elsewhere in addition to, or in lieu of, reports on Form N–CSR and proxy and information statements, and, if so, where (*e.g.,* the Statement of Additional Information)? Should we require that registered management investment companies tag these disclosures in XBRL format, as proposed? Why or why not? Are there any special considerations relating to registered management investment companies that make tagging this information more or less useful than similar tagging by operating companies? If so, please describe.

92. Should listed foreign private issuers, including MJDS filers, be exempt from the requirement to provide disclosure about compensation recovery policies? If so, please explain why.

E. Indemnification and Insurance

State indemnification statutes, indemnification provisions in an issuer's charter, bylaws, or general corporate policy and coverage under directors' and officers' liability insurance provisions may protect executive officers from personal liability for costs incurred in a successful defense against a claim or lawsuit resulting from the executive officer's service to the issuer.[230] Commenters requested clarification about whether issuers may indemnify executive officers whose compensation is recovered due to no fault of their own.[231] If the Commission does not prohibit such arrangements, these commenters asserted that issuers should be required to disclose the existence of these agreements in their proxy statements and other filings.

We believe that indemnification arrangements may not be used to avoid or nullify the recovery required by Section 10(D). Section 10D's listing standard requirement that ''the issuer will recover'' is inconsistent with indemnification because a listed issuer does not effectively ''recover'' the excess compensation from the executive officer if it has an agreement, arrangement or understanding that it will mitigate some or all of the consequences of the recovery.[232]

[230] In the context of Securities Act registration statements, a registrant is required to ''state the general effect of any statute, charter provisions, by-laws, contract or other arrangements under which any controlling persons, director or officer of the registrant is insured or indemnified in any manner against liability which he may incur in his capacity as such.'' Item 702 of Regulation S–K.

[231] *See* letters from Towers Watson and Baker, Donelson, Bearman, Caldwell & Berkowitz, PC.

[232] *See Cohen* v. *Viray,* 622 F.3d 188, 195 (2d Cir. 2010) (holding that an indemnification agreement cannot be used to release chief executive officer and chief financial officer from liability to repay compensation under Section 304 of SOX, in part because ''indemnification cannot be permitted where it would effectively nullify a statute''); *see, also* Senate Report at 136 (''[I]t is unfair to shareholders for corporations to allow executives to retain compensation that they were awarded erroneously.''). To the extent that an issuer indemnifies an executive officer, arranges for or provides insurance protecting against the risk that incentive-based compensation will be recovered pursuant to the issuer's recovery policy, whether directly by purchasing this coverage or indirectly by increasing the executive compensation to facilitate the executive's purchase of this coverage, the executive officer retains the excess compensation to which he or she was not entitled.

Congress designed the recovery policy required by Section 10D to apply on a no-fault basis, requiring listed issuers to develop and implement a policy to recover ''any compensation in excess of what would have been paid to the executive officer had correct accounting procedures been followed.'' [233] Indemnification arrangements that permit executive officers to retain compensation that they were not entitled to receive based on restated financial statements fundamentally undermine the purpose of Section 10D.[234]

We further believe that Section 29(a) of the Exchange Act would render any indemnification agreement unenforceable to the extent that the agreement purported to relieve the issuer of its obligation under Section 10(D), the proposed rule and rule amendments, and a resulting listing standard to recover erroneously-paid incentive compensation. Section 29(a) provides that ''[a]ny condition, stipulation, or provision binding any person to waive compliance with any provision of this title or of any rule or regulation thereunder, or of any rule of a self-regulatory organization, shall be void.'' [235] As courts have noted, ''by its terms, Section 29(a) 'prohibits waiver of the substantive obligations imposed by the Exchange Act.' . . . . The underlying concern of this section is 'whether the [challenged] agreement weakens [the] ability to recover under the Exchange Act.' '' [236] Thus, we believe that Section 29(a) would not permit an indemnification agreement to undermine an issuer's right and obligation to recover excess incentive-based compensation.[237]

For these reasons, Rule 10D–1, as proposed, would prohibit a listed issuer from indemnifying any executive officer or former executive officer against the loss of erroneously awarded compensation.[238] Further, while an executive officer may be able to purchase a third-party insurance policy to fund potential recovery obligations, the indemnification prohibition would prohibit an issuer from paying or reimbursing the executive for premiums for such an insurance policy. For the reasons stated above, we believe that indemnification and insurance premium payment or reimbursement arrangements would frustrate Section 10D's ultimate purpose of preventing an executive officer from retaining compensation ''that the executive would not have received if the accounting was done properly and was not entitled to.'' [239]

Request for Comment

93. Should we require the exchanges to adopt listing standards that would prohibit issuers from indemnifying executive officers and/or funding the purchase of insurance to protect against the risk that an executive officer will be subject to the issuer's recovery policy, as proposed?

94. Should such listing standards also prohibit issuers from indemnifying executive officers' litigation expenses in recovery actions?

95. As noted above, the anti-indemnification provisions of Rule 10D–1 would prohibit agreements, arrangements or understandings that directly or indirectly mitigate some or all of the consequences of recovery. Will the exchanges and issuers be able to distinguish between payments that are made to mitigate the effect of a recovery and those that are paid as compensation in the ordinary course of business?

96. Should we define ''indemnification'' for purposes of the recovery under Section 10D? If so, how should it be defined? Should it require that there be an agreement on the part of the indemnitor in advance of the event for which the indemnitee is being indemnified?

F. Transition and Timing

We received a number of comments regarding timing and transition issues. Commenters generally advocated for prospective application of the recovery policy required by the listing standard. Commenters who addressed the application of Section 10D to former executive officers expressed concern about retroactive application to persons who were executive officers before Section 10D was enacted.[240] Some commenters recommended specific dates after which incentive-based compensation should be subject to recovery, such as the enactment date of the Act,[241] the effective date of the final implementing rules,[242] the effective date of the listing standards approved by the Commission,[243] or the date the issuer implements the listing standard.[244]

Commenters also expressed concerns regarding how the recovery policy would affect existing compensation contracts and agreements.[245] Commenters asserted that issuers may be unable to apply recovery policies retroactively to arrangements in which compensation already has been granted or earned, or to compensation provided pursuant to pre-existing employment agreements.[246] One commenter recommended that the Commission establish a grandfathering rule that would exempt incentive-based compensation awards granted before the effective date of the Commission's final rules implementing Section 10D.[247] Another commenter asked whether the recovery policy would apply to compensation paid from the date the policy is effective, regardless of contract terms, and when issuers would be required to make their recovery policies first enforceable.[248]

Additionally, some commenters suggested that the Commission provide for delayed compliance after the effective date of proposed Rule 10D–1 or approval of the listing standards, during which time issuers could develop and implement a recovery policy and make necessary plan amendments. These commenters recommended a 12-month period following Commission approval of the listing standards,[249] or a one-year period after the issuance of final rules,[250] for issuers to develop and implement their recovery policies and make any necessary plan amendments.

We propose that each exchange file its proposed listing rules no later than 90

[233] *See* Senate Report at 136.

[234] *Cf.* First *Golden Bancorporation* v. *Weiszmann,* 942 F.2d 726, 729 (10th Cir. 1991) (finding any attempt by a corporate insider to seek indemnity against liability for short-swing profits under Section 16(b) of the Exchange Act void as against public policy where Congress had a clear intent to provide a ''catch-all, prophylactic remedy, not requiring proof of actual misconduct.'').

[235] 15 U.S.C. 77cc. National securities exchanges and national securities associations are self-regulatory organizations. 15 U.S.C. 78c(a)(26).

[236] *AES Corp.* v. *The Dow Chemical Company,* 325 F.3d 174, 179 (3d Cir. 2003) (quoting *Shearson/American Express, Inc.* v. *McMahon,* 482 U.S. 220, 228, 230 (1987)).

[237] *See Cohen* v. *Viray,* 622 F.3d at 195 (citing Section 29(a) in rejecting indemnification against SOX § 304 liability); *Allied Artists Pictures Corp.* v. *Giroux,* 312 F. Supp. 450 (S.D.N.Y. 1970) (Section 29(a) rendered general release given by corporation to former chairman ''unenforceable as a matter of law'' in action by corporation to recover short-swing profits action under Section 16(b) of the Exchange Act).

[238] Proposed Rule 10D–1(b)(1)(v).

[239] *See* Senate Report at 135.

[240] *See* letters from Baker, Donelson, Bearman, Caldwell & Berkowitz, PC; Davis Polk & Wardwell; and Towers Watson.

[241] *See* letter from Compensia, Inc.

[242] *See* letter from Davis Polk & Wardwell LLP.

[243] *See* letter from Center on Executive Compensation.

[244] *See* letter from ABA Business Law Section.

[245] *See* letters from Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, American Benefits Council and Towers Watson.

[246] *See* letters from ABA Business Law Section; American Benefits Council; and Davis Polk & Wardwell.

[247] *See* letter from American Benefits Council.

[248] *See* letter from Towers Watson.

[249] *See* letter from Center on Executive Compensation.

[250] *See* letter from American Benefits Council.

days following publication of the final adopted version of Rule 10D–1 in the **Federal Register**, and that its rules be effective no later than one year following that publication date,[251] and that each listed issuer shall adopt the recovery policy required by this section no later than 60 days following the date on which the exchanges' rules become effective.[252] We also propose that each listed issuer be required to recover all erroneously awarded incentive-based compensation received by executive officers and former executive officers as a result of attainment of a financial reporting measure based on or derived from financial information for any fiscal period ending on or after the effective date of Rule 10D–1 and that is granted, earned or vested on or after the effective date of Rule 10D–1 pursuant to the issuer's recovery policy.[253] Finally, we propose that a listed issuer be required to file the required disclosures in the applicable Commission filings required on or after the date on which the exchanges rules become effective.[254]

In light of the statutory purpose of Section 10D, we think it is appropriate to require exchanges to adopt listing standards that require issuers to comply with recovery policies that apply to incentive-based compensation that is based on or derived from financial information for periods that end on or after the effective date of Rule 10D–1. Issuer compliance would be required whether such incentive-based compensation is received pursuant to a pre-existing contract or arrangement, or one that is entered into after the effective date of the exchange's listing standard.

Request for Comment

97. Is the proposed schedule for exchanges to file their proposed listing rules and have them effective following the effective date of proposed Rule 10D–1 workable and appropriate? Similarly, is the proposal to require each listed issuer to adopt the required recovery policy within 60 days following the effective date of the exchanges' listing rules workable and appropriate? If not, what other schedule should apply?

98. Should the Commission provide that the recovery policy will apply to require recovery of all erroneously awarded incentive-based compensation received by a current or former executive officer on or after the effective date of Rule 10D–1 that results from attaining a financial reporting measure based on or derived from financial information for periods that end on or after the effective date of Rule 10D–1, as proposed? Alternatively, should the recovery policy apply to incentive-based compensation received by an executive officer on or after the effective date of the exchange's listing standard that results from attaining a financial reporting measure based on or derived from financial information for periods that end on or after the effective date of Rule 10D–1? If neither of these alternatives, what date(s) would be more appropriate and why? Should the Commission consider the date of compensation agreements and the ability of issuers to modify those agreements as part of the transition? If so, how?

99. Is there anything the Commission should do to address the potential effect proposed Rule 10D–1 will have on existing compensation plans and employment agreements that do not contemplate recovery under a policy required by the rule and rule amendments implementing Section 10D? To what extent will issuers need to amend their existing compensation plans and employment agreements to provide for the application of the recovery policy? Should the recovery policy only apply to new compensation plans and employment agreements entered into after the effective date of the exchange's listing standard? Why or why not?

100. As proposed, an exchange may not list an issuer that it has delisted or that has been delisted from another exchange for failing to comply with its recovery policy until it comes into compliance with that policy.[255] In this circumstance, should the exchange rules prohibit the issuer from obtaining a new listing at the same or a different exchange? Why or why not? If so, for how long?

101. Are there sufficient enforcement mechanisms to ensure compliance with the listing standard? Why or why not?

General Request for Comment

We request and encourage any interested person to submit comments on any aspect of our proposals, other matters that might affect the amendments, and any suggestions for additional changes. With respect to any comments, we note that they are of greatest assistance to our rulemaking initiative if accompanied by supporting data and analysis of the issues addressed in those comments and by alternatives to our proposals, where appropriate.

III. Economic Analysis

As discussed above, Section 954 of the Dodd-Frank Act amends the Exchange Act to include new Section 10D, which requires the Commission to direct the exchanges and associations to prohibit the listing of issuers that do not develop and implement policies to recover certain incentive-based compensation. The policies must provide that, in the event that the issuer is required to prepare an accounting restatement due to material noncompliance with any financial reporting requirement under the securities laws, the issuer will recover any compensation in excess of what would have been paid under the accounting restatement from any of its current or former executive officers who received incentive-based compensation during the three-year period preceding the date of the required restatement. Section 10D also calls for the listing standards to require each issuer to develop and implement a policy providing for disclosure of the issuer's policy on incentive-based compensation that is based on financial information required to be reported under the securities laws. We are proposing a new rule and rule amendments to satisfy the statutory mandates of Section 10D.

We have performed an analysis of the main economic effects that may flow from the rule and rule amendments being proposed today. We consider the economic impact—including the costs and benefits and the impact on efficiency, competition, and capital formation—of the proposed rule requirements on issuers and other affected parties, relative to the baseline discussed below.[256] We also consider the potential costs and benefits of reasonable alternative means of implementing Section 10D. Where practicable, we have attempted to quantify the effects of the proposed rule and rule amendments; however, in certain cases, we are unable to do so

[251] Proposed Rule 10D–1(a)(2)(i).

[252] Proposed Rule 10D–1(a)(2)(ii).

[253] *Id.*

[254] *Id.*

[255] Proposed Rule 10D–1(b)(1)(vi), described in Section II.C.2.c, above.

[256] Section 3(f) of the Exchange Act and Section 2(c) of the Investment Company Act require us, when engaging in rulemaking that requires us to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f); 15 U.S.C. 80a–2(c). Further, Section 23(a)(2) of the Exchange Act requires us, when proposing rules under the Exchange Act, to consider the impact that any new rule would have on competition and to not adopt any rule that would impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. *See* 15 U.S.C. 78w(a)(2).

because we lack the data necessary to provide a reasonable estimate.

We request comment on all aspects of the economic effects, including the costs and benefits of the proposals and possible alternatives. We also request comment on any effect the proposed requirements may have on efficiency, competition and capital formation. We appreciate comments that include both qualitative information and data quantifying the costs and the benefits identified in the analysis or alternative implementations of the proposed rule and rule amendments.

A. Baseline

The proposed rule and rule amendments require national securities exchanges and national securities associations to establish listing standards that would require each issuer to implement and disclose a policy providing for the recovery of erroneously paid incentive-based compensation. Consistent with Section 10D, the proposed rule and rule amendments require that the recovery of incentive-based compensation be triggered in the event the issuer is required to prepare an accounting restatement due to material noncompliance with any financial reporting requirement under the securities laws. In order to reduce the likelihood of a material accounting error, executive officers may have an enhanced incentive to ensure that greater care is exerted in preparing accurate financial reports, or a reduced incentive to engage in inappropriate accounting practices for the purpose of increasing incentive-based compensation awarded to them.[257] While these incentives could result in high-quality financial reporting that would benefit investors, they may also alter operating decisions of executive officers or divert resources away from activities that may involve more complex accounting judgments.

The proposed requirement that an issuer implement a recovery policy would introduce uncertainty about the amount of incentive-based compensation the executive officer will be able to retain. As a result, executive officers may demand that incentive-based compensation comprise a smaller portion of their pay packages, or that they receive a greater total amount of compensation, to account for the possibility that the awarded incentive-based compensation may be reduced due to future recovery. With these possible changes to the pay packages of executive officers, overall executive compensation may become less sensitive to the performance of the issuer, and the interests of the executive officers could diverge from those of the shareholders. Further, to the extent that executive officers respond negatively to the expected effects of the compensation recovery policies developed and implemented by issuers, the proposed rule and rule amendments may cause affected issuers to be less able to attract and retain executive talent, when competing for that talent against unlisted companies. We note that there may be other factors affecting the ability of an issuer to attract and retain executive talent. Further, the incremental effect of the proposed rule and rule amendments is mitigated to the extent that the labor markets for executives at listed issuers and at unlisted issuers do not overlap.

To assess the economic impact of the proposed rule and rule amendments, we are using as our baseline the current state of the market without a requirement for listed issuers to implement and disclose a compensation recovery policy consistent with Section 10D.

The proposed rule and rule amendments would dictate listing standards that require the recovery of excess incentive-based compensation that is based on financial reporting measures, including stock price and total shareholder return (''TSR''). Performance-based compensation can be either short-term or long-term, and each type can potentially be tied to different measures of performance. One study[258] found that, in the short-term incentive plans of chief executive officers (CEOs) at S&P 1500 companies in 2012, the three most common financial reporting measures used as performance metrics were earnings (36 percent), revenue (27 percent), and operating income (26 percent). In contrast, in long-term incentive plans, the three most common financial reporting measures used to compensate CEOs were TSR (48 percent), earnings (31 percent), and revenue (17 percent).[259] While earnings also was frequently used as a performance measure in long-term incentive plans, TSR was the most frequent metric used for such plans. The use of TSR was far less prevalent in short-term incentive plans, where only 10 percent of plans used it.[260] Based on Commission staff analysis of 145 randomly sampled issuers drawn from the full population of firms (both domestic and foreign) that filed an annual proxy statement in calendar year 2013, we estimate that approximately 21 percent of issuers used stock price and/or TSR as an element of their performance-based compensation.[261]

Under the proposed rule and rule amendments, the trigger for the recovery of excess incentive-based compensation would be when the issuer is required to prepare an accounting restatement as the result of a material error that affects a financial reporting measure based on which executive officers received incentive-based compensation. Hence, not all accounting restatements would trigger a recovery of compensation that was earned as a result of meeting performance measures. Using incentive-based compensation tied to revenue as an example, in order for that compensation to be required to be recovered, there would have to be a material accounting error that affects revenue. Based on one recent study, only 15 percent of all Item 4.02-reported accounting restatements made between 2005 and 2012 were due to errors involving revenue.[262] If the issuers that

[257] We note that not all executive officers affected by the proposed rule and rule amendments may have the ability to directly affect the financial reporting of the issuer.

[258] *See* Equilar *Measuring Short-Term and Long-Term Performance in 2012* (May 28, 2013), available at *http://www.equilar.com/publications/26-measuring-short-term-and-long-term-performance-in-2012.html.*

[259] *See* Equilar *Measuring Short-Term and Long-Term Performance in 2012* (May 28, 2013).

[260] Performance-based compensation may be tied to multiple measures of performance. The average number of performance measures to evaluate performance in the short-term and long-term is 1.8 and 1.7, respectively. *See* Equilar *Measuring Short-Term and Long-Term Performance in 2012* (May 28, 2013).

[261] We estimated the percentage of issuers that use stock price and/or TSR as performance metrics based on Commission staff analysis of information disclosed in annual proxy statements (DEF 14A). The sample comprises 145 proxy filers, which represents about 3 percent of the total number of DEF 14A filers in calendar year 2013. Staff manually examined the CD&A in each of the 145 proxy statements to find that 21 percent of the 145 randomly sampled issuers disclosed the use of stock price and/or TSR as compensation performance metrics in 2013. Another 30 percent of the 145 randomly sampled issuers do not disclose whether they use compensation performance metrics; however, if these companies use stock price and/or TSR as a compensation performance metric, it is likely not a material element of their compensation because Item 402 of Regulation S–K calls for disclosure in the CD&A if a performance target is a material element of compensation policies and practices.

[262] *See* Scholz, S. 2013. ''Financial Restatement: Trends in the United States: 2003–2012.'' Center for Audit Quality, available at: *http://thecaq.org/reports-and-publications/financial-restatement-trends-in-the-united-states-2003-2012/financial-restatement-trends-in-the-united-states-2003-2012*. In referring to findings of the study, we use the phrase *Item 4.02-reported accounting restatement* when the issuer filed an Item 4.02 to Form 8–K in connection with such restatement. The study characterizes these as ''4.02 restatements'' and observes that the filing of Item 4.02 to Form 8–K is required when an accounting error renders

Continued

had a material accounting error in revenue had been subject to the proposed rule requirements, those issuers that awarded incentive-based compensation tied to the restated revenue or other measures that are affected by the restatement of revenue would be required to recover the incentive-based compensation paid to executive officers.[263]

Further, the incidence of events where incentive-based compensation would be required to be recovered is affected by the number of restatements based on material errors that occur. A recent study reports that between 2005 and 2012 there was an average of 531 Item 4.02-reported accounting restatements per year, but the incidence of accounting restatements steadily declined over this period.[264] In calendar year 2012, there were 255 Item 4.02-reported accounting restatements, which represent approximately three percent of the population of issuers that potentially could have had an Item 4.02-reported accounting restatement.[265] This suggests that an event that would require an issuer to recover compensation (*i.e.,* payment of incentive-based compensation tied to a financial reporting measure *and* occurrence of a material accounting error) would be relatively infrequent.[266]

The proposed rule and rule amendments would require exchanges to apply the compensation recovery requirement to all listed issuers, including emerging growth companies (EGCs), smaller reporting companies (SRCs), foreign private issuers (FPIs), and controlled companies. We estimate that proposed Rule 10D–1 would be applicable to 4,845 registrants.[267] We estimate that, of those 4,845 registrants, there are 706 SRCs, 376 EGCs, 511 FPIs (filing annual reports on Form 20–F), and 128 MJDS issuers (filing annual reports on Form 40–F). There are a limited number of registered management investment companies that also would be affected by the proposed rule and rule amendments. We estimate that there are approximately seven registered management investment companies that are listed issuers and are internally managed, that may have executive officers who receive incentive-based compensation.

As outlined in the table below, we estimate that approximately 23 percent of all filers currently disclose some form of an executive compensation recovery policy.[268] We further estimate that approximately four percent of SRCs, two percent of EGCs, three percent of FPIs, and one percent of MJDS issuers disclose some form of a recovery policy.

	Number of filers that disclose a recovery policy	Number of filers affected (total)	Percent of filers that disclose a recovery policy
All affected filers (total)	1,116	4,845	23.0
SRCs	29	706	4.1
EGCs	9	376	2.4
FPIs	17	511	3.3
MJDS	1	128	0.8
All other filers	1,060	3,124	33.9

We note that larger issuers are more likely to have already implemented and disclosed a recovery policy. Using the staff estimates discussed above, as of June 30, 2014, approximately 64 percent (305 issuers) of the issuers that comprise the S&P 500 and approximately 50 percent (713 issuers) of the issuers that comprise the S&P 1500 report having a recovery policy of some form.[269]

In addition to the issuers referenced above, some issuers may have experience with recovering executive compensation given existing provisions of law concerning the recovery of such compensation under certain circumstances. Section 304 of SOX contains a recovery provision that is triggered when a restatement is the result of issuer misconduct. This provision applies only to CEOs and chief financial officers (''CFOs'') and the amount of required recovery is limited to compensation received in the 12-month period following the first public issuance or filing with the Commission of the improper financial statements.[270] In addition, the Interim Final Rules under Section 111 of EESA, as amended by ARRA, required institutions receiving assistance under TARP to mandate that Senior Executive Officers and the next twenty most highly compensated employees repay compensation if awards based on statements of earnings, revenues, gains,

previously-filed financial statement unreliable. The study also comments that these are generally more serious than other restatements, which it refers to as ''non-4.02 restatements.''

[263] Incentive-based compensation tied to financial reporting measures that are affected by more reported items on the financial statements is more likely to be recovered. For example, incentive-based compensation tied to earnings or operating income is more likely to be recovered because material accounting errors that involve either revenue or expenses could impact these measures and thereby trigger a required recovery. Between 2005 and 2012, 52 percent of significant restatements involved operating expenses. *See* Scholz, S. 2013. ''Financial Restatement: Trends in the United States: 2003–2012.'' Center for Audit Quality.

[264] *See* Scholz, S. 2013. ''Financial Restatement: Trends in the United States: 2003–2012.'' Center for Audit Quality.

[265] In calendar year 2012, approximately 8,000 registrants filed annual reports on Form 10–K and would be required to file Item 4.02 to Form 8–K. We note that the proposed rule and rule amendments would affect a subset of registrants subject to reporting on Form 8–K (*i.e.,* the listed issuers).

[266] These estimates are based on historical rates and types of restatements, which may not be indicative of future rates and types of restatements.

[267] We estimate the number of issuers subject to the proposed rule based upon Commission staff analysis of issuers that filed annual reports on Form 10–K, Form 20–F, or Form 40–F pursuant to Section 12(b) of the Exchange Act in the period from 7/1/2013 to 6/30/2014, regardless of the fiscal year of the filing. The staff used text analysis of an issuer's Form 10–K to determine if the issuer is an SRC. The staff performed a similar analysis of an issuer's Form 10–K and registration statement to determine if the issuer is an EGC. Examining filings in this manner involves a certain degree of error, and it is possible for issuers to be misclassified. Hence all numbers in this analysis should be taken as estimates.

[268] We estimate the number of issuers that have disclosed some form of recovery policy based on Commission staff analysis of information disclosed in Form 10–K, Form 20–F, Form 40–F, and an issuer's annual proxy statement (DEF 14A). Staff used text analysis and keyword searches similar to those of Babenko, Bennett, Bizjak, and Coles in their working paper *Clawback Provisions* (2012) available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2023292.* Examining filings in this manner involves a certain degree of error, and it is possible for issuers to be misclassified. Hence all numbers in this analysis should be taken as estimates.

[269] A report by Equilar finds that the prevalence of recovery policies in Fortune 100 companies has increased from less than 18 percent in 2006 to 84 percent in 2011 and more than 89 percent in 2013. *See* Equilar *Clawback Policy Report* (2013), available at *http://info.equilar.com/rs/equilar/images/equilar-2013-clawbacks-policy-report.pdf.* This increasing trend in the implementation of recovery policies is supported by Babenko, Bennett, Bizjak, and Coles in their working paper *Clawback Provisions* (2012).

[270] *See* 15 U.S.C. 7243.

or other criteria were later found to be materially inaccurate.[271] As discussed above, relative to either SOX or EESA, the compensation recovery requirement of the proposed rule and rule amendments has a different scope because it would affect any current or former executive officer of all listed issuers and would be triggered when the issuer is required to prepare an accounting restatement due to material noncompliance of the issuer with any financial reporting requirement under securities laws, regardless of issuer or executive misconduct or the role of the executive in preparing the financial statements. Finally, we note that currently issuers other than SRCs, EGCs, and FPIs are required to disclose in the CD&A, if material, their policies and decisions regarding adjustment or recovery of named executive officers' compensation if the relevant performance measures are restated or adjusted in a manner that would reduce the size of an award or payment.[272]

Many of the issuers that disclose having recovery policies do not require misconduct on the part of the executive to trigger recovery.[273] In a review by Commission staff[274] of a random sample of 104 issuers with disclosed recovery policies, 51 issuers (49 percent) did not require misconduct on the part of the executive, 34 issuers (33 percent) required misconduct on the part of the executive, and 19 issuers (18 percent) did not specify. By contrast, the proposed rule and amendments would require all listed issuers to have a recovery policy that applies to any material accounting error, without regard to misconduct.

There appears to be considerable variation in the coverage of employees subject to recovery under currently disclosed recovery policies.[275] Under the proposed rule and rule amendments, a listed issuer's compensation recovery policy would require recovery of excess incentive-based compensation received by an individual who served as an executive officer of the issuer at any time during the performance period for that incentive-based compensation. As a result, in some cases recovery would be required from individuals who may be former executive officers either at the time they receive the incentive-based compensation or at the date when the listed issuer is required to prepare an accounting restatement. In a review by Commission staff of the random sample of 104 issuers with disclosed recovery policies noted above, the recovery policies of 82 issuers (79 percent) applied to any current executive officer; and only three of those 82 issuers had recovery policies that applied to former executive officers.[276] Therefore, the majority of issuers examined disclose having recovery policies that require compensation recovery from a narrower range of individuals than a recovery policy that would comply with the proposed rule requirements.

The type and scope of compensation subject to recovery in currently disclosed recovery policies also appears to vary across issuers. In the staff's review of a random sample of 104 issuers that disclosed recovery policies, the recovery policies of 64 issuers (62 percent) applied to any form of performance-based compensation, and thus would satisfy the requirements of the proposed rule in this regard. Further, out of the 104 issuers with disclosed recovery policies, 29 issuers (28 percent) specified that only the excess performance-based compensation was subject to recoupment, while 47 issuers (45 percent) specified that all of the performance-based compensation was potentially recoverable.[277] Considered together, 76 of the 104 issuers (73 percent) examined may already have a recovery policy that covers excess incentive-based compensation as would be required by the proposed rule and rule amendments.

Moreover, 94 issuers (90 percent) specified either a look-back period of three years or did not specify a look-back period, which we interpret as having a potentially indefinite look-back period. Accordingly, a majority of the current policies the staff reviewed have a look-back period that is the same length or longer than the look-back period required in a recovery policy that would comply with the proposed rule requirements. We note, however, that due to the limited disclosure available in public filings, the staff was unable to determine if the start and end dates of the look-back window would cover the proposed required look-back period in the proposed rule. The results of this random sample indicate that, for issuers with disclosed recovery policies, the majority may already include look-back provisions consistent with the requirements under the proposed rule and rule amendments.

In summary, the staff's review of the disclosed recovery policies of 104 issuers found:

Proposed requirements	Existing policies
The recovery policy is "no fault" in nature	51 of the 104 policies examined do not require misconduct on the part of the executive.

[271] Under EESA a "Senior Executive Officer" is defined as an individual who is one of the top five highly paid executives whose compensation is required to be disclosed pursuant to the Securities Exchange Act of 1934. *See* Department of Treasury, TARP Standards for Compensation and Corporate Governance; Interim Final Rule (June 15, 2009), available at *http://www.gpo.gov/fdsys/pkg/FR-2009-06-15/pdf/E9-13868.pdf.*

[272] *See* Item 402(b)(2)(viii).

[273] In a sample of 2,326 companies in the Corporate Library database, DeHaan et al. (2013) find that 39 percent had compensation recovery policies that did not require executive misconduct in order to be triggered. DeHaan, Hodge, and Shevlin *Does Voluntary Adoption of a Clawback Provision Improve Financial Reporting Quality?* Contemporary Accounting Research 30 (2013) 1027–1062.

[274] In the staff review, 104 issuers out of the 1,116 issuers that disclosed a recovery policy in the period 7/1/2013 to 6/30/2014 were randomly selected for an in depth examination of their recovery policies. Each recovery policy disclosure was read, or if the recovery policy was incorporated by reference, the original disclosure was read. Staff examined each policy for (1) which employees were covered, (2) what type of compensation was at risk for recovery, (3) how much of that compensation was at risk for recovery, (4) what type of event or events triggered a recovery action, (5) if misconduct was required for a recovery action, and (6) the timing of the window for which compensation was at risk for recovery. The characterization of these policies, as set forth below, is based on limited information available from public filings and may involve some interpretation of otherwise ambiguous terms and conditions. Hence, all numbers presented should be taken as estimates.

[275] As of 2013 approximately 61 percent of S&P Fortune 100 companies had recovery policies that applied to key executives and employees including named executive officers; approximately 13 percent applied to all employees; approximately seven percent applied to just the CEO and/or CFO; and the remainder did not have a recovery policy or did not specify coverage. *See* Equilar *Clawback Policy Report* (2013).

[276] Of the remaining 22 issuers in the sample, the recovery policies of two applied to CEOs, two applied to both the CEO and CFO, one applied to the COO, and 17 did not specify to whom the recovery policy applied. From the current disclosure in public filings, the staff generally could not determine whether the definition of "executive officers" that issuers use for purposes of their compensation recovery policies is consistent with the definition of "executive officer" in the proposed rule and rule amendments. A subset of issuers specified that only named executive officers were covered, while others specified senior executives, executive officers, or employees vice-president and above. For purposes of this baseline discussion, we include these employees in the category "executive officer."

[277] As discussed above, the characterization of these policies is based on limited information available from public filings and may involve some interpretation of otherwise ambiguous terms and conditions. Hence, all numbers presented should be taken as estimates.

Proposed requirements	Existing policies
Former executive officers are covered	101 of the 104 policies examined do not disclose that former executive officers are covered.
Excess incentive-based compensation based on attainment of a financial reporting measure is recoverable	64 of the 104 policies examined apply to any form of performance-based compensation. 76 of the 104 policies examined may already allow for excess incentive-based compensation to be recovered.
Policy has a three year look-back period	94 of the 104 policies examined may already have a look-back period of three years or longer.

B. Analysis of Potential Economic Effects

The discussion below analyzes the economic effects of the proposed rule and rule amendments, including the anticipated costs and benefits as well as the likely impact on efficiency, competition, and capital formation. For purposes of this analysis, we address the potential economic effects resulting from the statutory mandate and from our exercise of discretion together, recognizing that it is often difficult to separate the costs and benefits arising from these two sources. Below we discuss the potential effects of the proposed rule and rule amendments on financial reporting quality, on executive compensation packages, on listed issuers, and on U.S. exchanges. We also discuss the potential effects arising from the proposed rule's prohibition on indemnification and payment or reimbursement of premiums for insurance against recovery.

1. Potential Effects on Financial Reporting

In seeking to maximize the value of their financial investments, shareholders rely on the financial reporting quality of issuers to make informed investment decisions about the issuer's securities. High-quality financial reporting should provide shareholders with an accurate estimate of the issuer's performance and should be informative about its firm value.[278] An accounting restatement due to material noncompliance with any financial reporting requirement under the securities laws may cause shareholders to question the accuracy of those estimates and may lead shareholders and other prospective investors to substantially revise their beliefs about the issuer's financial performance and prospects with potentially significant effects on firm value.

While incentive-based compensation is typically intended to provide incentives to executives to maximize the value of the enterprise, thus aligning their incentives with shareholders, it may also provide executives with incentives that conflict with shareholders' reliance on high-quality financial reporting. In particular, when setting the compensation for executives, the board of directors of an issuer may seek to align the interests of executives with those of the shareholders by tying executive compensation to financial reporting measures that the board believes will have a positive effect on firm value. To the extent that executives are in a position to affect the preparation of financial statements, this approach can, however, create the incentive for executives to influence the preparation of financial statements and related filings in ways that appear to achieve those measures. For example, certain financial performance measures require estimates and judgments, and if those estimates and judgements are influenced by the performance incentives that are part of the executive compensation packages, then the reported performance of the issuer may not reflect actual enhancement to firm value.

In some instances, executives might have incentives to pursue impermissible accounting methods under GAAP that result in a material misstatement of financial performance.[279] This potential for *deliberate* misreporting raises a principal-agent problem that is detrimental for shareholders.[280] Although civil and criminal penalties already create disincentives to deliberate misreporting, the recovery requirements under the proposed rule and rule amendments would reduce the financial benefits to executive officers who choose to pursue impermissible accounting methods, and thus may add another disincentive to engage in deliberate misreporting. The magnitude of this effect would likely depend on the particular circumstances of an issuer.

The proposed rule and rule amendments may also provide executives with an increased incentive to take steps to reduce the likelihood of *inadvertent* misreporting. Most directly, the executive may have the ability to reduce the uncertainty in her compensation by devoting more resources to the production of high-quality financial reporting, thereby reducing the likelihood of a material accounting error. For example, an executive could devote more labor or internal capital to strengthening internal controls over financial reporting. One study[281] found that, after the implementation of a recovery policy, an auditor is less likely to report a material weakness in an issuer's internal controls over financial reporting, which is consistent with issuers devoting more resources to internal controls over financial reporting.

Executives may also take other steps to reduce the likelihood of an inadvertent misreporting. An executive could change the business practices of the issuer, thereby affecting the opportunity for a material accounting error to arise. For example, an executive could simplify delivery terms of a project or a transaction in order to use accounting standards that are more straightforward to apply and perhaps require fewer accounting judgments,

[278] For purposes of this economic analysis, high-quality financial reporting means when financial disclosure is informative about the actual performance of the issuer.

[279] We also note that some estimates and judgments permissible under GAAP may allow executives to realize higher compensation, without resulting in a material misstatement of financial performance and thus without triggering recovery consistent with Section 10D.

[280] Among other decisions, executives must decide the extent of internal resources and personal attention to devote to achieving high-quality financial reporting and assuring that the financial disclosure is informative about the performance of the issuer. Given that the expected costs and benefits associated with any level of investment decision in financial reporting quality would ultimately be reflected in the issuer's firm value, in absence of a principal-agent problem, executives would likely decide to allocate the value maximizing amount of resources to producing high-quality financial statements and, as a result, the level of information value of the financial reporting would likely be optimal. A principal-agent problem, however, reduces the executive's incentive to allocate the appropriate amount of resources to produce high-quality financial statements, which reduces the information value of financial reporting.

[281] *See* Chan, Chen, Chen, and Yu *The effects of firm-initiated clawback provisions on earnings quality and auditor behavior* Journal of Accounting and Economics 54 (2012) 180–196.

which may reduce the likelihood of material accounting errors.[282] Taking steps such as these does not necessarily affect the selection of the project or transaction the issuer chooses to undertake (although it could, as discussed below), but could result in greater investor confidence in the quality of financial reporting and information value of the financial statements, and thus have a positive impact on capital formation.[283]

As a result of the proposed rule and rule amendments, we believe that the increased incentives to generate high-quality financial reporting may improve the overall quality of financial reporting. An increase in the quality of financial reporting could result in increased informational efficiency, enhanced investor confidence that may result in greater market participation, and a reduced cost of raising capital, thereby facilitating capital formation. While we lack the data to quantify the potential benefits to shareholders from a reduced likelihood of a material accounting error, evidence suggests that penalties imposed by the market for accounting restatements are likely to be substantial.[284] For example, one recent study [285] found that over the period 2005 to 2012 the market value of equity of the average issuer declined by 2.3 percent upon announcement of a significant financial restatement.[286]

More broadly, the availability of more informative or accurate information regarding the financial performance of issuers would also have the effect of increasing the efficient allocation of capital among corporate issuers. Because investors would be better informed about the potential investment opportunities at any given point in time, they would be more likely to allocate their capital according to its highest and best use. This would benefit all issuers, even those whose financial reporting would not be affected by the proposed rule requirements on exchanges' listing standards. In particular, issuers whose financial reporting is unaffected may have better access to capital by virtue of investors being able to make more informed comparisons between them and issuers whose financial reporting would become more accurate as a result of the proposed rule requirements.[287] In contrast, without the proposed rule and rule amendments, investors may improperly assess the value of the issuers whose financial reporting is based on erroneous information, which could result in an inefficient allocation of capital, inhibiting capital formation and competition.

We are aware, however, that these potential benefits of the proposed rule and rule amendments are not without associated costs. Under the proposed rule and rule amendments, the increased allocation of resources to the production of high-quality financial reporting may divert resources from other activities that may be value enhancing. Moreover, while the increased incentive to produce high-quality financial reporting and thus reduce the likelihood of material accounting errors should increase the informational efficiency of investment opportunities, it may also encourage executives to forgo value-enhancing projects if doing so would decrease the likelihood of a financial restatement.[288] For example, when choosing among investment opportunities for the issuer, executives may have less incentive to pursue those projects that would require more complicated accounting judgments, so as to reduce the likelihood of an unintentional but material accounting error.[289] That is, the proposed rule and rule amendments may create an incentive for an executive to forgo projects for which it is more difficult to generate high-quality financial reporting.[290] This could have an adverse impact on the value of the issuer to the extent that the foregone projects would have resulted in greater value than those that were ultimately chosen.

One study suggests that a compensation recovery policy could result in an increased likelihood of an executive making suboptimal operating decisions in order to affect specific financial reporting measures as a result of the decreased incentive to use accounting judgments to affect those financial reporting measures.[291] For example, if an executive is under pressure to meet an earnings target, rather than manage earnings through

[282] For example, the executive could make accounting judgments on loan loss reserves or expected returns on sales with complicated returns criteria that are less likely to result in an accounting restatement.

[283] An academic study shows that, when market competition is weak, the information environment affects the expected returns of equity securities. In particular, when financial disclosure quality is low, as measured by scaled accruals quality, companies with low market competition, as measured by the number of shareholders of record, have a higher expected return. All else being equal, higher expected returns make raising capital more costly for the company. *See* Armstrong, Core, Taylor, and Verrecchia *When Does Information Asymmetry Affect the Cost of Capital* Journal of Accounting Research Vol. 49 No. 1 March 2011. The academic literature has developed a measure of the quality of financial reporting denoted accruals quality. This measure quantifies how well accruals are explained either by the cash flow from operations (past, current, and future periods) or accounting fundamentals. For details on the construction and interpretation of the measure *see* Dechow and Dichev *The Quality of Accruals and Earnings: The Role of Accrual Estimation Errors* The Accounting Review, Vol. 77, Supplement 2002 pp. 35–39; and Francis, LaFond, Olsson, and Schipper *The market pricing of accruals quality* Journal of Accounting and Economics 29 (2005) 295–327.

[284] These penalties would likely include both revaluation and reputational effects, where the two types of effects are often difficult to separate.

[285] *See* Scholz, S. 2013. ''Financial Restatement: Trends in the United States: 2003–2012.'' Center for Audit Quality.

[286] In the 2005–2012 period, the average issuer paid approximately 0.48 percent of its market value of equity to all named executive officers in the form of non-salary compensation during that time period. Non-salary compensation data is from Standard and Poor's Executive Compensation database which tracks compensation for the companies currently or previously in the S&P 1500 index. Moreover, this comparison is inexact, because the proposed rule would require the recovery of only *excess* incentive-based compensation, and not all non-salary compensation, thereby reducing the percentage of market value paid to executives. The proposed rule and rule amendments would however, also require a recovery policy that applies to more than just the named executive officers, thereby increasing the percentage of market value paid to executives.

[287] *See* Bushee and Leuz *Economic consequences of SEC disclosure regulation: evidence from the OTC bulletin board* Journal of Accounting and Economics 39 (2005) 233–264.

[288] Projects that increase the volatility of cash flows from operations, the volatility of sales revenue, or percentage of soft assets have been associated with an increased likelihood of an SEC enforcement action (specifically, the likelihood of an issuer being the subject of a SEC Accounting and Auditing Enforcement Release). *See* Dechow and Dichev *The Quality of Accruals and Earnings: The Role of Accrual Estimation Errors* The Accounting Review, Vol. 77, Supplement 2002 pp. 35–39; Dechow, Ge, Larson, and Sloan *Predicting Material Accounting Misstatements* Contemporary Accounting Research Vol. 28 No. 1 (Spring 2011).

[289] For example, the issuer could select projects that do not add to the complexity of the required reporting systems, or select projects that have a shorter performance period and therefore may involve less difficult accounting judgments about the expected future costs.

[290] Babenko et al find that after the implementation of a compensation recovery policy, issuers spend less on research and development, file for fewer patents, and hold more cash. This is consistent with executives changing their project selection policy as the result of implementing a compensation recovery policy. *See* Babenko, Bennett, Bizjak, and Coles *Clawback Provisions* Working Paper (2015). We note, however, that the determination of whether or not to select a particular project is likely related to many characteristics of the project. These characteristics could include the value the project creates, the cash flows the project returns in the near term, and the strategic objectives of the issuer.

[291] Chan, Chen, Chen, and Yu document that after the implementation of a compensation recovery policy issuers reduce accruals manipulation but increase real transaction management. They further document that the increase in real transaction management results in improved short-term performance, as measured by changes in return on assets, but diminished long-term performance. In the context of their study, real transaction management is when executive officers structure operating decisions to affect reported financial performance. *See* Chan, Chen, Chen, and Yu *The effects of firm-initiated clawback provisions on earnings quality and auditor behavior* Journal of Accounting and Economics 54 (2012) 180–196.

accounting judgments, an executive may elect to reduce or defer to a future period research and development or advertising expenses. This could improve reported earnings in the short-term, but could result in a suboptimal level of investment that adversely affects performance in the long run. The study also documents that the propensity of executives to undertake such actions may be particularly high in issuers that are characterized as having strong growth opportunities.[292] The incentive to use operating decisions to affect financial reporting measures could be partially mitigated to the extent that the board's compensation committee would expect this behavior after the implementation of a recovery policy and construct metrics that take into account the possibility of such actions. They might also design internal controls to detect such actions, such as rigorous budget variance analyses.

Under the proposed rule and rule amendments, if it appears that previously filed financial statements may contain a material accounting error, there may also be an incentive for issuers or individual executives (to the extent they are in a position to do so) to cause the company to delay investigating the error or to characterize as immaterial an accounting error that would otherwise be properly characterized as material. The incentive to delay is present because only excess incentive-based compensation received in the three fiscal years prior to the determination of a material accounting error is subject to recovery under the proposed rule and rule amendments.[293] The incentive to characterize an accounting error as immaterial that would otherwise properly be characterized as material is present because compensation recovery is only required after the conclusion a material accounting error exists.[294] To the extent that these incentives discourage the timely and accurate reporting of material accounting errors, it could result in loss of confidence in financial information disclosures by investors and hinder capital formation.

These incentives to delay the conclusion that a restatement is necessary or to mischaracterize material accounting errors are mitigated, however, by several factors. For example, the proposed definition of the date on which an issuer is required to prepare an accounting restatement, which is the date on which the issuer concludes, or reasonably should have concluded, that the issuer's previously issued financial statements contain a material error would provide an objective basis for assessing when the required three year look-back period begins. Moreover, the potential for the issuer and individual executives to incur additional legal liability, including potential criminal prosecution, for the deliberate or negligent delay in investigating and reporting a material accounting error or mischaracterization of an accounting error, combined with the likelihood that such conduct would be detected,[295] may offset the incentives arising from the required three year look-back period prior to the determination of a material accounting error.

2. Potential Effects on Executive Compensation

When setting the compensation for executives, the board of directors of an issuer frequently incorporates into the total compensation package a payout that is tied to one or more measures of the issuer's performance. The purpose of tying compensation to performance is to provide an incentive for executives to maximize the value of the enterprise, thus aligning their incentives with other shareholders. The proportion of the pay package that relies on performance incentives generally depends on factors such as the level of risk inherent in the issuer's business activities, the issuer's growth prospects, and the scarcity and specificity of executive talent needed by the issuer. It also may reflect personal preferences influenced by characteristics of the executive such as age, wealth, and aversion to risk. In particular, the executive's risk aversion may make pay packages with strong performance incentives undesirable because of the less predictable payments. These factors contribute not only to the magnitude of the expected compensation, but also to how an executive views and responds to the compensation.[296]

We anticipate that the requirements of the proposed rule and rule amendments could meaningfully affect the size and composition of the compensation packages awarded to executives of listed issuers. As noted above, risk averse executives prefer predictable compensation, and the mandatory implementation of a recovery policy that meets the requirements of the proposed rule and rule amendments would introduce an additional source of uncertainty in the compensation of the executive. Moreover, because the mandated recovery policy would be required to be ''no-fault'' in nature, the occurrence of a material accounting error would require executives to return excess incentive-based compensation even if they had no role in the material accounting error. A recovery policy would, therefore, introduce uncertainty in the amount of incentive-based compensation that executives will ultimately retain, with those executives less directly involved with financial reporting incurring relatively more uncertainty.

For executives who already have established compensation packages, the proposed rule and rule amendments may create an incentive to negotiate changes to their composition.[297] In particular, because of the increased uncertainty, risk averse executives may lower the value that they attach to the incentive-based component of their pay and may as a result demand an offset to bear the increased uncertainty. The offset could come in the form of a smaller portion of pay being comprised of incentive-based compensation,[298] which could weaken incentive alignment, *i.e.,* pay-for-performance sensitivity,[299] or through an increase in expected total compensation, which would come at a greater cost to the

[292] *Id.*

[293] For example, suppose that in November 2015 an issuer with a fiscal year ending in December suspects that there is a material accounting error in its financial statements. Further, suppose that the executives of the issuer had received a large incentive-based compensation award in 2012. If the issuer investigates immediately and concludes in November 2015 that there was a material accounting error, then incentive-based compensation received in 2012 is at risk for recovery. The issuer might choose to delay its investigation until 2016 in order to avoid this result.

[294] *See* Files, Swanson, and Tse *Stealth Disclosure of Accounting Restatements* The Accounting Review 84 (2009), 1495–1520; Myers, Scholz, and Sharp *Restating Under the Radar? Determinants of Restatement Disclosure Choices and the Related Market Reactions* Working Paper (2013), available at: *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1309786&download=yes.*

[295] Outside auditors' oversight may play as an additional mitigating factor.

[296] Executives typically have personal preferences regarding the form of compensation received. To the extent that executives have different levels of risk aversion, they can arrive at different personal valuations of the same performance-based compensation package. Hence, more risk-averse executives may require additional compensation when paid in the form of less certain performance-based compensation.

[297] *See* letters from Stuart R. Lombardi and Towers Watson.

[298] We note that, if the offset comes as a reduced weight placed on incentive-based compensation, the recoverable funds if a material accounting error occurs would be reduced.

[299] Pay-for-performance sensitivity is a measure of incentive alignment used in academic research. The measure captures the correlation of an executive officer's compensation with changes in shareholder wealth. *See, e.g.,* Jensen and Murphy, Journal of Political Economy, Vol. 98, No. 2 (Apr., 1990), pp. 225–264.

issuer.[300] Research suggests that as a result of bearing this new source of uncertainty the total compensation of executives would increase.[301] The extent of any such increase would depend on the structure and conditions of the labor market for executives as well as other economic factors, including the negotiating environment and particular preferences of executives.

Notably, under a recovery policy that implements the proposed rule requirements, incentive-based compensation tied to stock price metrics such as TSR is included within the scope of compensation that may be subject to recovery. The stock price of an issuer incorporates investor expectations of cash flows and future earnings of that issuer and can be materially impacted by inaccurate reporting of financial information. In particular, inaccurate financial information could lead investors to incorrectly estimate future cash flows and potential earnings of the issuer with concurrent effects on the valuation of its stock. If the receipt of incentive-based compensation by executives is tied to stock price, then executives could receive erroneously awarded compensation and a subsequent accounting restatement due to material noncompliance with a financial reporting requirement could trigger recovery of such compensation tied to stock price.

While the economic effects associated with the inclusion of stock price and TSR within the scope of financial reporting measures would be the same as for the proposed rule and rule amendments in general, we discuss below the more specific effects stemming from this inclusion. Specifically, in the case of stock price and TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the cost of recovering incentive-based compensation may be higher. The significance of these costs would depend on the size and financial condition of the issuer, as well as the board's approach to determining the amount, if any, of excess incentive-based compensation to be recovered following a material accounting error. Since the proposed rule would require that this amount be based on a reasonable estimate of the effect of the accounting restatement on the financial reporting measure, a reasonable estimate of the ''but for'' price of the stock (*i.e.,* the stock price that would have been if financial statements originally had been presented as later restated) must be first determined.[302]

To reasonably estimate the ''but for'' price of the stock, there are a number of possible methods with different levels of complexity of the estimations and related costs.[303] One such method, which is often used in accounting fraud cases to determine the effects of corrective disclosure on the market price of an issuer's stock, is an ''event study.'' An event study captures the market's view of the valuation impact of an event or disclosure. In the case of a restatement, the event study estimates the drop in the stock price attributed to the announcement [304] that restated financial information is required, separate from any change in the stock price due to market factors. An event study therefore measures the net-of-market drop in the stock price,[305] which is a key input to establish the ''but for'' price at which the security is presumed to have traded in the absence of the inaccurate financial statements. In the context of an event study, to determine the net-of-market drop in the stock price, certain decisions have to be made, such as determining the appropriate proxy for the market return and statistical adjustment method (*i.e.,* a model to account for the potential difference in risk between the company and market); the model estimation period; the date and time that investors learned about the restatement; and the length of time it took for investors to incorporate the information from the restatement into the issuer's stock price. If designed appropriately, the implementation of a robust event study method would include an evaluation of the various design choices that are anchored on objective and commonly accepted practices by the industry and relevant literature.[306] The effects of these design choices may vary from case to case. Some of the potential choices may have no effect on the results while other choices may significantly drive the results and could generate considerable latitude in calculating a reasonable estimate of the excess amount of incentive-based compensation that was erroneously awarded.

Under any reasonable methodology, calculating the ''but for'' price can be complicated when stock prices are simultaneously affected by information other than the announcement of a restatement on the event date. Confounding information potentially affecting an issuer's stock price on the event date could include other plans released by the issuer related to potential corporate actions (*e.g.,* mergers, acquisitions, or capital raising), announcements of non-restatement related performance indicators, and news related to macro-economic events (*e.g.,* news about the industry the issuer operates in, changes to the state of the

[300] Increased expected total compensation could come in the form of an increase in base salary, incentive-based compensation, or other compensation. While increasing the incentive-based component of an executive's compensation package increases the variability of the executive's compensation beyond the additional variability due to the recovery policy, the issuer may find this to be the least costly way to compensate the executive. For example, an issuer may choose to increase the incentive-based compensation component, instead of increasing base salary, because the executive's current base salary is near the limit for tax deductibility under 162(m) of the Internal Revenue Code and an increase in base salary may therefore not be tax deductible.

[301] *See* DeHaan, Hodge, and Shevlin *Does Voluntary Adoption of a Clawback Provision Improve Financial Reporting Quality?* Contemporary Accounting Research 30 (2013) 1027–1062; Babenko, Bennett, Bizjak, and Coles *Clawback Provisions* Working Paper (2012).

[302] *See* Section II.C.3.a for a discussion of the determination of the recoverable amount.

[303] The complexity of a particular methodology involves a trade-off between the potential for more precise estimates of the ''but for'' price and the assumptions and expert judgments required to implement such methodology.

[304] Event studies can have multiple event dates. For example an event study can measure the stock price impact attributed to the announcement that amended filings are required, as well as the stock price impact attributed to when the actual amended filings are made available for the investors to examine.

[305] Over the 2005–2012 period, the average stock price reaction to restatements disclosed under Item 4.02 of Form 8–K was negative 2.3 percent. *See* Scholz, S. 2013. ''Financial Restatement: Trends in the United States: 2003–2012.'' Center for Audit Quality. This study documents a substantial drop in the number and severity of restatements in the years following the enactment of SOX. The study includes 4,246 restatements reported by U.S. and foreign filers registered with the Commission from 2005 to 2012 on Form 8–K under Item 4.02. The number of restatement announcements peaked in 2006 (940), soon after implementation of SOX Section 404 internal control reporting. In subsequent years, the number of Item 4.02 restatements declined significantly, with 255 reported in 2012, a reduction of approximately 73 percent from the 2006 peak year. Restatement periods are shorter in later years, declining from an average 29 months in 2006 to 18 months in 2012.

[306] The complexity of an event study depends on the circumstances of the event and the particular approach taken. For example, one event study could use a broad market index in estimating a market model, while another event study could use a more tailored index that may take into account industry specific price movements but would require judgments on the composition of the issuers in the more tailored index. For further discussion on the complexities of event studies see Mitchell, M. and J. Netter, ''The Role of Financial Economics in Securities Fraud Cases: Applications at the Securities and Exchange Commission,'' *The Business Lawyer,* vol 49, Feb 1994, p. 565; Kothari, S.P, and J. Warner, ''Econometrics of Event Studies,'' *Handbook of Corporate Finance: Empirical Corporate Finance* (Elsevier/North-Holland), 2004; and Campbell, John Y., A. Lo, and A. C. MacKinlay, *The Econometrics of Event Studies,* NJ: Princeton University Press, 1997.

economy, and information about expected inflation). Because an issuer has influence over the timing of the release of issuer-specific information, the issuer has the ability to complicate the estimation of a reasonable ''but for'' price. For example, if an accounting restatement is expected to have a negative effect on an issuer's stock price, the executive has an incentive and often the ability to contemporaneously release positive information in an attempt to mitigate any reduction in the issuer's stock price. The strategic release of confounding information may make it more difficult for investors to evaluate the effect of the restatement on the performance of the issuer.

The proposed rule and rule amendments do not require an event study to calculate a reasonable estimate of the excess incentive-based compensation tied to stock price to be recovered after a material accounting error. Instead, the proposed rule and rule amendments would permit an issuer to use any reasonable estimate of the effect of the restatement on stock price and TSR. In addition, the proposed rule and rule amendments allow the board of directors to forego recovery if the aggregate direct costs of seeking recovery from a current or former executive officer would exceed the amount of excess incentive-based compensation to be recovered. We note that an issuer would need to incur the direct costs associated with implementing a methodology to reasonably estimate the ''but for'' price *prior to* determining whether any amount of incentive-compensation is required to be recovered under the proposed rule and rule amendments. In choosing a methodology to derive a reasonable estimate of the effect of the accounting restatement on stock price and/or TSR, issuers would likely weigh the costs of implementing any methodology against the complexity of the ''but for'' price estimate and the potential need to justify that estimate, under their unique facts and circumstances.

Some issuers may decide to use a methodology that is testable, supported by published literature, or follows procedures that derive from objective standards because such a methodology may reduce the likelihood that the reasonableness of the amount of excess incentive-based compensation required to be recovered would be challenged by interested parties, including the executives subject to recovery and the exchanges that are required to ensure that the proposed rule and rule amendments are enforced as a listing standard. The implementation of such methodology may be complex because it would likely include extensive checks of the assumptions and design choices made to generate the estimate of the ''but for'' price. If these issuers have a reasonable basis to believe that some amount of incentive-based compensation is required to be recovered, they may decide to retain an expert for the implementation of such methodology and determination of the ''but for'' price.

If an issuer chooses to retain an expert, the monetary costs that would be incurred to estimate the ''but for'' price and subsequent calculation of the amount of excess incentive-based compensation required to be recovered could be substantial. In these circumstances, we expect that the determination of the ''but for'' price would require a significant number of hours of work by highly skilled experts. In addition, once a ''but for'' price is estimated, the determination of the amount of excess incentive-based compensation could involve complex calculations and assumptions that may require additional hours of work by the expert.[307] To establish a proxy for billing rates of experts who have specialized knowledge in financial economics, we examined expert witness fees by areas of expertise. For example, based on survey responses from 21 financial experts, SEAK, Inc. 2014 Survey of Expert Witness Fees reports that the hourly fee for case review/preparation ranges from $175 to $800 with an average fee of $337 per hour.[308]

Other issuers may decide to use a methodology that results in less complex implementations to estimate the ''but for'' price [309] because, for example, by using simpler implementations, issuers may already be in a position to determine with reasonable confidence that, after taking into account a reasonable range of variation in the ''but for'' price, no amount of incentive-based compensation tied to stock price and/or TSR was erroneously awarded to executive officers in the first place and consequently no recovery is required. If an issuer chooses to implement a less complex methodology, the determination of the ''but for'' price and subsequent calculation of the amount of excess incentive-based compensation required to be recovered would entail a significantly lower number of hours of work that can be likely performed internally without retaining an expert.

Under any methodology, the variation in assumptions used to determine a reasonable estimate of the ''but for'' price (*e.g.,* determining a proxy for market returns; the date and time that investors learned about the restatement; and the length of time it took for investors to incorporate the information from the restatement into the issuer's stock price) and of the amount of excess incentive-based compensation may increase the level of perceived uncertainty that risk averse executives attach to the incentive-based component of their pay. This uncertainty may in turn make it more costly and difficult for issuers to retain executive officers' talent, when competing for that talent against unlisted companies. We note that there may be other factors affecting the ability of an issuer to attract and retain executive talent. Further, the incremental effect of the proposed rule and rule amendments is mitigated to the extent that the labor markets for executives at listed issuers and at unlisted issuers do not overlap.

The significant complications of establishing a reasonable estimate of the ''but for'' price, in conjunction with the likely monetary costs incurred to calculate it, make it difficult to assess the relative costs and benefits accruing to an issuer from enforcing a recovery policy that covers compensation based on stock price and/or TSR. These uncertainties also could undermine issuers' incentives to enforce their recovery policies and make it more difficult for exchanges to monitor compliance.[310] This effect may be partially or entirely mitigated by the requirement for issuers to provide documentation to the relevant exchange of any reasonable estimates used or attempts to recover compensation, which will assist exchanges in monitoring compliance and incentivize

[307] For example, if an executive receives at-the-money options as a form of incentive-based compensation, where the number of options is based on the current stock price, the issuer may determine that a reasonable estimate of the amount to be recovered involves recalculating both the number of options awarded as well as the value of those options that would have been issued at a different strike price.

[308] *See* SEAK, Inc. 2014 Survey of Expert Witness Fees, available at: *http://store.seak.com/2014-survey-of-expert-witness-fees/.*

[309] For example, issuers may use historical estimates of beta that are publicly available on several sources to substitute for a more complex estimation of the market model. The beta estimate of a stock captures the correlation of that stock's return with the return of the overall market over a certain period of time.

[310] Due to the discretion that an issuer may have in choosing both the method and the assumptions underlying the method to estimate a ''but for'' price, it may be difficult for an exchange to determine if the ''but for'' price resulted in a reasonable estimate of the excess incentive-based compensation required to be recovered. This may make it more difficult for exchanges to monitor compliance.

issuers to carefully document the considerations that went into the determination to enforce (or not enforce) their recovery policy. On balance, we think other aspects of the proposed rule and rule amendments, such as the ability to use reasonable estimates and the board's discretion not to pursue recovery when the direct enforcement costs would exceed the amount to be recovered, may serve to mitigate these costs; however, below we request comment on this aspect of the proposed rule and rule amendments to help us better understand its economic effects.

Notably, incentive-based compensation as defined in the proposed rule and rule amendments would not include base salary; compensation tied to operational metrics that are not financial reporting measures; or compensation awarded solely at the issuer's discretion. These forms of compensation would not be subject to recovery under a policy that meets the proposed rule requirements. These exclusions may create the incentive to shift compensation from forms that are subject to recovery to forms that are not subject to such recovery. This would apply to both re-negotiated compensation packages as well as newly instituted ones. The incentive to shift compensation away from forms that are subject to a recovery policy may affect the level of incentive alignment between executive interests and shareholder interests in terms of the enhancement of firm value, which depends on how well performance metrics used as triggers in compensation contracts capture the relationship between an executive's effort to enhance firm value and the actual enhancement of firm value.

The incentive to substitute away from incentive-based compensation tied to financial reporting measures may result in base salary or performance-based compensation tied to operational metrics being a larger portion of the executive officer's compensation package. This could reduce pay-for-performance sensitivity and may reduce the correlation between the executive officer's effort to enhance value and executive compensation if these alternative metrics are poor substitutes for financial reporting measures. In addition, as a result of the proposed rule and rule amendments, an issuer's board of directors may use increased discretion in setting compensation awards, since compensation that is solely awarded at the discretion of the board, such as bonuses, would not be subject to recovery under the proposed rule and rule amendments. Issuers may adjust compensation policies to be more dependent on the discretion of the board, which may make it more difficult for investors to understand the incentives of executives and may result in lower pay-for-performance sensitivity.[311]

The implementation of a mandatory recovery policy may also make it less costly overall to use incentive-based compensation. Without a recovery policy, as noted above, a compensation package with significant incentive-based compensation components based on financial reporting measures may provide incentives for an executive to engage in conduct that could result in inaccurate financial reporting. If a recovery policy encourages business practices and accounting judgments that are less likely to result in a material accounting error, the benefits to the issuer of having higher quality financial reporting could more than offset the additional compensation executives require to bear the increased uncertainty about the compensation they expect to ultimately retain.[312]

The proposed rule and rule amendments may have effects on the competition among issuers for executive officers. By increasing uncertainty and reducing the perceived value of the expected incentive-based compensation of an executive, companies where the proposed rule and rule amendments apply (*i.e.,* listed issuers) may have more difficulty attracting talented executives and, as such, may be at a comparative disadvantage to companies that are not covered (*i.e.,* unlisted issuers and private companies). It is unclear to what extent the labor market for executives at listed issuers and the labor market for executives at unlisted issuers and private companies overlap. The more these labor markets are segmented, the lower the comparative disadvantage potentially imposed by the proposed rule requirements.

3. Additional Potential Effects on Listed Issuers

We anticipate several effects of the proposed rule and rule amendments on listed issuers. Although we believe some issuers have already implemented recovery policies broadly consistent with the proposed rule requirements, the most immediate outcome of the proposed rule and rule amendments would be the establishment of listing standards that would result in issuers implementing recovery policies consistent with Section 10D. Under such recovery policies, an immediate benefit for a listed issuer would be the recovery of incentive-based compensation that was erroneously paid to executive officers, which would then be available for the issuer to invest in productive assets that may generate value for shareholders. Although recovery of erroneously paid compensation would provide an immediate benefit for issuers and shareholders, we note that, in many cases, these funds are not likely to be significant in the context of the issuer's business operations, and thus this effect may not be as consequential as the other, more indirect effects that we discussed above on financial reporting quality and executive compensation packages.[313]

We also anticipate direct benefits to flow from the disclosure of the recovery policy that are separate from any pecuniary recovery following an accounting restatement. Currently, an issuer could have a compensation recovery policy but choose not to disclose the existence or the terms of that policy. Under the proposed rule and rule amendments, the issuer's recovery policy would be required to be filed as an exhibit to the issuer's annual report on Form 10–K, 20–F or 40–F or, for registered management investment companies, on Form N–CSR. The proposed rule and rule amendments also require the disclosure be provided in interactive data format using XBRL. This may facilitate the extraction and analysis of the information contained in the disclosure across a large number of issuers or, eventually, over several years. This requirement would impose additional costs and burdens on issuers,

[311] If the issuer transitions to compensation that is not payable on account of the attainment of one or more performance goals, such as compensation payable solely at the discretion of the board of directors, the issuer may lose the ability to deduct a portion of executive compensation under Section 162(m) of the Internal Revenue Code. This may mitigate the incentive for companies to transition compensation away from performance-based metrics.

[312] A voluntarily implemented recovery policy may not reduce the expected cost of issuing incentive-based compensation because of insufficient incentive for board members to enforce the recovery after a material restatement. The proposed rule, which conditions initial and continued listing of securities on compliance with the recovery policy, substantially increases the incentives of board members to enforce the policy.

[313] Based on an analysis of executive compensation using Standard & Poor's Compustat and Executive Compensation databases, in fiscal year 2013 non-salary compensation for all named executive officers combined was 0.4 percent of net income. This represents an upper bound for the amount of incentive-based compensation for named executive officers. This number does not include current and former executive officers that would be covered by the proposed rule but are not named executive officers.

but despite these costs, some shareholders and prospective investors may benefit from the data tagging requirement to the extent that it is helpful in extracting the tagged information across large number of filings.

With this information investors would have a better understanding of the incentives of the issuer's executive officers, owing to more complete disclosure of the issuer's compensation policies, including its recovery policy. Moreover, while all listed issuers would be required to adopt and comply with a recovery policy satisfying the requirements of the proposed rule and rule amendments, issuers would have the choice to implement recovery policies that are more extensive than these requirements. For example, issuers may choose to establish more stringent recovery policies (*e.g.,* a longer look-pack period, more forms of compensation subject to recovery, or more individuals covered) to provide a positive signal to the market regarding their approach to executive compensation. If variation in the scope of issuers' recovery policies emerges across issuers, disclosure of those policies may improve allocative efficiency by allowing investors to make more informed investment decisions based on a better understanding of the incentives of the executives. The requirement to publish recovery policies may make such variation more likely to emerge.[314]

Further, if at any time during the last completed fiscal year a listed issuer's recovery policy required that issuer to recover excess incentive-based compensation, the proposed rule and rule amendments would require the issuer to disclose details of the recovery efforts under proposed Item 402(w) of Regulation S–K. These disclosures would allow existing and prospective shareholders to observe whether issuers are enforcing their recovery policies consistent with Section 10D. This would also help exchanges monitor compliance. Similarly, the requirement to disclose instances in which the board does not pursue recovery and its reasons for doing so (*i.e.,* because the expense of enforcing recovery rights would exceed the recoverable amount or because the recovery would violate a home country's laws), would permit shareholders to be aware of the board's actions in this regard and thus potentially hold board members accountable for their decisions.

There are a number of direct costs for issuers resulting from the proposed rule and rule amendments. As part of the implementation of a recovery policy that meets the proposed rule requirements, issuers would likely incur legal and consulting fees to develop policies that comply with the proposed requirements and to modify the compensation packages of executive officers to conform to those policies. Moreover, even those issuers that already have recovery policies would likely incur some costs to revise those policies to comply with the proposed rule requirements. We note, however, that those issuers that currently have recovery policies similar to the proposed rule requirements likely would not incur significant additional costs. While we do not have the data to quantify the implementation costs, we expect that these costs will vary with the complexity of the compensation practices of the issuer as well as the number of executive officers the recovery policy will apply to. In addition to these implementation costs, issuers also would incur direct costs to provide the required disclosures about their compensation recovery policies, including costs to tag the required disclosure in XBRL format, as described above. For purposes of our Paperwork Reduction Act (PRA) Analysis, we estimate that the proposed disclosure requirement would impose a minimal internal burden of approximately one hour. If an issuer is required to recover erroneously awarded compensation, the issuer would incur a direct cost to prepare and disclose the information required by proposed Item 402(w) (and for registered management investment companies, new Item 12 to Form N–CSR and Item 22(b)(20) of Schedule 14A) and the corresponding narrative. For purposes of our PRA, we estimate that proposed disclosure requirement would impose a burden of approximately 21 hours.[315]

There would also be costs attendant upon any recovery actions taken under the new mandated recovery policy. The proposed rule and rule amendments would require a recovery policy to recover excess compensation that was paid based on the achievement of a financial reporting measure that was later restated. The issuer would likely face costs to calculate the amount to be recovered. This could be done internally or the issuer could choose to retain an accountant or other expert to calculate this amount. The costs of calculating the amount to be recovered likely will vary depending on the nature of the restatement, the type of compensation involved and the periods affected. Given this variation, it is difficult to derive a precise estimate of these costs; however, we believe that if outside professionals are retained to assist with the calculations, they will likely charge between $200 and $400 per hour for their services.[316] Whatever the precise costs, we note they are likely to be significantly less than the costs associated with performing the restatement itself.

Depending on the circumstances, there may be other costs associated with enforcing the mandatory recovery policy. For example, the issuer may incur costs to trace specific shares to determine if the executive sold shares that were awarded based on an erroneous financial reporting measure. If the current or former executive officer is unwilling to return excess incentive-based compensation, the issuer may incur legal expenses to pursue recovery through litigation or arbitration. If the aggregate direct costs incurred to seek recovery from an executive or former executive officer would exceed the erroneously paid incentive-based compensation, the proposed rule and rule amendments would allow discretion on the part of the board of directors in determining whether to pursue recovery. This discretion may mitigate the direct costs of enforcement to issuers. Finally, if an issuer does not take action when required under its recovery policy, then the issuer may also incur costs associated with the listing exchange's proceedings to delist its securities.

These effects of the proposed rule and rule amendments may vary across different types of listed issuers. In particular, the effects of implementing a recovery policy could be greater (or lower) on SRCs, relative to non-SRCs, to the extent that SRCs use a higher (or lower) proportion of incentive-based compensation than other issuers.

[314] In the absence of a mandatory requirement for issuers to implement and disclose a recovery policy, investors may be uncertain about whether the implementation of a voluntary recovery policy by an issuer is a credible signal of the issuer's approach to executive compensation. By increasing the likelihood of a recovery policy being enforced, the proposed rules and rule amendments may make the signal more credible and allow issuers to differentiate themselves based on variation in the scope of a recovery policy.

[315] *See* Section IV.C, below, for a more extensive discussion of these disclosure burdens, including the monetization and aggregation across issuers of these direct costs.

[316] Staff estimate is based on wage information compiled by the U.S. Bureau of Labor Statistics, Occupational Employment Statistics for the Financial Analyst occupation. As of May 2014, the median hourly wage for a financial analyst was $37.80 and the 90th percentile hourly wage was $74.36. The hourly wage is multiplied by a factor of 5.35 to account for bonuses, employee benefits, and overhead.

Analysis by Commission staff finds evidence that SRCs, on average, use a lower proportion of performance-based compensation than non-SRCs, suggesting a lower potential impact of the proposed rule and rule amendments on SRCs.[317] However, there is also evidence that companies that are typically required to restate financial disclosures are generally smaller than those that are not required to restate financial disclosures, suggesting that there could be a greater incidence of recoveries at SRCs.[318] One academic study suggests that the likelihood of reporting a material weakness in internal controls over financial reporting decreases as the size of the issuer increases.[319] This may imply that, relative to non-SRCs, the proposed rule and rule amendments may cause executives at SRCs to devote proportionately more resources to the production of high-quality financial reporting. Finally, to the extent that implementation of the proposed rule and rule amendments entails fixed costs, SRCs, because of their smaller size, would incur a greater proportional compliance burden than larger issuers.

The proposed rule and rule amendments also may affect EGCs differently than non-EGCs. Relative to non-EGCs, EGCs can be characterized as having higher expected growth in the future and potentially higher risk investment opportunities.[320] As such, relative to non-EGCs, the market valuations of EGCs may be driven more by future prospects than by the value of current assets. As discussed previously, a recovery policy could reduce the incentive of an executive officer to invest in certain value-enhancing projects that may increase the likelihood of a material accounting error. The reduced incentive of executive officers could have a greater adverse effect for EGCs, relative to non-EGCs, to the extent that executives at EGCs are more likely to forgo value-enhancing growth opportunities as a result of the proposed rule and rule amendments, which as discussed above, may have a larger impact on the market value of equity of EGCs, relative to non-EGCs. However, EGCs also tend to be smaller than non-EGCs,[321] which may imply that EGCs have a higher likelihood of an accounting restatement and a higher likelihood of reporting a material weakness in internal controls over financial reporting. Similar to SRCs, this may imply that, relative to non-EGCs, the proposed rule and rule amendments may cause executives at EGCs to devote proportionately more resources to the production of high-quality financial reporting.

4. Potential Effects on U.S. Exchanges

Proposed Rule 10D–1 would affect U.S. exchanges by requiring them to adopt listing standards that prohibit the initial or continued listing of an issuer that does not comply with the proposed rule and rule amendments. The requirement places a direct burden on exchanges to amend applicable listing standards. This burden could involve deploying legal and regulatory personnel to develop listing standards that comply with the proposed rule requirements. Moreover, the exchanges are likely to incur some costs associated with tracking the compliance of each issuer. We anticipate these costs to be minimal as exchanges likely already have robust compliance tracking systems and personnel that are dedicated to ensuring listing standards are met. Finally, if an issuer chooses not to implement a recovery policy or does not take action when required under its recovery policy, the exchanges would incur costs to enforce the listing standards required by the proposed rule and rule amendments. This would also result in a loss of the revenue associated with the delisted issuer.

In the event that issuers alter their decisions regarding where to list due to the proposed rule and rule amendments, revenue of U.S. exchanges may be affected. For example, there could be revenue effects for U.S. exchanges if issuers choose to list their securities on a foreign exchange without such a compensation recovery policy requirement. More generally, if the mandated listing requirements are perceived to be particularly burdensome for listed issuers, this could adversely impact the competitive position of U.S. exchanges vis-à-vis those foreign exchanges that do not enforce similar listing standards. However, given the costs associated with transferring a listing and the broad applicability of the proposed rule to securities listed on U.S. exchanges, we do not believe it is likely that the proposed rule requirements would compel a typical issuer in the short-term to find a new trading venue not subject to these requirements. The proposed rule and rule amendments may result in a loss of potential revenue to exchanges to the extent that issuers, who would have decided to list on an exchange in the absence of the proposed rule requirements, choose to forgo listing or delay listing until the issuers' circumstances change.[322] The magnitude of this effect on exchanges is not quantifiable given the absence of data. It could be significant because the loss in potential revenue from the total number of issuers that have chosen to forgo or delay listing aggregates over

[317] Commission staff analyzed the composition of total compensation paid to all named executive officers whose compensation was reported in the Summary Compensation Table for 50 randomly selected SRCs and 50 randomly selected non-SRCs in fiscal year 2013. Staff found that, on average, SRCs pay 60 percent of total compensation in base salary versus 36 percent for non-SRCs; SRCs pay 13 percent of total compensation in stock awards versus 27 percent for non-SRCs; and SRCs pay 5 percent of total compensation in non-equity incentive plan compensation versus 16 percent for non-SRCs. Since the Summary Compensation Table does not provide sufficient information to determine if stock awards or non-equity incentive plan compensation would constitute ''incentive-based compensation'' as defined in the proposed rule, these differences should be taken as maximum estimated differences of incentive-based compensation for named executives. Staff did not find significant differences between SRCs and non-SRCs in the percent of compensation paid as a bonus, in option awards, in nonqualified deferred compensation, or in other compensation. We also note that the proposed rule covers a broader set of employees than the named executives required to report within the Summary Compensation Table.

[318] *See* Scholz, S. 2013. ''Financial Restatement: Trends in the United States: 2003–2012.'' Center for Audit Quality.

[319] *See* Doyle, Ge, and McVay *Determinants of weaknesses in internal control over financial reporting* Journal of Accounting and Economics 44 (2007) 193–223.

[320] In an analysis of 270 EGCs with fiscal year 2013 data available in the Standard & Poor's Compustat and the CRSP monthly stock returns databases, Commission staff found that on average EGCs have higher research and development expenses as a percent of total assets. Further, on average EGCs have a lower book-to-market ratio, which is indicative of shareholders expecting higher than average growth in the future. For this analysis staff set book-to-market to the 0.025 and 0.975 percentile for values outside of that range; staff set research and development to the 0.975 percentile for values about that level; and staff restricted the analysis to companies that issued common equity and were listed on NYSE, NYSE MKT, or NASDAQ.

[321] Using the same dataset referenced in note 322 above, staff found that the average market capitalization of EGCs is approximately $1.08 billion while the average market capitalization of non-EGCs is approximately $6.09 billion. Staff also found that the smallest EGCs tend to be similar in market capitalization to the smallest non-EGCs, with the 10th percentile of the distributions of the market capitalization of EGCs and non-EGCs being approximately $48 million and $45 million, respectively. Conversely, staff found that the largest EGCs tend to have substantially lower market capitalizations than the largest non-EGCs, with the 90th percentile of the distributions of the market capitalization of EGCs and non-EGCs being approximately $2.49 billion and $11.59 billion.

[322] We note that capital formation could be hindered if an issuer chooses to forgo or delay listing because of the proposed rule and rule amendments and the alternative methods of raising capital result in less liquid securities being issued or less thorough disclosures being required. We also note that other factors may affect the decision for an issuer to list and any effect from the proposed rule and rule amendments would be incremental to these other factors.

time, thus having lasting impact on the exchanges' revenue.

While we believe the typical issuer is unlikely to transfer listing in the short-term as a result of the proposed rule and rule amendments, the potential response of foreign issuers is less clear. On one hand, by virtue of listing on a U.S. exchange, a foreign issuer has demonstrated willingness to list outside of the issuer's home country. The issuer presumably chose to list on a U.S. exchange because the particular U.S. exchange is an advantageous trading venue for the issuer's securities. Although the direct costs are not expected to be substantial, the proposed rule and rule amendments would increase the compliance burden on listed issuers and could thereby potentially reduce the advantage of listing on a U.S. market. As a result, foreign issuers could choose to delist from U.S. exchanges. Further, foreign issuers that are not currently listed on U.S. exchanges, but are considering listing on a non-home country exchange, may choose to list on a foreign exchange because of the increased burden of our proposed rule and rule amendments. At the same time, we understand that many foreign issuers list on a U.S. exchange to signal their high quality, which is achieved by subjecting themselves to more rigorous corporate governance rules and regulations. As a result, many foreign issuers may gain the ability to raise capital at a reduced cost compared to their home market by listing on U.S. exchanges. Hence, some foreign issuers seeking access to U.S. capital markets may view the requirements as beneficial. Therefore, the revenue effect on U.S. exchanges resulting from the behavior of foreign issuers is unclear, because while some foreign issuers may choose to delist as a result of the proposed rule and rule amendments, others may choose to list because of them.

Finally, the proposed rule and rule amendments apply to all issuers who list securities on a national securities exchange. As such there are unlikely to be competitive effects between national securities exchanges due to all national securities exchanges being affected by the proposed rule requirements.

5. Indemnification and Insurance

The benefits discussed above would result from an executive's changes in behavior as a result of incentive-based compensation being at risk for recovery should a material accounting error occur. These benefits would be substantially undermined if the issuer were able to indemnify the executive for the loss of compensation. Moreover, shareholders would bear the cost of providing such indemnification. Therefore, the proposed rule and rule amendments expressly prohibit listed issuers from indemnifying executives against the loss of erroneously awarded compensation or paying or reimbursing executives for insurance premiums to cover losses incurred under the recovery policy.

Although reimbursement of insurance premiums by issuers would be prohibited, the insurance market may develop a policy that would allow an executive, as an individual, to purchase insurance against the loss of incentive-based compensation when the material accounting error is not attributable to the executive. In that event, an executive would be able to hedge the risk that results from a recovery policy. If an executive purchased this type of insurance policy, the benefits of the issuer's recovery policy could be reduced to the extent that insurance reduces the executive's incentive to ensure accurate financial reporting. However, to the extent an insurance policy does not cover losses resulting from the recovery of compensation attributed to a material accounting error that resulted from inappropriate actions by the insured executive, then incentives would remain for the executive to ensure accurate financial reporting.

The development of this type of private insurance policy for executives would also have implications for issuers. Overall, it could make it less costly for an issuer to compensate an executive after implementing a recovery policy. Without insurance, an issuer that implemented a recovery policy would likely have to adjust compensation to account for the loss in expected incentive-based compensation in addition to the increased uncertainty in incentive-based compensation. If an active insurance market develops such that the executive could hedge against the uncertainty caused by the recovery policy, then market-determined compensation packages would likely increase to cover the cost of such policy. While the proposed rule and rule amendments explicitly prohibit issuers from reimbursing an executive for the cost of such insurance policy, a market-determined compensation package would likely account for the hedging cost and incorporate it into the base salary of the executive's compensation. This increase would likely be less than the increase in the market-determined compensation packages if an insurance policy was unavailable because a risk averse executive would no longer need to bear recovery policy induced uncertainty.

C. Alternatives

Below we discuss possible alternatives to the proposed rule and rule amendments we considered and their likely economic effects.

1. Exemptions for Certain Categories of Issuers

We considered exempting (or permitting the exchanges to exempt) SRCs and EGCs from proposed Rule 10D–1. As discussed above, the proposed rule and rule amendments may impose certain disproportionate costs on SRCs and EGCs. However, SRCs and EGCs may have an increased likelihood of reporting a material accounting error and may be more likely to report a material weakness in internal controls over financial reporting, due to their smaller size relative to non-SRCs and non-EGCs. As such, we believe the benefits of the proposed rule and rule amendments may be particularly salient for these categories of issuers. For these reasons, SRCs or EGCs would not be exempt from the proposed rule and rule amendments.

One commenter suggested that we consider exempting FPIs, arguing that home countries would generally have a greater interest in determining whether issuers should have recourse against executives.[323] As discussed previously in the context of foreign issuers generally, the potential effect of the proposed rule and rule amendments on FPIs is difficult to predict. On the one hand, due to the potential differences in home country law, the proposed rule requirements may be especially burdensome for FPIs relative to non-FPIs.[324] On the other hand, there is evidence that many FPIs may be listing on U.S. exchanges in part in order to credibly signal to investors their willingness and ability to be subjected to stricter governance standards.[325] While FPIs may face a relatively higher burden from the proposed rule and rule amendments, they also may experience a relatively higher benefit.

2. Excluding Incentive-Based Compensation Tied to Stock Price

As discussed above, the proposed rule and rule amendments may result in

[323] *See* letter from the American Bar Association.

[324] We note that if recovery of excess incentive-based compensation would violate home country law, the proposed rule and rule amendments permit the board of directors discretion to forgo recovery as impracticable, subject to certain conditions.

[325] *See* Doidge, Karolyi, and Stulz *Why Do Foreign Firms Leave U.S. Equity Markets?* The Journal of Finance, Vol. LXV, No. 4, August 2010.

issuers incurring significant costs to recover incentive-based compensation tied to stock price. If incentive-based compensation tied to stock price were excluded from the proposed rule and rule amendments, issuers would not incur the costs associated with recovery. However, a significant component of the total performance-based compensation would be excluded from the scope of the proposed rule and rule amendments without generating the related potential benefits. In addition, the exclusion of performance-based compensation tied to stock price would provide issuers with an incentive to shift compensation away from forms subject to recovery to forms tied to market-based metrics such as stock price and TSR that would not be subject to recovery.

The economic effect of any incentive to shift away from compensation subject to recovery is difficult to predict due to the nature of incentive-based compensation tied to stock price. On one hand, incentive-based compensation tied to metrics that are market-based, such as stock price or TSR, could be highly correlated with the interests of shareholders and therefore may be beneficial to shareholders. On the other hand, because market-based measures may be influenced by factors that are unrelated to the performance of the executive officer, these metrics may not fully capture or represent the effort and actions taken by the executives. In particular, market-based measures incorporate expectations about future earnings, which may not be closely tied to the executive officer's current performance. In contrast, the use of accounting-based measures, such as those derived from revenue, earnings, and operating income, can be tailored to match a specific performance period and provide direct measures of financial outcomes.[326] To this end, accounting-based measures of performance—although not directly tied to issuer value enhancement—may better capture the effect of an executive's actions during the relevant performance period. Therefore, if incentive-based compensation tied to stock price was excluded, the incentive to substitute away from accounting-based measures to market-based measures of performance may result in compensation that is less tied to the consequences of an executive's actions during the performance period.

The optimal compensation package likely contains a mix of incentive-based compensation tied to market-based measures and accounting-based measures. Empirically, the use of market-based performance metrics is more prevalent in long-term incentive plans than in short-term incentive plans.[327] Using market-based measures of performance in short-term incentive plans may be undesirable for the executive in that the stock price may be volatile and may not reflect the executive's efforts to enhance firm value in the performance period. The relatively higher use of market-based measures in long-term incentive plans could reflect that in the long-term the executive's efforts to enhance firm value may be more likely to be incorporated in the market value of the firm. Short-term and long-term performance-based compensation may act as complements, with the different performance measures used to award each type reflecting the compensation committee's effort to align the executive's interests with those of the shareholders. The exclusion of incentive-based compensation tied to stock price may affect the relative mix of short-term and long-term performance-based compensation, or the performance measures that each type is linked to, and as such a recovery policy may have large economic effects through a change in the incentives of the executive.

3. Other Alternatives Considered

One commenter suggested that the Commission specifically authorize the use of a nonqualified deferred compensation plan (*e.g.,* a ''holdback plan'' or ''bonus bank'') to aid in the recovery of erroneously awarded incentive-based compensation.[328] A bonus bank would likely reduce the enforcement costs of recovering erroneously awarded incentive-based compensation. On the other hand, a bonus bank may further augment any increase in compensation necessary to offset the expected cost to the executive of a recovery policy. This is due to the executive not having access to the funds she has earned and having to delay consumption that would otherwise be possible. Further, as the commenter acknowledged, a bonus bank implicitly makes the executive a creditor to the issuer, resulting in reduced risk-taking incentives for the executive. While for some companies reduced risk-taking incentives may be value increasing, for other companies reduced risk-taking incentives may be value decreasing. Further, by making the executive a creditor to the issuer, a bonus bank reduces the incentive alignment between equity holders and the executive officer.

One commenter suggested that the Commission also require issuers to recover a proportionate amount of the compensation tied to qualitative variables or board judgment after a material accounting error.[329] Relative to the proposed rule and rule amendments, this alternative implementation would reduce the incentive to alter the composition of an executive's compensation package to more heavily weight qualitative variables or board judgment, while increasing the incentive to more heavily weight base salary as well as performance-based compensation tied to metrics other than financial reporting measures. To the extent that performance compensation based on qualitative variables and board judgment allows the board to compensate the executive officer for performance that is otherwise difficult to measure, the reduced weight on this form of performance-based compensation could make it more difficult for the board to align the executive officer's interests with those of the shareholders. On the other hand, reduced weight on this form of performance-based compensation could make it easier for shareholders to understand the incentives of the executive officer. Because a greater amount of performance-based compensation would be at risk for recovery, implementing this alternative implementation could also increase the amount of expected compensation the executive officer would require in order to voluntarily bear the increased uncertainty.

D. Request for Comment

We request data to quantify the costs and benefits described throughout this release. We seek estimates of these costs and benefits, as well as any costs and benefits not already identified, that may result from the adoption of the proposed rule and rule amendments. We also request qualitative feedback on the nature of the economic effects, including the benefits and costs, we have identified and any benefits and costs we may have overlooked.

To assist in our consideration of the economic effects of the proposed rule and rule amendments, we request comment on the following:

[326] Six of the eight most frequently used metrics to award compensation in short-term incentive plans were accounting-based measures. Those measures are earnings, revenue, operating income, EBITDA, cash flow, and return on capital. *See* Equilar *Measuring Short-Term and Long-Term Performance in 2012.*

[327] *See* Equilar *Measuring Short-Term and Long-Term Performance in 2012.*

[328] *See* letter from Clark Consulting.

[329] *See* letter from AFL–CIO.

1. We request comment on all aspects of the economic effects, including the costs and benefits of the proposed rule and rule amendments, and identification and assessment of any effects not discussed herein. In addition, we seek estimates and views regarding these costs and benefits for particular types of issuers, including SRCs, EGCs, FPIs, registered management investment companies, and issuers that only have listed debt or preferred equity securities, as well as the costs or benefits for any other types of issuers that may result from the adoption of these proposed amendments.

2. What, if any, effects on financial reporting or executive compensation practices might arise from the requirement for listed issuers to recover erroneously awarded incentive-based compensation as proposed?

3. Would proposed Rule 10D–1 lead to higher quality financial reporting? If so, explain how this would occur, and how the rule might be revised to mitigate any adverse unintended consequences?

4. Would proposed Rule 10D–1 incentivize listed issuers to conclude that a material error is not material in order to avoid recovery of incentive-based compensation? Would the proposed rule and rule amendments incentivize listed issuers to delay investigating or reporting a material error?

5. What is the likely effect of the requirement on executive compensation practices of listed companies, and how would this effect likely vary according to the issuer's size or line of business?

6. What is the likely burden that listed issuers would incur to modify the compensation packages of executive officers?

7. What would be the burden if issuers were required to recover only the amount of excess incentive-based compensation tied to accounting-based performance metrics? Would the burden be different in the case of recovery of excess incentive-based compensation tied to market-based performance metrics? What are the benefits of each approach?

8. What implementation issues, if any, would issuers encounter in conducting an event study or otherwise establishing the ''but-for'' price?

9. What is the cost of establishing a ''but for'' price and determining the amount of excess incentive-based compensation to be recovered? What factors affect the determination of reasonable estimates of the ''but for'' price and of this amount? Would issuers seek expert help in making such determinations? If so, what would be the costs to issuers of retaining such experts?

10. Would it be more difficult for exchanges to monitor compliance with the proposed rule and rule amendments for compensation tied to market-based performance metrics? Is the documentation required to support the analyses of the issuer sufficient for compliance monitoring? If not, what other documentation should be required?

11. Would there be any significant transition costs imposed on listed issuers as a result of the proposals, if adopted? Please be detailed and provide quantitative data or support, as practicable.

12. How is this rulemaking likely to affect the market for executive officers?

13. What is the likely effect of this rulemaking on the decision to be a listed issuer in the United States, and how does this effect vary according to the size or line of business of the issuer?

14. Are there additional alternatives to the proposals we should consider that would satisfy the requirements of new Section 10D of the Exchange Act? If so, please describe.

IV. Paperwork Reduction Act

A. Background

Certain provisions of the proposed rule and rule amendments contain a ''collection of information'' within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[330] The Commission is submitting the proposed rule and rule amendments to the Office of Management and Budget (''OMB'') for review in accordance with the PRA.[331] An agency may not conduct or sponsor, and a person is not required to comply with, a collection of information unless it displays a currently valid OMB control number. The titles for the collections of information are:[332]

''Regulation S–K'' (OMB Control No. 3235–0070);

''Regulation 14A and Schedule 14A'' (OMB Control No. 3235–0059);

''Regulation 14C and Schedule 14C'' (OMB Control No. 3235–0065);

''Form 10–K'' (OMB Control No. 3235–0063);

''Form 20–F'' (OMB Control No. 3235–0288);

''Form 40–F'' (OMB Control No. 3235–0381);

''Rule 20a–1 under the Investment Company Act of 1940, Solicitations of Proxies, Consents, and Authorizations'' (OMB Control No. 3235–0158); and

''Form N–CSR'' under the Securities Exchange Act of 1934 and under the Investment Company Act of 1940, Certified Shareholder Report of Registered Management Investment Companies'' (OMB Control No. 3235–0570).

Regulation S–K was adopted under the Securities Act and the Exchange Act. Regulations 14A and 14C and the related schedules, Form 10–K, Form 20–F and Form 40–F were adopted under the Exchange Act. Rule 20a–1 was adopted under the Investment Company Act, and Form N–CSR was adopted under the Exchange Act and Investment Company Act. The regulations, schedules and forms set forth the disclosure requirements for proxy and information statements and annual reports filed by issuers to help shareholders make informed voting and investment decisions. Our proposed rule and rule amendments to existing regulations, schedules and forms are intended to implement new Section 10D of the Exchange Act.

The hours and costs associated with preparing and filing the forms and preparing, filing and sending the schedules constitute reporting and cost burdens imposed by each collection of information. Compliance with the amendments is mandatory. Responses to the information collections will not be kept confidential and there is no mandatory retention period for the information disclosed.

B. Summary of Proposed Rule and Rule Amendments

We are proposing new Rule 10D–1 under the Exchange Act and amendments to Items 601, 402 and 404 of Regulation S–K, Schedule 14A, Form 20–F, Form 40–F, and Form N–CSR to implement the provisions of Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, which added Section 10D to the Securities Exchange Act of 1934. Section 10D requires the Commission to adopt rules directing the exchanges and associations to prohibit the listing of any security of an issuer that is not in compliance with Section 10D's requirements concerning disclosure of the issuer's policy on incentive-based compensation and recovery of erroneously awarded compensation. In accordance with the statute, proposed Rule 10D–1 directs the exchanges to establish listing standards that, among other things, require each issuer to adopt and comply with a policy

[330] 44 U.S.C. 3501 *et seq.*

[331] 44 U.S.C. 3507(d) and 5 CFR 1320.11.

[332] The paperwork burden from Regulation S–K is imposed through the forms that are subject to the requirements in those regulations and is reflected in the analysis of those forms. To avoid a Paperwork Reduction Act inventory reflecting duplicative burdens and for administrative convenience, we assign a one-hour burden to Regulation S–K.

providing for recovery, under certain circumstances, of incentive-based compensation received by current or former executive officers and to file all disclosure with respect to that policy in accordance with Commission rules.

To implement Section 10D(b)(1), we are proposing to add new disclosure provisions to Items 601 and 402 of Regulation S–K, Schedule 14A, Form 20–F, Form 40–F, and Form N–CSR. The new disclosure provisions would require each listed issuer to file the issuer's policy, if applicable, regarding recovery of incentive-based compensation from its executive officers as an exhibit to its Exchange Act annual report or, in the case of a listed registered management investment company, its Form N–CSR annual report. A new instruction to the Summary Compensation Table would require that any amounts recovered pursuant to the listed issuer's policy reduce the amount reported in the applicable column and total column for the fiscal year in which the amount recovered initially was reported.

In addition, if during the last completed fiscal year, either a restatement was completed that required recovery of excess incentive-based compensation pursuant to a listed issuer's recovery policy, or there was an outstanding balance of excess incentive-based compensation from the application of the policy to a prior restatement, proposed Item 402(w) would require the listed issuer to disclose: [333]

- For each restatement,
  - The date on which the listed issuer was required to prepare an accounting restatement;
  - The aggregate dollar amount of excess incentive-based compensation attributable to the restatement;
  - The estimates used to determine the excess incentive-based compensation attributable to such accounting restatement, if the financial reporting measure related to a stock price or total shareholder return metric; and
  - The aggregate dollar amount of excess incentive-based compensation that remained outstanding as of the end of the last completed fiscal year;
- The name of each person, if any, from whom during the last completed fiscal year the listed issuer decided not to pursue recovery, the amount forgone from each such person, and a brief description of the listed issuer's reasons for not pursuing recovery; and
- The name of, and amount due from, each person from whom, at the end of its last completed fiscal year, excess incentive-based compensation had been outstanding for 180 days or longer since the date the issuer determined the amount the person owed.

We propose that the same disclosure requirements apply to listed U.S. issuers and listed foreign private issuers, including MJDS filers. These disclosure requirements would increase the amount of information that listed U.S. issuers and listed foreign private issuers must compile and disclose in their schedules and forms. For listed U.S. issuers, other than registered management investment companies, the proposed amendments to Items 402 and 601 of Regulation S–K would require additional disclosure in Exchange Act annual reports and proxy or information statements filed on Schedule 14A or Schedule 14C relating to an annual meeting of shareholders, or a special meeting in lieu of an annual meeting, at which directors are to be elected and would increase the burden hour and cost estimates for each of those forms. For a listed management investment company registered under the Investment Company Act of 1940, the proposed amendments to Form N–CSR and Schedule 14A would require additional disclosure and would increase the burden hour and cost estimates associated with Form N–CSR and Rule 20a–1, if the registered investment company pays incentive-based compensation. For a listed foreign private issuer filing an annual report on Form 20–F, Form 40–F or, if a foreign private issuer elects to use U.S. registration and reporting forms, on Form 10–K, the proposed amendments to those forms and the proposed amendment to Item 402(a)(1), respectively, would require additional disclosure in annual reports and would increase the burden hour and costs estimates for each of these forms. The disclosure required by proposed Item 402(w), proposed paragraph 22(b)(20) to Schedule 14A, proposed new Item 12 to Form N–CSR, and proposed Item 6.F of Form 20–F would be required to be block-text tagged in XBRL.

C. Paperwork Reduction Act Burden Estimates

As proposed, the information a listed U.S. issuer is required to compile and disclose regarding its policy on incentive-based compensation pursuant to Item 402(w) would supplement information that U.S. issuers that are not registered management investment companies, smaller reporting companies or emerging growth companies are already required to provide elsewhere in their executive compensation disclosure, if material. Specifically, these issuers are required to provide information relating to the compensation of the named executive officers, including policies and decisions regarding the adjustment or recovery of awards or payments if the relevant performance measures upon which they are based are restated or otherwise adjusted in a manner that would reduce the size of an award or payment.[334] With respect to registered management investment companies subject to proposed Rule 10D–1, information mirroring the proposed Item 402(w) disclosure would be included in annual reports on Form N–CSR and in proxy statements and information statements relating to the election of directors.[335] Such information would also supplement existing disclosures.

Similarly, for a listed foreign private issuer filing an annual report on Form 20–F or, if a foreign private issuer elects to use U.S. registration and reporting forms, on Form 10–K, the proposed amendments would supplement existing disclosures. Currently, Item 7.B of Form 20–F requires disclosure of transactions between the issuer and senior management of the nature and extent of any transactions that are material to the company or related party that are unusual in their nature or conditions involving services to which the company was a party. Although this disclosure requirement generally would require disclosure of the recovery of excess incentive-based compensation, it may not elicit the same information required to be provided under the proposed rule and rule amendments.

We arrived at the estimates discussed below by reviewing our burden estimates for similar disclosure and

[333] *See* proposed Item 402(w) of Regulation S–K, proposed Item 6.F of Form 20–F, and proposed Paragraph (17) of Paragraph B of Form 40–F. We also are proposing to amend the instructions to Items 404(a) of Regulation S–K so that a listed issuer that complies with Item 402(w) disclosure requirements would not need to disclose any incentive-based compensation recovery pursuant to those requirements. We are also proposing to amend Form N–CSR and Item 22 of Schedule 14A to require registered management investment companies that would be subject to Rule 10D–1 to provide information that would mirror the disclosure requirements of proposed Item 402(w).

[334] *See* Item 402(b)(2)(viii) of Regulation S–K.

[335] Proposed Item 12 of Form N–CSR; proposed Item 22(b)(20) of Schedule 14A. We are also proposing to amend General Instruction D to Form N–CSR to permit registered management investment companies subject to proposed Rule 10D–1 to answer the information required by proposed Item 12 by incorporating by reference from the company's definitive proxy statement or definitive information statement.

considering our experience with other tagged data initiatives. We believe that the preparation of the information required by proposed Item 402(w) and the corresponding narrative disclosure provisions is comparable to an issuer's preparation of the disclosure required by the amendments to enhance certain aspects of proxy disclosure.[336] The amendments in that release were largely designed to enhance existing disclosure requirements. Similarly, we believe that the proposed Item 402(w) amendments would enhance the disclosure that is already required by Item 402 of Regulation S–K and disclosure that is required by Section 10D(b)(1). We believe that certain of the information required to prepare the new disclosure would be readily available to some U.S. issuers because this information, if material, is required to be gathered, determined or prepared in order to satisfy the other disclosure requirements of Item 402 of Regulation S–K. For other listed issuers, we believe that the information required to prepare the new disclosure requirement will not impose a significant burden because the issuer controls and possesses this information, which is a compilation of facts related to an issuer's implementation of its recovery policy if during the last completed fiscal year the issuer was required to recover excess incentive-based compensation or there was an outstanding balance of excess incentive-based compensation not recovered pursuant to that policy. In the Proxy Disclosure Enhancements release, we estimated that the amendments would impose on average an incremental burden of 25 hours for accelerated filers and 17 hours for non-accelerated filers to prepare their proxy and information statements. We believe the proposed disclosure regarding an issuer's policy on recovery of erroneously awarded compensation requires less new information than the amendments in the Proxy Disclosure Enhancements Release. We believe the primary cost elements for issuers preparing the proposed disclosure would be determining the types of incentive-based compensation awards an issuer grants to executive officers that could be subject to recovery under the issuer's recovery policy and, if necessary, gathering the information regarding the application and implementation of this recovery policy if required by a restatement.

As a result, we estimate that the average incremental burden for an issuer to prepare the new narrative disclosure would be 21 hours. This estimate includes the time and cost of preparing disclosure that has been appropriately reviewed by management, in-house counsel, outside counsel and members of the board of directors, as well as block-text tagging the data in XBRL format. Because this estimate is an average, the burden could be more or less for any particular company, and may vary depending on a variety of factors, such as the degree to which companies use the services of outside professionals or internal staff and resources to tag the data in XBRL. Issuers subject to Item 402(w) would provide the required disclosures by either including the information directly in Exchange Act annual reports or incorporating the information be reference from a proxy statement on Schedule 14A or information statement on Schedule 14C. For purposes of our PRA estimates, consistent with past amendments to Item 402,[337] we have assumed that all of the burden relating to the new narrative disclosure requirements would be associated with Form 10–K, even if registrants include the new disclosure required in Form 10–K by incorporating that disclosure by reference from the proxy statement on Schedule 14A.[338]

We believe that the requirement to file a listed issuer's recovery policy as an exhibit to its annual report pursuant to proposed Item 601(b)(96) and the corresponding provisions (and for registered investment companies, as an exhibit to its annual report on Form N–CSR pursuant to proposed Item 13(a)(2) of Form N–CSR) will be minimal. A listed issuer will be required simply to file the policy that it otherwise would be required to have pursuant to the listing standards of the exchange on which it lists securities. We estimate this burden to be approximately one hour.

As a result of the estimates discussed above, we estimate for purposes of the PRA that the total incremental burden on all listed issuers with respect to the proposed amendments would be 5,961 hours for internal company time and $203,700 for the services of outside professionals. The total incremental burden for Form 10–K would be 5,246 hours for internal company time and $138,600 for the services of outside professionals.[339] The total incremental burden for Form N–CSR would be 23 hours for internal company time and $2,100 for the services of outside professionals.[340] The total incremental burden for Form 20–F would be 553 hours for internal company time and $50,400 for the services of outside professionals and for Form 40–F would be 139 hours for internal company time and $12,600 for the services of outside professionals.[341] For Form 10–K and

[336] *See* Release No. 33–9089, *Proxy Disclosure Enhancements,* (Dec. 16, 2009) [74 FR 68334] (''Proxy Disclosure Enhancements''). The release adopted amendments to make new or revised disclosures about: Compensation policies and practices that present material risks to the company; stock and option awards of executives and directors; director and nominee qualifications and legal proceedings; board leadership structure; the board's role in risk oversight; and potential conflicts of interest of compensation consultants that advise companies and their boards of directors.

[337] We took a similar approach in connection with the rules for Summary Compensation Table disclosure required by the 2006 amendments to Item 402. *See Executive Compensation and Related Person Disclosure,* Release No. 33–8732A, n. 326 (Aug. 29, 2006) [71 FR 53158].

[338] Similarly, for purposes of the PRA estimates, we are also assuming that all of the burden relating to the new narrative disclosure requirements for registered investment companies would be associated with Form N–CSR, and therefore, we are not allocating a separate burden estimate for Rule 20a–1.

[339] This includes one hour to file the recovery policy as an exhibit to the annual report as well as the burden associated with providing Item 402(w) disclosure, when applicable. We estimate the number of responses for filing the recovery policy based on the number of listed domestic issuers filing annual reports in 2014, or 4,206 issuers. Proposed Item 402(w) would require disclosure when a listed issuer completes a restatement that requires recovery of excess incentive-based compensation pursuant to its compensation recovery policy or when there is an outstanding balance of excess incentive-based compensation from the application of the policy to a prior restatement. To estimate the burden associated with this disclosure, we looked to the number of listed issuers that filed an Item 4.02 Form 8–K (Non-Reliance on Previously Issued Financial Statements) in 2014, or 66 issuers. To calculate the total annual incremental burden arising from the new narrative disclosure, we multiplied the estimated number of annual responses (66) by 21 burden hours. We note that the number of restatements filed in any given year will vary and that, depending on the nature of their recovery efforts, certain issuers may be required to provide Item 402(w) disclosure for more than one year.

[340] We estimate seven registered management investment companies that are listed issuers and are internally managed that may have executive officers who receive incentive-based compensation. Of these seven, we assume for PRA purposes that one registered management investment company per year will be required to prepare the new narrative disclosure required by proposed new Item 12 of Form N–CSR. As indicated below, for Form N–CSR, we estimate that 75% of the burden of preparation will be carried by the registrant internally and the remaining 25% of the burden will be carried by outside professionals retained by the company at an average cost of $400 per hour. On the basis of the foregoing, we estimate an aggregate internal burden hour of 22 hours ((7 registrants × 1 hour per registrant to file the policy pursuant to proposed new Item 13(a)(2)) + (1 registrant × 21 hours per registrant to prepare the new narrative disclosure required by proposed new Item 12×75%) = 23 hours), and estimate an aggregate increase of $2,100 for the services of outside professionals (1 registrant × 21 hours per registrant to retain outside professionals to prepare the new narrative disclosure required by proposed new Item 12×25% × $400 per hour) = $2,100).

[341] Consistent with our estimates for Form 10–K, we estimate the number of responses for filing the

Form N–CSR we estimate that 75% of the burden of preparation is carried by the company internally and that 25% of the burden of preparation is carried by outside professionals retained by the company at an average cost of $400 per hour. For Forms 20–F and 40–F we estimate that 25% of the burden of preparation is carried by the company internally and that 75% of the burden of preparation is carried by outside professionals retained by the company at an average cost of $400 per hour. There is no change to the estimated burden of Regulation S–K because the burdens that this regulation imposes are reflected in our revised estimates for the forms. Similarly, there is no change to the estimated burden of Schedule 14A, Schedule 14C and Rule 20a–1 because, as noted above, the burdens associated with the proposed disclosures are allocated to Form 10–K and Form N–CSR, respectively.

We derived our new burden hour and cost estimates by estimating the total amount of time it would take a listed issuer to prepare and review the disclosure requirements contained in the final rules. This estimate represents the average burden for all listed issuers, both large and small. In deriving our estimates, we recognize that the burdens will likely vary among individual listed issuers based on a number of factors, including the size and complexity of their organizations. We believe that some listed issuers will experience costs in excess of this average in the first year of compliance with the amendments and some issuers may experience less than the average costs. A summary of the proposed changes is included in the table below.

TABLE 1—CALCULATION OF INCREMENTAL PRA BURDEN ESTIMATES [342]

	Current annual responses (A)	Proposed annual responses (B)	Current burden hours (C)	Increase in burden hours (D)	Proposed burden hours (E) = C + D	Current professional costs (F)	Increase in professional costs (G)	Proposed professional costs = F + G
Form 10–K	8137	8137	12,198,095	5,246	12,203,089	$1,627,400,000	$138,600	$1,627,538,600
Form 20–F	942	942	623,021	553	623,795	743,277,230	50.400	743,277,630
Form 40–F	205	205	22,034	139	22,425	26,440,500	12,600	26,453,100
Form N–CSR	6,576	6,576	177,799	23	177,822	3,189,771	2,100	3,191,871
Total	15,860	15,860	13,020,949	5,961	13,026,910	2,400,257,501	203,700	2,400,461,201

D. Solicitation of Comments

We request comments in order to evaluate: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information would have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information; (3) whether there are ways to enhance the quality, utility and clarity of the information to be collected; and (4) whether there are ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.[343]

Any member of the public may direct to us any comments concerning the accuracy of these burden estimates and any suggestions for reducing these burdens. 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 should send a copy to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090, with reference to File No. S7–12–15. Requests for materials submitted to OMB by the Commission with regard to these collections of information should be in writing, refer to File No. S7–12–15, and be submitted to the Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–0213. 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 best assured of having its full effect if OMB receives it within 30 days of publication.

V. Small Business Regulatory Enforcement Fairness Act

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA),[344] we solicit data to determine whether the proposed rule and rule amendments constitute 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.

Commenters should provide empirical data on (1) the potential annual effect on the economy; (2) any increase in costs or prices for consumers or individual industries; and (3) any potential effect on competition, investment or innovation.

VI. Initial Regulatory Flexibility Act Analysis

This Initial Regulatory Flexibility Analysis (''IRFA'') has been prepared in accordance with the Regulatory Flexibility Act.[345] This IRFA involves proposals to direct the exchanges and associations to prohibit the listing of a security of an issuer that is not in compliance with Section 10D's requirements concerning recovery of erroneously awarded compensation and to implement disclosure requirements related to the recovery of such compensation.

recovery policy based on the number of listed foreign private issuers and MJDS issuers filing annual reports in 2014, or 639 issuers. To estimate the burden associated with the disclosure required when a foreign private issuer or MJDS issuer is required to pursue recovery pursuant to its policy, we looked to the number of listed foreign private issuers and MJDS issuers that restated financial statements in 2014, or 8 foreign private issuers filing on Form 20–F and 2 MJDS issuers filing on Form 40–F. To calculate the total annual incremental burden arising from the new narrative disclosure, we multiplied the estimated number of annual responses (8 and 2, respectively) by 21 burden hours and allocated the resulting burden estimate to the relevant form.

[342] The number of responses reflected in the table equals the three-year average of the number of schedules and forms filed with the Commission and currently reported by the Commission to OMB.

[343] We request comment pursuant to 44 U.S.C. 3506(c)(2)(B).

[344] 5 U.S.C. 801 *et seq.*

[345] 5 U.S.C. 603.

A. Reasons for, and Objectives of, the Proposed Action

We are proposing a new rule and rule amendments to implement the provisions of Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, which adds Section 10D to the Securities Exchange Act of 1934. Section 10D requires the Commission to adopt rules directing the exchanges and associations to prohibit the listing of any security of an issuer that is not in compliance with Section 10D's requirements concerning disclosure of the issuer's policy on incentive-based compensation and recovery of erroneously awarded compensation. In accordance with the statute, the proposed rule would direct the exchanges to establish listing standards that require each issuer to adopt and comply with a policy providing for the recovery of incentive-based compensation based on financial information required to be reported under the securities laws that is received by current or former executive officers, and to file all disclosure with respect to that policy in accordance with Commission rules.

The primary objective of the proposed rule and rule amendments is to require that all listed issuers have a policy in place to recover compensation based on material noncompliance with any financial reporting requirement. This policy would require executives to return erroneously awarded compensation without the need for shareholders to embark on costly litigation.[346] The disclosure requirements in the proposed rule and rule amendments are intended to promote consistent disclosure among issuers as to both the substance of a listed issuer's recovery policy and how the listed issuer implements that policy in practice.

B. Legal Basis

We are proposing the rule and rule amendments pursuant to Sections 6, 7, 10, and 19(a) of the Securities Act; Sections 10D, 13, 14, 23(a) and 36 of the Exchange Act and Sections 20, 30, and 38 of the Investment Company Act of 1940.

C. Small Entities Subject to the Proposed Action

The proposals would affect, among other entities, exchanges that list securities and listed issuers subject to our proxy rules. The Regulatory Flexibility Act defines ''small entity'' to mean ''small business,'' ''small organization,'' or ''small governmental jurisdiction.''[347] The Commission's rules define ''small business'' and ''small organization'' for purposes of the Regulatory Flexibility Act for each of the types of entities regulated by the Commission. Exchange Act Rule 0–10(e) provides that the term ''small business'' or ''small organization,'' when referring to an exchange, means any exchange that: (1) Has been exempted from the reporting requirements of Exchange Act Rule 601;[348] and (2) is not affiliated with any person (other than a natural person) that is not a small business or small organization, as defined under Exchange Act Rule 0–10.[349] No exchanges are small entities because none meet these criteria. Securities Act Rule 157[350] and Exchange Act Rule 0–10(a)[351] define an issuer, other than an investment company, to be a ''small business'' or ''small organization'' if it had total assets of $5 million or less on the last day of its most recent fiscal year and is engaged or proposing to engage in an offering of securities which does not exceed $5 million. The proposed rule and rule amendments would affect small entities that have a class of securities that are registered under Section 12(b) of the Exchange Act. We estimate that there are approximately 27 listed issuers, other than registered investment companies, that may be considered small entities. An investment company, including a business development company, is considered to be a ''small business'' 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.[352] We believe that certain of the rule and rule amendments would affect small entities that are investment companies, including business development companies, with a class of securities registered under Section 12(b) of the Exchange Act. We estimate that there are approximately 13 listed investment companies, including business development companies, that may be considered small entities.

D. Reporting, Recordkeeping, and Other Compliance Requirements

Under the proposals, the exchanges will be directed to prohibit the listing of an equity security of an issuer that does not comply with Section 10D's requirements concerning development and implementation of a policy requiring recovery of erroneously awarded incentive-based compensation, and disclosure of that policy. Large and small entities would be subject to the same recovery and disclosure requirements.

Proposed Rule 10D–1 would require exchanges to adopt listing standards that would require a listed issuer (including a small entity) to develop and implement a policy providing that, in the event that the issuer is required to prepare an accounting restatement due to material noncompliance with any financial reporting requirement, the issuer will recover from any of its current or former executive officers who received incentive-based compensation during the preceding three-year period based on the erroneous data, any such compensation in excess of what would have been paid under the accounting restatement.

If during the last completed fiscal year, either a restatement was completed that required recovery of excess incentive-based compensation pursuant to the listed small entity's compensation recovery policy, or there was an outstanding balance of excess incentive-based compensation from the application of the policy to a prior restatement, proposed Item 402(w) would require the listed small entity to disclose and provide in block-text tagged XBRL format:

- For each restatement,
  - The date on which the listed issuer was required to prepare an accounting restatement;
  - The aggregate dollar amount of excess incentive-based compensation attributable to the restatement; and
  - The aggregate dollar amount of excess incentive-based compensation that remained outstanding as of the end of the last completed fiscal year;
- The name of each person subject to recovery of excess incentive-based compensation attributable to an accounting restatement, if any, from whom during the last completed fiscal year the listed small entity decided not to pursue recovery, the amount forgone from each such person, and a brief description of the listed small entity's reasons for not pursuing recovery; and
- The name of, and amount due from, each person from whom, at the end of its last completed fiscal year, excess incentive-based compensation had been outstanding for 180 days or longer since the date the small entity determined the amount the person owed.

In addition, proposed Item 601(b)(96) and the corresponding amendment to Form N–CSR would require a listed

[346] Senate Report at 135–36.

[347] 5 U.S.C. 601(6).

[348] 17 CFR 242.601.

[349] 17 CFR 240.0–10(e).

[350] 17 CFR 230.157.

[351] 17 CFR 240.0–10(a).

[352] 17 CFR 270.0–10(a).

small entity to file, as an exhibit to its Exchange Act annual report or, in the case of a listed registered management investment company, its Form N–CSR annual report, its policy regarding the recovery of erroneously awarded incentive-based compensation.

The proposals will impose additional requirements on small entities in order to comply with the new listing standards and to collect, record and report the disclosures. For example, it can reasonably be expected that listed small entities would need to engage the professional services of attorneys to develop their recovery policies and would also need the services of both attorneys and accountants to implement those policies in the event of an accounting restatement. Such services will likely be needed to compute recoverable amounts, especially for incentive-based compensation based on stock price or total shareholder return metrics. Small entities also will incur costs to tag the required disclosures in XBRL format and may need to engage the services of outside professionals to assist with this process.

Our existing disclosure rules require smaller reporting companies to provide compensation information for named executive officers for the last two completed fiscal years in the Summary Compensation Table pursuant to Item 402(n) of Regulation S–K. We also believe that small entities do not typically grant their executive officers complex incentive-based compensation awards or use many different types of incentive-based compensation awards, which would significantly minimize the impact of the proposal, including the proposed reporting requirements, on small entities. To the extent a small entity may not currently be required to disclose the information the proposals require in the event there is a restatement and the restatement requires application of the small entity's recovery policy, this information should be readily available to the small entity as it controls how it implements its recovery policy. Where a small entity may be required to disclose this type of information in such filings pursuant to Item 404(a) of Regulation S–K, the proposed new instruction to Item 404 will provide that Item 404 disclosure is not required if the transaction involves the recovery of excess incentive-based compensation that is disclosed pursuant to Item 402(w).

In addition, we believe that the impact of the proposals on small entities will be lessened because the proposals apply only to listed issuers, and the quantitative listing standards applicable to issuers listing securities on an exchange, such as market capitalization, minimum revenue, and shareholder equity requirements, will serve to limit the number of small entities that would be affected.

E. Duplicative, Overlapping or Conflicting Federal Rules

As noted above, other statutes and rules administered by the Commission address the recovery of executive compensation. Section 304 of SOX provides for recovery of executive compensation when there has been material noncompliance of the issuer, as a result of misconduct, with any financial reporting measure. In addition, existing CD&A disclosure requirements call for disclosure of an issuer's policies and decisions regarding recovery of executive compensation in the event of an accounting restatement, to the extent material. Outside of the federal securities laws, EESA contains an executive compensation recovery provision applicable to financial institutions that sell troubled assets to the Secretary of the Treasury under TARP. As explained above, the proposed rule and rule amendments are generally broader in scope, and more specific in detail, than these existing provisions. For example, the proposed rule and rule amendments—unlike Section 304 of SOX—would require recovery in the event of an accounting restatement regardless of issuer misconduct. Similarly, the clawback provisions in EESA apply only to financial institutions that sold troubled assets to and have not repaid the Treasury, whereas the proposed rules apply to all listed issuers. Thus, although there may be some overlap between the proposed rule and rule amendments and these existing provisions, we do not believe the proposed rule and rule amendments would duplicate or conflict with other federal rules or statutes.

F. Significant Alternatives

The Regulatory Flexibility Act directs us to consider alternatives that would accomplish our stated objectives, while minimizing any significant adverse impact on small entities. In connection with the proposed disclosure amendments, we considered the following alternatives:

- Clarifying, consolidating or simplifying compliance and reporting requirements under the rules for small entities;
- Exempting small entities from all or part of the requirements; and
- Establishing different compliance or reporting requirements or timetables that take into account the resources available to small entities.

In some respects, we have used performance standards in crafting the proposals. Specifically:

- Proposed Rule 10D–1 uses a standard-based definition of ''incentive based compensation'' subject to recovery;
- Proposed Rule 10D–1 provides boards of directors with limited discretion to determine whether and how much compensation to pursue and broader discretion to determine the means of recovery; and
- Proposed Rule 10D–1 adopts a standard-based approach to determining the amount of excess incentive-based compensation subject to recovery.

We believe that high quality financial reporting is important for promoting investor confidence in the financial markets. The proposed rule and rule amendments would further this objective by requiring that all listed issuers have policies requiring the recovery of executive compensation that was received based on material noncompliance with financial reporting requirements. The disclosure requirements in the proposed rule and rule amendments would require clear disclosure of a listed issuer's policy on recovery of incentive-based compensation, and provide investors with useful information regarding the application of that policy. We believe that our proposed rule and rule amendments will promote consistent compliance with recovery obligations and related disclosure across all listed issuers without unduly burdening small entities. We note that the proposal provides issuers flexibility to forgo recovery in circumstances where the costs of enforcing recovery would exceed the recoverable amounts. This will help to limit costs for all issuers subject to the rule, including small entities.

Although we preliminarily believe that an exemption for small entities from coverage of the proposals would not be appropriate, we seek comment on whether we should exempt small entities from any of the proposed requirements or scale the proposed disclosure amendments to reflect the characteristics of small entities and the needs of their investors.[353]

At this time, we do not believe that different compliance methods or timetables for small entities would be appropriate. The proposals are intended to further the statutory goal of assuring that executive officers do not retain

[353] See Sections II.A.1 and II.D, above, and related requests for comment.

incentive-based compensation that they received erroneously. The specific disclosure requirements in the proposals will promote consistent disclosure among all issuers, including small entities. Separate compliance requirements or timetables for small entities could interfere with achieving the goals of the statute and our proposals. Nevertheless, we solicit comment on whether different compliance requirements or timetables for small entities would be appropriate, and consistent with the purposes of Section 954 of the Act.[354]

G. Solicitation of Comments

We encourage the submission of comments with respect to any aspect of this Initial Regulatory Flexibility Analysis. In particular, we request comments regarding:

- How the proposed rule and rule amendments can achieve their objective while lowering the burden on small entities;
- The number of small entities that may be affected by the proposed rule and rule amendments;
- Whether small entities should be exempt from the rule and rule amendments;
- The existence or nature of the potential impact of the proposed amendments on small entities discussed in the analysis; and
- How to quantify the impact of the proposed rule and rule amendments.

Respondents are asked to describe the nature of any impact and provide empirical data supporting the extent of the impact. Such comments will be considered in the preparation of the Final Regulatory Flexibility Analysis, if the proposed rule and rule amendments are adopted, and will be placed in the same public file as comments on the proposed rule and rule amendments themselves.

VII. Statutory Authority and Text of the Proposed Amendments Amendments

The amendments contained in this release are being proposed under the authority set forth in Sections 6, 7, 10, and 19(a) of the Securities Act, Sections 10D, 13, 14, 23(a) and 36 of the Exchange Act, and Sections 20, 30, and 38 of the Investment Company Act of 1940.

List of Subjects in 17 CFR Parts 229, 240, 249 and 274

Reporting and recordkeeping requirements, Securities, Investment companies.

[354] See Section II.F, above, and related requests for comment.

Text of the Proposed Amendments

For the reasons set out in the preamble, the Commission proposes to amend title 17, chapter II, of the Code of Federal Regulations as follows:

PART 229—STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975—REGULATION S–K

■ 1. The general authority citation for part 229 is revised to read as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77z–2, 77z–3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 777iii, 77jjj, 77nnn, 77sss, 78c, 78i, 78j, 78j–3, 78*l,* 78m, 78n, 78n–1, 78o, 78u–5, 78w, 78*ll,* 78mm, 80a–8, 80a–9, 80a–20, 80a–29, 80a–30, 80a–31(c), 80a–37, 80a–38(a), 80a–39, 80b–11, and 7201 *et seq.;* and 18 U.S.C. 1350.

* * * * *

■ 2. Section 229.402, as proposed to be amended at 78 FR 60559 [Oct. 1, 2013] and 80 FR 26329 [May 7, 2015], is further amended by:

■ a. Revising paragraph (a)(1);

■ b. Adding Instruction 5 to paragraph (c);

■ c. Adding Instruction 5 to paragraph (n); and

■ d. Adding paragraph (w).

The revision and additions read as follows:

§ 229.402 (Item 402) Executive compensation.

(a) * * *

(1) *Treatment of foreign private issuers.* A foreign private issuer will be deemed to comply with this Item if it provides the information required by Items 6.B, 6.E.2 and 6.F of Form 20–F (17 CFR 240.220f), with more detailed information provided if otherwise made publicly available or required to be disclosed by the issuer's home jurisdiction or a market in which its securities are listed or traded, or paragraph (17) of General Instruction B of Form 40–F (17 CFR 240.240f), as applicable. A foreign private issuer that elects to provide domestic Item 402 disclosure shall provide the disclosure required by Item 402(w) in its annual report or registration statement, as applicable.

* * * * *

(c) * * *

Instructions to Item 402(c). * * *

5. Any amounts recovered pursuant to a listed registrant's erroneously awarded compensation recovery policy shall reduce the amount reported in the applicable Summary Compensation Table column for the fiscal year in which the amount recovered initially was reported as compensation, and shall be identified by footnote.

* * * * *

(n) * * *

Instructions to Item 402(n). * * *

5. Any amounts recovered pursuant to the erroneously awarded compensation recovery policy of a smaller reporting company that is a listed registrant shall reduce the amount reported in its applicable Summary Compensation Table column for the fiscal year in which the amount recovered initially was reported as compensation, and shall be identified by footnote.

* * * * *

(w) *Disclosure of a listed registrant's action to recover erroneously awarded compensation.* If at any time during the last completed fiscal year either a restatement that required recovery of excess incentive-based compensation pursuant to the listed registrant's compensation recovery policy was completed or there was an outstanding balance of excess incentive-based compensation from the application of the policy to a prior restatement, the listed registrant shall provide the following information:

(1) For each restatement:

(i) The date on which the listed registrant was required to prepare an accounting restatement, as defined in 17 CFR 240.10D–1(c)(2);

(ii) The aggregate dollar amount of excess incentive-based compensation attributable to such accounting restatement;

(iii) The estimates that were used in determining the excess incentive-based compensation attributable to such accounting restatement, if the financial reporting measure related to a stock price or total shareholder return metric; and

(iv) The aggregate dollar amount of excess incentive-based compensation that remains outstanding at the end of the last completed fiscal year;

(2) If during the last completed fiscal year the listed registrant decided not to pursue recovery from any individual subject to recovery of excess incentive-based compensation attributable to an accounting restatement, for each such individual, the name and amount forgone and a brief description of the reason the listed registrant decided in each case not to pursue recovery;

(3) The name of each individual from whom, as of the end of the last completed fiscal year, excess incentive-based compensation had been outstanding for 180 days or longer since the date the issuer determined the amount the individual owed, and the

dollar amount of outstanding excess incentive-based compensation due from each such individual; and

(4) The disclosure required to be provided pursuant to this paragraph (w) shall appear with, and in the same format as, the rest of the disclosure required to be provided pursuant to this Item 402 and, in addition, shall be electronically formatted using the eXtensible Business Reporting Language (XBRL) interactive data standard in accordance with the EDGAR Filer Manual (17 CFR 232.11) as an exhibit to definitive Schedule 14A (17 CFR 240.14a–101) or definitive Schedule 14C (17 CFR 240.14c–101), as applicable, and Form 10–K (17 CFR 249.310). The XBRL format disclosure required to be provided pursuant this paragraph (w) must be block-text tagged.

Instructions to Item 402(w).

1. A *listed registrant* is a registrant that had a class of securities listed on a national securities exchange registered pursuant to section 6 of the Exchange Act (15 U.S.C. 78f) or a national securities association registered pursuant to section 15A of the Exchange Act (15 U.S.C. 78o–3) at any time during its last completed fiscal year.

2. A *compensation recovery policy* is the policy required by the listing standards adopted pursuant to 17 CFR 240.10D–1.

3. *Excess incentive-based compensation* is the erroneously awarded compensation computed as provided in 17 CFR 240.10D–1(b)(1)(iii) and the applicable listing standards for the listed registrant's securities.

4. For Item 402(w)(1), if the aggregate dollar amount of excess incentive-based compensation has not yet been determined, disclose this fact and explain the reason(s).

5. The information required by Item 402(w) must be disclosed only in proxy or information statements that call for Item 402 disclosure and the listed registrant's annual report on Form 10–K. The information required by this Item 402(w) will not be deemed to be incorporated by reference into any filing under the Securities Act, except to the extent that the listed registrant specifically incorporates it by reference.

* * * * *

■ 3. Amend § 229.404 by:

■ a. Removing ''or'' at the end of Instruction 5.a.i. to the Instructions to Item 404(a);

■ b. Removing the ''.'' and adding in its place '';or'' in Instruction 5.a.ii. to the Instructions to Item 404(a); and

■ c. Adding Instruction 5.a.iii. to the Instructions to Item 404(a).

The addition reads as follows:

§ 229.404 (Item 404) Transactions with related persons, promoters and certain control persons.

* * * * *

Instructions to Item 404(a). * * *

5.a. * * *

iii. The transaction involves the recovery of excess incentive-based compensation, as defined in Instruction 3 to § 229.402(w), that is disclosed pursuant to Item 402(w) (§ 229.402(w)).

* * * * *

■ 4. Amend § 229.601 adding paragraphs (96) and (97) to the exhibit table in paragraph (a) and adding paragraphs (b)(96) and (97) to read as follows:

§ 229.601 (Item 601) Exhibits.

(a) * * *

EXHIBIT TABLE

	Securities Act Forms										Exchange Act Forms					
	S–1	S–3	SF–1	SF–3	S–4[1]	S–8	S–11	F–1	F–3	F–4[1]	10	8–K[2]	10–D	10–Q	10–K	ABS–EE
* * *	*			*				*			*					
(96) *Listed Registrant Policy Relating to Recovery of Erroneously Awarded Compensation*	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	.....
(97) *Listed Registrant Compensation Recovery Disclosure under Item 402(w) of Regulation S–K in XBRL Electronic Format*	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	.....
* * *	*			*				*			*					

[1] An exhibit need not be provided about a company if: (1) With respect to such company an election has been made under Form S–4 or F–4 to provide information about such company at a level prescribed by Form S–3 or F–3; and (2) the form, the level of which has been elected under Form S–4 or F–4, would not require such company to provide such exhibit if it were registering a primary offering.

[2] A Form 8–K exhibit is required only if relevant to the subject matter reported on the Form 8–K report. For example, if the Form 8–K pertains to the departure of a director, only the exhibit described in paragraph (b)(17) of this section need be filed. A required exhibit may be incorporated by reference from a previous filing.

(b) * * *

(96) *Listed Registrant Policy Relating to Recovery of Erroneously Awarded Compensation.* A listed registrant must provide as an exhibit to its Exchange Act annual report the policy required by the applicable listing standards adopted pursuant to 17 CFR 240.10D–1. For purposes of this Item, a *listed registrant* is a registrant that had a class of securities listed on a national securities exchange registered pursuant to section 6 of the Exchange Act (15 U.S.C. 78f) or a national securities association registered pursuant to section 15A of the Exchange Act (15 U.S.C. 78o–3) at any time during its last completed fiscal year.

(97) *Listed Registrant Compensation Recovery Disclosure under Item 402(w) of Regulation S–K in XBRL Electronic Format.* The compensation recovery disclosure required to be provided by a listed registrant under Item 402(w) of Regulation S–K (§ 229.402(w)) in electronic format using the XBRL interactive data standard in accordance with the EDGAR Filer Manual (17 CFR 232.11). The exhibit must be block-text tagged.

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 5. The authority citation for part 240 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78j–4, 78k, 78k–1, 78*l*, 78m, 78n, 78n–1, 78*o*, 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll*, 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, 7201 *et seq.*, and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C.5221(e)(3); 18 U.S.C. 1350; and Pub. L. 111–203, 939A, 124 Stat.1376 (2010), unless otherwise noted.

* * * * *

■ 6. Add § 240.10D–1 to read as follows:

§ 240.10D–1—Listing standards relating to recovery of erroneously awarded compensation.

(a) Pursuant to section 10D(a) of the Act (15 U.S.C. 78j–4(a)):

(1) *National securities exchanges and associations.* The rules of each national securities exchange registered pursuant to section 6 of the Act (15 U.S.C. 78f) and each national securities association registered pursuant to section 15A of the Act (15 U.S.C. 78o–3), to the extent such national securities association lists securities in an automated inter-dealer quotation system must, in accordance with the provisions of this section, prohibit the initial or continued listing of any security of an issuer that is not

in compliance with the requirements of any portion of paragraph (b) or (c) of this section.

(2) *Implementation.* (i) Each national securities exchange and national securities association that lists securities must file with the Commission, no later than 90 days after publication of this section in the **Federal Register,** proposed rules or rule amendments that comply with this section. Such rules or rule amendments that comply with this section must be approved by the Commission and be effective no later than one year after publication of this section in the **Federal Register**.

(ii) Each listed issuer shall adopt the recovery policy required by this section no later than 60 days following the effective date of the listing standard referenced in paragraph (a)(2)(i) of this section. Each listed issuer shall comply with that recovery policy for all incentive-based compensation received by executive officers on or after the effective date of this section that results from attainment of a financial reporting measure based on or derived from financial information for any fiscal period ending on or after the effective date of this section. Each listed issuer shall provide the required disclosures in the applicable Commission filings required on or after the effective date of the listing standard referenced in paragraph (a)(2)(i) of this section.

(b) *Required standards.* The requirements of this section are as follows:

(1) *Recovery of erroneously awarded compensation.* The issuer shall adopt and comply with a written policy providing that, in the event that the issuer is required to prepare an accounting restatement due to the material noncompliance of the issuer with any financial reporting requirement under the securities laws, the issuer will recover the amount of erroneously awarded incentive-based compensation as provided below. The issuer shall file all disclosures with respect to such recovery policy in accordance with the requirements of the federal securities laws.

(i) To be subject to the issuer's recovery policy, incentive-based compensation:

(A) Must have been received while the issuer has a class of securities listed on a national securities exchange or a national securities association; and

(B) Must have been received by an individual who served as an executive officer of the issuer at any time during the performance period for that incentive-based compensation.

(ii) The issuer's recovery policy shall apply to any incentive-based compensation received during the three completed fiscal years immediately preceding the date that the issuer is required to prepare a restatement of its previously issued financial statements to correct a material error. In addition to these last three completed fiscal years, the recovery policy shall apply to any transition period (that results from a change in the issuer's fiscal year) within or immediately following those three completed fiscal years. However, a transition period that comprises a period of nine to 12 months would be deemed a completed fiscal year. A ''transition period'' refers to the period between the last day of the issuer's previous fiscal year end and the first day of its new fiscal year. An issuer's obligation to recover excess incentive-based compensation is not dependent on if or when the restated financial statements are filed.

(iii) The amount of incentive-based compensation subject to the issuer's recovery policy (the ''erroneously awarded compensation'') shall be the amount of incentive-based compensation received that exceeds the amount of incentive-based compensation that otherwise would have been received had it been determined based on the accounting restatement, and shall be computed without regard to any taxes paid. For incentive-based compensation based on stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement:

(A) The amount shall be based on a reasonable estimate of the effect of the accounting restatement on the stock price or total shareholder return upon which the incentive-based compensation was received; and

(B) The issuer shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the exchange or association.

(iv) The issuer must recover erroneously awarded compensation in compliance with its recovery policy except to the extent that it would be impracticable to do so. Recovery would be impracticable only if the direct expense paid to a third party to assist in enforcing the policy would exceed the amount to be recovered, or if recovery would violate home country law. Before concluding that it would be impracticable to recover any amount of erroneously awarded compensation based on expense of enforcement, the issuer must first make a reasonable attempt to recover that erroneously awarded compensation. The issuer shall document such reasonable attempt(s) to recover, and provide that documentation to the exchange or association. Before concluding that it would be impracticable to recover any amount of erroneously awarded compensation based on violation of home country law, the issuer must obtain an opinion of home country counsel, not unacceptable to the applicable national securities exchange or association, that recovery would result in such a violation, and shall provide such opinion to the exchange or association. In addition, the home country law must have been adopted in such home country prior to the date of publication in the **Federal Register** of proposed Rule 10D–1. In either case, the issuer's committee of independent directors responsible for executive compensation decisions, or in the absence of such a committee, a majority of the independent directors serving on the board, shall make any determination that recovery would be impracticable.

(v) The issuer is prohibited from indemnifying any executive officer or former executive officer against the loss of erroneously awarded compensation.

(vi) An issuer that has been delisted from any national securities exchange or national securities association for failing to comply with the recovery policy required by this section may not list its securities on any national securities exchange or national securities association until the issuer comes into compliance with that policy.

(2) *General exemptions.* The requirements of this section shall not apply to the listing of:

(i) A security futures product cleared by a clearing agency that is registered pursuant to section 17A of the Act (15 U.S.C. 78q–1) or that is exempt from the registration requirements of section 17A(b)(7)(A) (15 U.S.C. 78q–1(b)(7)(A)).

(ii) A standardized option, as defined in § 240.9b–1(a)(4), issued by a clearing agency that is registered pursuant to section 17A of the Act (15 U.S.C. 78q–1).

(iii) Any security issued by a unit investment trust, as defined in 15 U.S.C. 80a–4(2).

(iv) Any security issued by a management company, as defined in 15 U.S.C. 80a–4(3), that is registered under section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a–8), if such management company has not awarded incentive-based compensation to any executive officer of the company in any of the last three fiscal years, or in the case of a company that has been listed for less than three fiscal years, since the listing of the company.

(c) *Definitions.* Unless the context otherwise requires, all terms used in this section have the same meaning as in the Act and the rules and regulations thereunder. In addition, unless the context otherwise requires, the following definitions apply for purposes of this section:

(1) *Accounting restatement.* For purposes of this rule, an accounting restatement is the result of the process of revising previously issued financial statements to reflect the correction of one or more errors that are material to those financial statements.

(2) *Date on which an issuer is required to prepare an accounting restatement.* For purposes of Section 10D of the Act (15 U.S.C. 78j–4), the date on which an issuer is required to prepare an accounting restatement is the earlier to occur of:

(i) The date the issuer's board of directors, a committee of the board of directors, or the officer or officers of the issuer authorized to take such action if board action is not required, concludes, or reasonably should have concluded, that the issuer's previously issued financial statements contain a material error; or

(ii) The date a court, regulator or other legally authorized body directs the issuer to restate its previously issued financial statements to correct a material error.

Note to paragraph (c)(2): The date specified in paragraph (c)(2)(i) of this section generally is expected to coincide with the occurrence of the event described under Item 4.02(a) of Exchange Act Form 8–K (17 CFR 249.308). Neither date specified in paragraph (c)(2) of this section is predicated on if or when a Form 8–K is filed.

(3) *Executive officer.* For purposes of Section 10D of the Act (15 U.S.C. 78j–4), an *executive officer* is the issuer's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the issuer in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the issuer. Executive officers of the issuer's parent(s) or subsidiaries shall be deemed executive officers of the issuer if they perform such policy making functions for the issuer. In addition, when the issuer is a limited partnership, officers or employees of the general partner(s) who perform policy-making functions for the limited partnership are deemed officers of the limited partnership. When the issuer is a trust, officers or employees of the trustee(s) who perform policy-making functions for the trust are deemed officers of the trust.

Note to paragraph (c)(3): *Policy-making function* is not intended to include policy-making functions that are not significant. If pursuant to Item 401(b) of Regulation S–K (§ 229.401(b)) the issuer identifies a person as an executive officer, it is presumed that the Board of Directors has made that judgment and that the persons so identified are the executive officers for purposes of Section 10D of the Act (15 U.S.C. 78j–4), as are such other persons enumerated in this paragraph (c)(3) but not in Item 401(b).

(4) *Incentive-based compensation.* For purposes of Section 10D (15 U.S.C. 78j–4), *incentive-based compensation* is any compensation that is granted, earned or vested based wholly or in part upon the attainment of a financial reporting measure. Financial reporting measures are measures that are determined and presented in accordance with the accounting principles used in preparing the issuer's financial statements, any measures that are derived wholly or in part from such measures, and stock price and total shareholder return. A financial reporting measure need not be presented within the financial statements or included in a filing with the Commission.

(5) *Material noncompliance.* For purposes of Section 10D (15 U.S.C. 78j–4), a restatement to correct an error that is material to previously issued financial statements shall be deemed to result from material noncompliance of the issuer with a financial reporting requirement under the securities laws.

(6) *Received.* For purposes of Section 10D (15 U.S.C. 78j–4), incentive-based compensation is deemed received in the issuer's fiscal period during which the financial reporting measure specified in the incentive-based compensation award is attained, even if the payment or grant of the incentive-based compensation occurs after the end of that period.

■ 7. Amend Section 240.14a–101, by adding Item 22(b)(20) and Item 25 to read as follows:

§ 240.14a–101 Schedule 14A. Information required in proxy statement.

SCHEDULE 14A INFORMATION

* * * * *

Item 22. * * *

(b) * * *

(20) In the case of a Fund that is an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a) that is required to develop and implement a policy regarding the recovery of erroneously awarded compensation pursuant to § 240.10D–1(b)(1), if at any time during the last completed fiscal year either a restatement that required recovery of excess incentive-based compensation pursuant to the Fund's compensation recovery policy was completed or there was an outstanding balance of excess incentive-based compensation from the application of the policy to a prior restatement, the Fund shall provide the following information:

(i) For each restatement:

(A) The date on which the Fund was required to prepare an accounting restatement, as defined in § 240.10D–1(c)(2);

(B) The aggregate dollar amount of excess incentive-based compensation attributable to such accounting restatement;

(C) The estimates that were used in determining the excess incentive-based compensation attributable to such accounting restatement, if the financial reporting measure related to a stock price or total shareholder return metric; and

(D) The aggregate dollar amount of excess incentive-based compensation that remains outstanding at the end of the last completed fiscal year;

(ii) If during the last completed fiscal year the Fund decided not to pursue recovery from any individual subject to recovery of excess incentive-based compensation attributable to an accounting restatement, for each such individual, the name and amount forgone and a brief description of the reason the Fund decided in each case not to pursue recovery; and

(iii) The name of each individual from whom, as of the end of the last completed fiscal year, excess incentive-based compensation had been outstanding for 180 days or longer since the date the issuer determined the amount the individual owed, and the dollar amount of outstanding excess incentive-based compensation due from each such individual.

Instructions to paragraph 22(b)(20).

1. Information provided under this paragraph is deemed to satisfy the requirements of paragraphs (b)(8) and (b)(11) of Item 22 with respect to the recovery of erroneously awarded compensation pursuant to § 240.10D–1(b)(1).

2. A *compensation recovery policy* is the policy required by the listing standards adopted pursuant to § 240.10D–1.

3. Excess incentive-based compensation'' is the erroneously awarded compensation computed as provided in § 240.10D–1(b)(1)(iii) and the applicable listing standards for the Fund's securities.

4. If the aggregate dollar amount of excess incentive-based compensation has not yet been determined, disclose this fact and explain the reason(s).

* * * * *

Item 25. Exhibits.

Provide the information required to be disclosed by Item 402(w) of Regulation S–K (17 CFR 229.402(w)), or Item 22(b)(20) of this Schedule 14A, in an exhibit to this Schedule 14A electronically formatted using the eXtensible Business Reporting Language (XBRL) interactive data standard in accordance with the EDGAR Filer Manual (17 CFR 232.11). The exhibit must be block-text tagged.

* * * * *

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 8. The authority citation for part 249 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78a *et seq.,* 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78j–3, 78*l,* 78m, 78n, 78n–1, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 80b–11, and 7201 *et seq.;* 12 U.S.C. 5461 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

* * * * *

■ 9. Amend Form 20–F (referenced in § 249.220f) by adding Item 6.F and Instructions to Item 6.F, and adding Instruction 17 to the Instructions as to Exhibits, of Form 20–F, to read as follows:

Note: The text of Form 20–F does not, and this amendment will not, appear in the Code of Federal Regulations.

FORM 20–F

* * * * *

Item 6. Directors, Senior Management and Employees

* * * * *

F. *Disclosure of a listed issuer's action to recover erroneously awarded compensation.* If at any time during the last completed fiscal year either a restatement that required recovery of excess incentive-based compensation pursuant to the listed issuer's compensation recovery policy was completed or there was an outstanding balance of excess incentive-based compensation from the application of the policy to a prior restatement, the listed issuer shall, in its annual report on Form 20–F, provide the following information:

(1) For each restatement:

(i) The date on which the listed issuer was required to prepare an accounting restatement, as defined in Rule 10D–1(c)(2) under the Exchange Act (17 CFR 240.10D–1(c)(2));

(ii) The aggregate dollar amount of excess incentive-based compensation attributable to such accounting restatement;

(iii) The estimates that were used in determining the excess incentive-based compensation attributable to such accounting restatement, if the financial reporting measure related to a stock price or total shareholder return metric; and

(iv) The aggregate dollar amount of excess incentive-based compensation that remains outstanding at the end of the last completed fiscal year;

(2) If during the last completed fiscal year the listed issuer decided not to pursue recovery from any individual subject to recovery of excess incentive-based compensation attributable to an accounting restatement, for each such individual, the name and amount forgone and a brief description of the reason the listed issuer decided in each case not to pursue recovery; and

(3) The name of each individual from whom, as of the end of the last completed fiscal year, excess incentive-based compensation had been outstanding for 180 days or longer since the date the issuer determined the amount the individual owed, and the dollar amount of outstanding excess incentive-based compensation due from each such individual.

(4) The disclosure required to be provided by Item 6.F shall appear with, and in the same format as, the rest of the disclosure required to be provided by Item 6 and, in addition, shall be electronically formatted using the eXtensible Business Reporting Language (XBRL) interactive data standard in accordance with the EDGAR Filer Manual (17 CFR 232.11) as an exhibit to this Form. The XBRL format disclosure required to be provided by this Item 6.F must be block-text tagged.

Instructions to Item 6.F.

1. For purposes of this Item, a ''listed issuer'' is an issuer that had a class of securities listed on a national securities exchange registered pursuant to section 6(a) of the Exchange Act (15 U.S.C. 78f) or a national securities association registered pursuant to section 15A(a) of the Exchange Act (15 U.S.C. 78o–3) at any time during its last completed fiscal year.

2. A ''compensation recovery policy'' is the policy required by the listing standards adopted pursuant to Rule 10D–1 under the Exchange Act (17 CFR 240.10D–1).

3. ''Excess incentive-based compensation'' is the erroneously awarded compensation computed as provided in Rule 10D–1(b)(1)(iii) under the Exchange Act (17 CFR 240.10D–1(b)(1)(iii)) and the applicable listing standards for the listed issuer's securities.

4. If the aggregate dollar amount of excess incentive-based compensation has not yet been determined, disclose this fact and explain the reason(s).

5. The information required by Item 6.F must be disclosed only in annual reports and does not apply to registration statements on Form 20–F. The information required by this Item 6.F will not be deemed to be incorporated by reference into any filing under the Securities Act, except to the extent that the listed issuer specifically incorporates it by reference.

* * * * *

Item 7. Major Shareholders and Related Party Transactions

* * * * *

Instructions to Item 7.B * * *

4. Disclosure need not be provided pursuant to this Item if the transaction involves the recovery of excess incentive-based compensation that is disclosed pursuant to Item 6.F.

* * * * *

INSTRUCTIONS AS TO EXHIBITS

* * * * *

96. A listed issuer must provide as an exhibit to its Exchange Act annual report on Form 20–F the compensation recovery policy required by the applicable listing standards adopted pursuant to Rule 10D–1 under the Exchange Act (17 CFR 240.10D–1) . For purposes of this paragraph, a ''listed issuer'' is a registrant that had a class of securities listed on a national securities exchange registered pursuant to section 6 of the Exchange Act (15 U.S.C. 78f) or a national securities association registered pursuant to section 15A of the Exchange Act (15 U.S.C. 78o–3) at any time during its last completed fiscal year.

97. The compensation recovery disclosure is required to be provided by a listed issuer under Item 6.F in electronic format using the XBRL interactive data standard in accordance with the EDGAR Filer Manual (17 CFR 232.11). The exhibit must be block-text tagged. 17 through 95 and 98 through 99 [Reserved]

* * * * *

■ 10. Amend Form 40–F (referenced in § 249.240f) by adding paragraph (17) to General Instruction B and Instructions to paragraph (17) of General Instruction B to read as follows:

Note: The text of Form 40–F does not, and this amendment will not, appear in the Code of Federal Regulations.

FORM 40–F

* * * * *

(17) *Recovery of erroneously awarded compensation.*

(a) A listed issuer shall include as exhibit 96 the compensation recovery policy required by the applicable listing standards adopted pursuant to Exchange Act Rule 10D–1 (17 CFR 240.10D–1).

(b) If at any time during the last completed fiscal year either a restatement that required recovery of excess incentive-based compensation pursuant to the listed issuer's compensation recovery policy was completed or there was an outstanding balance of excess incentive-based compensation from the application of the policy to a prior restatement, the listed issuer shall, in its annual report on Form 40–F, provide the following information:

(1) For each restatement:

(i) The date on which the listed issuer was required to prepare an accounting restatement, as defined in Exchange Act Rule 10D–1(c)(2) (17 CFR 240.10D–1(c)(2));

(ii) The aggregate dollar amount of excess incentive-based compensation attributable to such accounting restatement;

(iii) The estimates that were used in determining the excess incentive-based compensation attributable to such accounting restatement, if the financial reporting measure related to a stock price or total shareholder return metric; and

(iv) The aggregate dollar amount of excess incentive-based compensation that remains outstanding at the end of the last completed fiscal year;

(2) If during the last completed fiscal year the listed issuer decided not to pursue recovery from any individual subject to recovery of excess incentive-based compensation attributable to an accounting restatement, for each such individual, the name and amount forgone and a brief description of the reason the listed issuer decided in each case not to pursue recovery; and

(3) The name of each individual from whom, as of the end of the last completed fiscal year, excess incentive-based compensation had been outstanding for 180 days or longer since the date the issuer determined the amount the individual owed, and the dollar amount of outstanding excess incentive-based compensation due from each such individual.

(4) The disclosure required to be provided by paragraph (17) of General Instruction B shall appear with, and in the same format as generally required for, the rest of the disclosure required to be provided by General Instruction B and, in addition, shall be electronically formatted using the eXtensible Business Reporting Language (XBRL) interactive data standard in accordance with the EDGAR Filer Manual (17 CFR 232.11) as exhibit 97 to this Form. The XBRL format disclosure required to be provided by paragraph (17) of General Instruction B must be block-text tagged.

Instructions to paragraph (17).

1. For purposes of this paragraph, a ''listed issuer'' is an issuer that had a class of securities listed on a national securities exchange registered pursuant to section 6 of the Exchange Act (15 U.S.C. 78f) or a national securities association registered pursuant to section 15A of the Exchange Act (15 U.S.C. 78o–3) at any time during its last completed fiscal year.

2. A ''compensation recovery policy'' is the policy required by the listing standards adopted pursuant to Exchange Act Rule 10D–1 (17 CFR 240.10D–1).

3. ''Excess incentive-based compensation'' is the erroneously awarded compensation computed as provided in Exchange Act Rule 10D–1(b)(1)(iii) (17 CFR 240.10D–1(b)(1)(iii)) and the applicable listing standards for the listed issuer's securities.

4. If the aggregate dollar amount of excess incentive-based compensation has not yet been determined, disclose this fact and explain the reason(s).

5. The information required by paragraph (17) of General Instruction B must be disclosed only in annual reports and does not apply to registration statements on Form 40–F. The information required by this paragraph (17) will not be deemed to be incorporated by reference into any filing under the Securities Act, except to the extent that the listed issuer specifically incorporates it by reference.

* * * * *

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

■ 11. The general authority citation for Part 274 is revised to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78j–4, 78*l*, 78m, 78n, 78*o*(d), 80a–8, 80a–24, 80a–26, 80a–29, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

* * * * *

■ 12. Amend Form N–CSR (referenced in 17 CFR 274.128) by:

■ a. Revising General Instruction D;

■ b. Redesignating Item 12 as Item 13;

■ c. Adding new Item 12;

■ d. Redesignating paragraph (a)(2) of newly designated Item 13 (Exhibits) as paragraph (a)(4); and

■ e. Adding paragraphs (a)(2) and (a)(3) to redesignated Item 13 (Exhibits).

The additions read as follows:

Note: The text of Form N–CSR does not, and this amendment will not, appear in the Code of Federal Regulations.

FORM N–CSR

* * * * *

GENERAL INSTRUCTIONS * * *

D. Incorporation by Reference

A registrant may incorporate by reference information required by Items 4, 5, 12, and 13(a)(1). No other Items of the Form shall be answered by incorporating any information by reference. The information required by Items 4, 5, and 12 may be incorporated by reference from the registrant's definitive proxy statement (filed or required to be filed pursuant to Regulation 14A (17 CFR 240.14a–1 *et seq.*)) or definitive information statement (filed or to be filed pursuant to Regulation 14C (17 CFR 240.14c–1 *et seq.*)) which involves the election of directors, if such definitive proxy statement or information statement is filed with the Commission not later than 120 days after the end of the fiscal year covered by an annual report on this Form. All incorporation by reference must comply with the requirements of this Form and the following rules on incorporation by reference: Rule 10(d) of Regulation S–K under the Securities Act of 1933 (17 CFR 229.10(d)) (general rules on incorporation by reference, which, among other things, prohibit, unless specifically required by this Form, incorporating by reference a document that includes incorporation by reference to another document, and limits incorporation to documents filed within the last 5 years, with certain exceptions); Rule 303 of Regulation S–T (17 CFR 232.303) (specific requirements for electronically filed documents); Rules 12b–23 and 12b–32 under the Exchange Act (additional rules on incorporation by reference for reports filed pursuant to Sections 13 and 15(d) of the Exchange Act); and Rules 0–4, 8b–23, and 8b–32 under the Investment Company Act of 1940 (17 CFR 270.0–4, 270.8b–23, and 270.8b–32) (additional rules on incorporation by reference for investment companies).

* * * * *

Item 12. Recovery of Erroneously Awarded Compensation

In the case of a registrant that is required to develop and implement a

policy regarding the recovery of erroneously awarded compensation pursuant to Rule 10D–1(b)(1) under the Exchange Act (17 CFR 240.10D–1), if at any time during the last completed fiscal year either a restatement that required recovery of excess incentive-based compensation pursuant to the registrant's compensation recovery policy was completed or there was an outstanding balance of excess incentive-based compensation from the application of the policy to a prior restatement, the registrant shall provide the following information:

(a) For each restatement:

(1) The date on which the registrant was required to prepare an accounting restatement, as defined in Rule 10D–1(c)(2) under the Exchange Act (17 CFR 240.10D–1(c)(2));

(2) The aggregate dollar amount of excess incentive-based compensation attributable to such accounting restatement;

(3) The estimates that were used in determining the excess incentive-based compensation attributable to such accounting restatement, if the financial reporting measure related to a stock price or total shareholder return metric; and

(4) The aggregate dollar amount of excess incentive-based compensation that remains outstanding at the end of the last completed fiscal year;

(b) If during the last completed fiscal year the registrant decided not to pursue recovery from any individual subject to recovery of excess incentive-based compensation attributable to an accounting restatement, for each such individual, the name and amount forgone and a brief description of the reason the registrant decided in each case not to pursue recovery; and

(c) The name of each individual from whom, as of the end of the last completed fiscal year, excess incentive-based compensation had been outstanding for 180 days or longer since the date the issuer determined the amount the individual owed, and the dollar amount of outstanding excess incentive-based compensation due from each such individual.

Instructions

1. The information required by this Item is only required in an annual report on Form N–CSR.

2. A ''compensation recovery policy'' is the policy required by the listing standards adopted pursuant to Rule 10D–1 under the Exchange Act (17 CFR 240.10D–1).

3. ''Excess incentive-based compensation'' is the erroneously awarded compensation computed as provided in Rule 10D–1(b)(1)(iii) under the Exchange Act (17 CFR 240.10D–1(b)(1)(iii)) and the applicable listing standards for the listed registrant's securities.

4. If the aggregate dollar amount of excess incentive-based compensation has not yet been determined, disclose this fact and explain the reason(s).

Item 13. Exhibits

(a) * * *

(2) Any policy required by the listing standards adopted pursuant to Rule 10D–1 under the Exchange Act (17 CFR 240.10D–1) by the registered national securities exchange or registered national securities association upon which the registrant's securities are listed.

Instruction to Paragraph (a)(2)

The exhibit required by this paragraph (a)(2) is only required in an annual report on Form N–CSR.

(3) Unless the information required by Item 12 is answered by incorporating by reference from the registrant's definitive proxy statement or definitive information statement pursuant to General Instruction D, provide the information required to be disclosed by Item 12 in an exhibit to this Form electronically formatted using the eXtensible Business Reporting Language (XBRL) interactive data standard in accordance with the EDGAR Filer manual (17 CFR 232.11). The exhibit must be block-text tagged.

Instruction to Paragraph (a)(3)

The exhibit required by this paragraph (a)(3) is only required in an annual report on Form N–CSR.

* * * * *

By the Commission.

Dated: July 1, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–16613 Filed 7–13–15; 8:45 am]

BILLING CODE 8011–01–P

FEDERAL REGISTER

Vol. 80 Tuesday,

No. 134 July 14, 2015

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 510

Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 510

[CMS–5516–P]

RIN 0938–AS64

Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services

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

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to implement a new Medicare Part A and B payment model under section 1115A of the Social Security Act, called the Comprehensive Care for Joint Replacement (CCJR) model, in which acute care hospitals in certain selected geographic areas will receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. All related care within 90 days of hospital discharge from the joint replacement procedures will be included in the episode of care. We believe this model will further our goals in improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures.

DATES: *Comment period:* To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EDT on September 8, 2015.

ADDRESSES: In commenting, please refer to file code CMS–5516–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5516–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5516–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Claire Schreiber, *Claire.Schreiber@cms.hhs.gov,* 410–786–8939
Gabriel Scott, *Gabriel.Scott@cms.hhs.gov,* 410–786–3928

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EDT. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/.*

Alphabetical List of Acronyms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this proposed rule, we are listing the acronyms, abbreviations and short forms used and their corresponding terms in alphabetical order.

μSA Micropolitan Statistical Area
ACO Accountable Care Organization
ASPE Assistant Secretary for Planning and Evaluation
BPCI Bundled Payments for Care Improvement
CBSA Core-Based Statistical Area
CMS Centers for Medicare & Medicaid Services
CPT Current Procedural Terminology
CCJR Comprehensive Care for Joint Replacement
CSA Combined Statistical Area
DME Durable Medical Equipment
FFS Fee-for-service
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HHA Home health agency
HOPD Hospital outpatient department
HHPPS Home Health Prospective Payment System
HIQR Hospital Inpatient Quality Reporting
HRRP Hospital Readmissions Reductions Program
HRR Hospital Referral Region
HVBP Hospital Value Based Purchasing Program
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
IPPS Inpatient Prospective Payment System
IPF Inpatient psychiatric facility
IRF Inpatient rehabilitation facility
LEJR Lower extremity joint replacement
LOS Length of stay
LTCH Long term care hospital
LUPA Low Utilization Payment Adjustment

MAC Medicare Administrative Contractor
MCC Major complications or comorbidities
MSA Metropolitan Statistical Area
MS–DRG Medical Severity Diagnosis-Related Group
MP Malpractice
NPP Nonphysician Practitioner
NPRA Net Payment Reconciliation Amount
OPPS Outpatient Prospective Payment System
PAC Post-acute care
SNF Skilled nursing facility
THA Total hip arthroplasty
TKA Total knee arthroplasty

Table of Contents

I. Executive Summary
A. Purpose
B. Summary of the Major Provisions
1. Model Overview: LEJR Episodes of Care
2. Model Scope
3. Payment
4. Similar Previous and Concurrent Models
5. Overlap With Ongoing CMS Efforts
6. Quality Measures and Reporting Requirements
7. Data Sharing Process
8. Beneficiary Protections
C. Summary of Economic Effects
II. Background
III. Provisions of the Proposed Rule
A. Proposed Definition of the Episode Initiator and Selected Geographic Areas
1. Background
2. Proposed Definition of Episode Initiator
3. Financial Responsibility for the Episode of Care
4. Proposed Geographic Unit of Selection and Exclusion of Selected Hospitals
a. Overview and Options for Geographic Area Selection
b. MSA Selection Methodology
(1) Exclusion of Certain MSAs
(2) Proposed Selection Strata
(a) MSA Average Wage-adjusted Historic LEJR Episode Payments
(b) MSA Population Size
(c) Analysis of Strata
(3) Factors Considered but Not Used in Creating Proposed Strata
(4) Sample Size Calculations and the Number of Selected MSAs
(5) Method of Selecting MSAs
B. Episode Definition for the Comprehensive Care for Joint Replacement (CCJR) Model
1. Background
2. Clinical Dimension of Episodes of Care
a. Definition of the Clinical Conditions Included in the Episode
b. Definition of Related Services Included in the Episode
3. Duration of Episodes of Care
a. Beginning the Episode and Beneficiary Care Inclusion Criteria
b. Middle of the Episode
c. End of the Episode
C. Proposed Methodology for Setting Episode Prices and Paying Model Participants Under the CCJR Model
1. Background
2. Performance Years, Retrospective Episode Payment, and Two-Sided Risk Model
a. Performance Period
b. Proposed Retrospective Payment Methodology
c. Proposed Two-Sided Risk Model
3. Adjustments to Payments Included in Episode
a. Proposed Treatment of Special Payment Provisions Under Existing Medicare Payment Systems
b. Proposed Treatment of Payment for Services That Extend Beyond the Episode
c. Proposed Pricing Adjustment for High Payment Episodes
4. Proposed Episode Price Setting Methodology
a. Overview
b. Proposed Pricing Features
(1) Different Target Prices for Episodes Anchored by MS–DRG 469 vs. MS–DRG 470
(2) Three Years of Historical Data
(3) Proposed Trending of Historical Data to the Most Recent Year of the Three
(4) Update Historical Episode Payments for Ongoing Payment System Updates
(a) Proposed Inpatient Acute Services Update Factor
(b) Proposed Physician Services Update Factor
(c) Proposed IRF Services Update Factor
(d) Proposed SNF Services Update Factor
(e) Proposed HHA Services Update Factor
(f) Proposed Other Services Update Factor
(5) Blend Hospital-Specific and Regional Historical Data
(6) Define Regions as U.S. Census Divisions
(7) Normalize for Provider-Specific Wage Adjustment Variations
(8) Proposed Combination of CCJR Episodes Anchored by MS–DRGs 469 and 470
(9) Discount Factor
c. Proposed Approach To Combine Pricing Features
5. Proposed Use of Quality Performance in the Payment Methodology
a. Background
b. Proposed Implementation of Quality Measures for Reconciliation Payment Eligibility
(1) General Selection of Proposed Quality Measures
(2) Proposal To Adjust the Payment Methodology for Voluntary Submission of Data for Patient-Reported Outcome Measure
(3) Measure Risk-Adjustment and Calculations
(4) Applicable Time Period
(5) Criteria for Applicable Hospitals and Performance Scoring
(a) Identification of Applicable Hospitals for the CCJR Model
(b) Methodology to Determine Performance on the Quality Measures
(c) Proposed Methodology To Link Quality and Payment
(i) Background
(ii) Alternatives Considered To Link Quality and Payment
(iii) Proposal To Link Quality and Payment through Thresholds for Reconciliation Payment Eligibility
6. Proposed Process for Reconciliation
a. Net Payment Reconciliation Amount
b. Payment Reconciliation
7. Proposed Adjustments for Overlaps With Other Innovation Center Models and CMS Programs
a. Overview
b. CCJR Beneficiary Overlap With BPCI Episodes
c. Accounting for CCJR Reconciliation Payments and Recoupments in Other Models and Programs
d. Accounting for Per Beneficiary Per Month (PBPM) Payments in the Episode Definition
e. Accounting for Overlap With Shared Savings Programs and Total Cost of Care Models
8. Proposals To Limit or Adjust Hospital Financial Responsibility
a. Overview
b. Proposed Limit on Raw NPRA Contribution to Repayment Amounts and Reconciliation Payments
(1) Proposed Limit on Raw NPRA Contribution to Repayment Amounts
(2) Proposed Limit on Raw NPRA Contribution to Reconciliation Payments
c. Proposed Policies for Certain Hospitals to Further Limit Repayment Responsibility
d. Proposed Hospital Responsibility for Increased Post-Episode Payments
9. Proposed Appeal Procedures for Reconciliation
a. Payment Processes
b. Calculation Error
c. Dispute Resolution
(1) Limitations on Review
(2) Matters Subject to Dispute Resolution.
(3) Dispute Resolution Process.
10. Proposed Financial Arrangements, Beneficiary Incentives, and Proposed Program Rule Waivers and Amendments
a. Financial Arrangements and Beneficiary Incentives
(1) Financial Arrangements Permitted Under the CCJR Model
(a) CCJR Sharing Arrangement Requirements.
(b) Participation Agreements Requirements.
(c) Gainsharing Payment and Alignment Payment Conditions and Restrictions.
(d) Documentation and Maintenance of Records
(2) Beneficiary Incentives Permitted Under the CCJR Model
(3) Compliance with Fraud and Abuse Laws
11. Proposed Waivers of Medicare Program Rules
a. Overview
b. Post-Discharge Home Visits
c. Billing and Payment for Telehealth Services
d. SNF 3-Day Rule
e. Waivers of Medicare Program Rules To Allow Reconciliation Payment or Recoupment Actions Resulting From the Net Payment Reconciliation Amount12. Proposed Enforcement Mechanisms
D. Quality Measures and Display of Quality Metrics Used in the CCJR Model
1. Background
a. Purpose of Quality Measures in the CCJR Model
b. Public Display of Quality Measures in the CCJR Model
2. Proposed Quality Measures for Performance Year 1 (CY 2016) and Subsequent Years

a. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550)
(1) Background
(2) Data Sources
(3) Cohort
(4) Inclusion and Exclusion Criteria
(5) Risk-Adjustment
(6) Calculating the Risk-Standardized Complication Rate and Performance Period
b. Hospital-Level 30-day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551)
(1) Background
(2) Data Sources
(3) Cohort
(4) Inclusion and Exclusion Criteria
(5) Risk-Adjustment
(6) Calculating the Risk-Standardized Readmission Rate and Performance Period
c. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey
(1) Background
(2) Data Sources
(3) Cohort
(4) Inclusion and Exclusion Criteria
(5) Case-Mix-Adjustment
(6) HCAHPS Scoring
(7) Performance period
d. Applicable Time Period
3. Possible New Outcomes for Future Measures
a. Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty
(1) Background
(2) Data Sources
(3) Cohort
(4) Inclusion and Exclusion Criteria
(5) Outcome
(6) Risk-Adjustment (if Applicable)
(7) Calculating the Risk-Standardized Rate
(8) Performance Period
(9) Requirements for Successful Submission of THA/TKA Voluntary Data
b. Measure that Captures Shared Decision-Making Related to Elective Primary Total Hip and/or Total Knee Arthroplasty
c. Future Measures Around Care Planning
d. Future Considerations for Use of Electronic Health Records
4. Form, Manner and Timing of Quality Measure Data Submission
5. Proposed Display of Quality Measures and Availability of Information for the Public From the CCJR Model
E. Data Sharing
1. Overview
2. Beneficiary Claims Data
3. Aggregate Regional Data
4. Timing and Period of Baseline Data
5. Frequency and Period of Claims Data Updates for Sharing Beneficiary-Identifiable Claims Data During the Performance Period
6. Legal Permission to Share Beneficiary-Identifiable Data
F. Monitoring and Beneficiary Protection
1. Introduction and Summary
2. Beneficiary Choice and Beneficiary Notification
3. Monitoring for Access to Care
4. Monitoring for Quality of Care
5. Monitoring for Delayed Care
G. Coordination With Other Agencies
IV. Evaluation Approach
A. Background
B. Design and Evaluation Methods
C. Data Collection Methods
D. Key Evaluation Research Questions
E. Evaluation Period and Anticipated Reports
V. Collection of Information Requirements
VI. Response to Comments
VII. Regulatory Impact Analysis
A. Statement of Need
B. Overall Impact
C. Anticipated Effects
1. Overall Magnitude of the Model and its Effects on the Market
2. Effects on the Medicare Program
a. Assumptions and Uncertainties
b. Analyses
c. Further Consideration
3. Effects on Beneficiaries
4. Effects on Small Entities
5. Effects on Small Rural Hospitals
6. Unfunded Mandates
D. Alternatives
E. Accounting Statement
F. Conclusion
Regulations Text

I. Executive Summary

A. Purpose

The purpose of this proposed rule is to propose the creation and testing of a new payment model called the Comprehensive Care for Joint Replacement (CCJR) Model under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center or CMMI). Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. The intent of the CCJR model is to promote quality and financial accountability for episodes of care surrounding a lower-extremity joint replacement (LEJR) or reattachment of a lower extremity procedure.[1] CCJR will test whether bundled payments to acute care hospitals for LEJR episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate the CCJR model being proposed would benefit Medicare beneficiaries by improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare Fee-For-Service (FFS), encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care spectrum spanning the episode of care. We propose to test CCJR for a 5 year performance period, beginning January 1, 2016, and ending December 31, 2020. Under FFS, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of treatment (an episode of care). With the amount of payments dependent on the volume of services delivered, providers may not have incentives to invest in quality improvement and care coordination activities. As a result, care may be fragmented, unnecessary, or duplicative.

We have previously used our statutory authority under section 1115A of the Act to test bundled payment models such as the Bundled Payments for Care Improvement (BPCI) initiative. Bundled payments for multiple services in an episode of care hold participating organizations financially accountable for an episode of care. They also allow participants to receive payment in part based on the reduction in expenditures for Medicare arising from their care redesign efforts.

We believe the CCJR model being proposed would further the mission of the Innovation Center and the Secretary's goal of increasingly paying for value and outcomes, rather than for volume,[2] because it would promote the alignment of financial and other incentives for all health care providers caring for a beneficiary during an LEJR episode. In the proposed CCJR model, the acute care hospital that is the site of surgery would be held accountable for spending during the episode of care. Participant hospitals would be afforded the opportunity to earn performance-based payments by appropriately reducing expenditures and meeting certain quality metrics. They would also gain access to data and educational resources to better understand post-acute care and associated spending. Payment approaches that reward providers that assume financial and performance accountability for a particular episode of care create

[1] In this proposed rule, we use the term LEJR to refer to all procedures within the Medicare Severity-Diagnosis Related Groups (MS–DRGs) we propose to select for the model, including reattachment of a lower extremity, as described in section III.B. of this proposed rule.

[2] *Sylvia Mathews Burwell, HHS Secretary, Progress Towards Achieving Better Care, Smarter Spending, Healthier People, http://www.hhs.gov/blog/2015/01/26/progress-towards-better-care-smarter-spending-healthier-people.html* (Jan 26, 2015).

incentives for the implementation and coordination of care redesign between hospitals and other providers.

The proposed model would require the participation of hospitals in multiple geographic areas that might not otherwise participate in the testing of bundled payments for episodes of care for LEJR procedures. Other episode-based, bundled payment models being tested by Centers for Medicare & Medicaid Services (CMS), such as the BPCI initiative, are voluntary in nature. Interested participants must apply to such models to participate. To date, we have not tested an episode payment model with bundled payments in which providers are required to participate. We recognize that realizing the full potential of new payment models will require the engagement of an even broader set of providers than have participated to date, providers who may only be reached when new payment models are applied to an entire class of providers of a service. As such, we are interested in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those hospitals that may not otherwise participate in such a test.

This proposed model would allow CMS to gain experience with making bundled payments to hospitals who have a variety of historic utilization patterns; different roles within their local markets; various volumes of services; different levels of access to financial, community, or other resources; and various levels of population and health provider density including local variations in the availability and use of different categories of post-acute care providers. We believe that by requiring the participation of a large number of hospitals with diverse characteristics, the proposed model would result in a robust data set for evaluation of this bundled payment approach, and would stimulate the rapid development of new evidence-based knowledge. Testing the model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for common LEJR procedure episodes. This learning potentially could inform future Medicare payment policy.

Within this proposed rule we propose a model focused on episodes of care for LEJR procedures. We chose LEJR episodes for the proposed model because as discussed in depth in section III.C. of this proposed rule, these are high-expenditure, high utilization procedures commonly furnished to Medicare beneficiaries,[3] where significant variation in spending for procedures is currently observed. The high volume of episodes and variation in spending for LEJR procedures create a significant opportunity to test and evaluate the proposed model that specifically focuses on a defined set of procedures. Moreover, there is substantial regional variation in post-acute care referral patterns and the intensity of post-acute care provided for LEJR patients, thus resulting in significant variation in post-acute care expenditures across LEJR episodes initiated at different hospitals. The proposed model would enable hospitals to consider the most appropriate post-acute care for their LEJR patients. The proposed model additionally would offer hospitals the opportunity to better understand their own processes with regard to LEJR, as well as the processes of post-acute providers. Finally, while many LEJR procedures are planned, the proposed model would provide a useful opportunity to identify efficiencies both for when providers can plan for LEJR procedures and for when the procedure must be performed urgently.

We note that we seek public comment on the proposals contained in this proposed rule, and also on any alternatives considered as well.

B. Summary of the Major Provisions

1. Model Overview: LEJR Episodes of Care

LEJR procedures are currently paid under the Inpatient Prospective Payment System (IPPS) through one of two Medicare Severity-Diagnosis Related Groups (MS–DRGs): MS–DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) or MS–DRG 470 (Major joint replacement or reattachment of lower extremity without MCC). Under the proposed model, as described further in section III.B of this proposed rule, episodes would begin with admission to an acute care hospital for an LEJR procedure that is assigned to MS–DRG 469 or 470 upon beneficiary discharge and paid under the IPPS and would end 90 days after the date of discharge from the acute care hospital. This episode of care definition offers operational simplicity for providers and CMS. The episode would include the LEJR procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services.

2. Model Scope

We propose that participant hospitals would be the episode initiators and bear financial risk under the proposed CCJR model. In comparison to other health care facilities, hospitals are more likely to have resources that would allow them to appropriately coordinate and manage care throughout the episode, and hospital staff members are already involved in hospital discharge planning and post-acute care recommendations for recovery, key dimensions of high quality and efficient care for the episode. We propose to require all hospitals paid under the IPPS and physically located in selected geographic areas to participate in the CCJR model, with limited exceptions. Eligible beneficiaries who receive care at these hospitals will automatically be included in the model. We propose to select geographic areas through a stratified random sampling methodology within strata based on the following criteria: Historical wage adjusted episode payments and population size. Our proposed geographic area selection process is detailed further in section III.A of this proposed rule.

3. Payment

We propose to test the CCJR model for 5 performance years. During these performance years we propose to continue paying hospitals and other providers according to the usual Medicare FFS payment systems. However, after the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, would be combined to calculate an actual episode payment. The actual episode payment is defined as the sum of related Medicare claims payments for items and services furnished to a beneficiary during a CCJR episode. The actual episode payment would then be reconciled against an established CCJR target price, with consideration of additional payment adjustments based on quality performance and post-episode spending. The amount of this calculation, if

[3] For example, Total Hip Arthroplasty and Total Knee Arthroplasty procedures are very high volume LEJR procedures that together represent the largest payments for procedures under Medicare. Suter L, Grady JL, Lin Z et al.: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html;* Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of Medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008; 23(6 Suppl 1):133–138.

positive, would be paid to the participant hospital. This payment would be called a reconciliation payment. If negative, we would require repayment from the participant hospital. We propose Medicare would require repayment of the difference between the actual episode payments and the CCJR target price from a participant hospital if the CCJR target price is exceeded.

We propose to make reconciliation payments to participant hospitals that achieve quality outcomes and cost efficiencies relative to the established CCJR target prices in all performance years of the model. We also propose to phase in the requirement that participant hospitals whose actual episode payments exceed the applicable CCJR target price pay the difference back to Medicare beginning in performance year 2. Under this proposal, Medicare would not require repayment from hospitals for performance year 1 for actual episode payments that exceed their target price in performance year 1.

We also propose to limit how much a hospital can gain or lose based on its actual episode payments relative to target prices. We also propose additional policies to further limit the risk of high payment cases for all participant hospitals and for special categories of participant hospitals as described in section III.C. of this proposed rule.

4. Similar Previous and Concurrent Models

This proposed model is informed by other models and demonstrations currently and previously conducted by CMS and would explore additional ways to enhance coordination of care and improve the quality of services through bundled payments.

We recently announced the Oncology Care Model (OCM), a new voluntary payment model for physician practices administering chemotherapy. Under OCM, practices will enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. We plan to coordinate with other payers to align with OCM in order to facilitate enhanced services and care at participating practices. More information on the OCM can be found on the Innovation Center's Web site at: *http://innovation.cms.gov/initiatives/Oncology-Care/.*

Medicare tested innovative approaches to paying for orthopedic services in the Medicare Acute Care Episode (ACE) demonstration, a prior demonstration, and is currently testing additional approaches under BPCI. Both of these models have also informed the design of the CCJR model.

Under the authority of section 1866C of the Act, we conducted a 3-year demonstration, the Medicare Acute Care Episode (ACE) Demonstration. The demonstration used a prospective global payment for a single episode of care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode of care was defined as a combination of Part A and Part B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MS–DRGs. The MS–DRGs tested included 469 and 470, those proposed for inclusion in the CCJR model. The discounted bundled payments generated an average gross savings to Medicare of $585 per episode for a total of $7.3 million across all episodes (12,501 episodes) or 3.1 percent of the total expected costs for these episodes. After accounting for increased post-acute care costs that were observed at two sites, Medicare saved approximately $4 million, or 1.72 percent of the total expected Medicare spending. More information on the ACE Demonstration can be found on the Innovation Center's Web site at: *http://innovation.cms.gov/initiatives/ACE/.*

We are currently testing the BPCI initiative. The BPCI initiative is comprised of four related payment models, which link payments for multiple services that Medicare beneficiaries receive during an episode of care into a bundled payment. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. Episodes of care under the BPCI initiative begin with either—(1) an inpatient hospital stay or (2) post-acute care services following a qualifying inpatient hospital stay. The BPCI initiative is evaluating the effects of episode-based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. Each of the four models tests LEJR episodes of care. While final evaluation results for the models within the BPCI initiative are not yet available, we believe that CMS' experiences with BPCI support the design of the CCJR model. Under section 1115A(c) of the Act, the Secretary may, taking into consideration an evaluation conducted under section 1115A(b)(4) of the Act, ''through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under'' the Innovation Center's authority. CCJR is not an expansion of BPCI, and BPCI may be expanded in the future. CMS published a discussion item soliciting public comment on a potential future expansion of one or more of the models within BPCI in the CY2016 IPPS rule, 80 FR 24414 through 24418. CCJR would not be not an expansion or modification of BPCI; nor does it reflect comments received in response to the NPRM for the 2016 IPPS Rule. CCJR is a unique model that tests a broader, different group of hospitals than BPCI. It is necessary to provide CMS with information about testing bundled payments to hospitals that are required to participate in an alternative payment model. For a discussion of why we are requiring hospitals to participate in the CCJR model, see section III.A of this proposed rule.

The CCJR model's design was informed to a large degree by our experience with BPCI Model 2. BPCI's Model 2 is a voluntary episode payment model in which a qualifying acute care hospitalization initiates a 30, 60 or 90 day episode of care. The episode of care includes the inpatient stay in an acute care hospital and all related services covered under Medicare Parts A and B during the episode, including post-acute care services. More information on BPCI Model 2 can be found on the Innovation Center's Web site at: *http://innovation.cms.gov/initiatives/BPCI-Model-2/.*

Further information of why elements of the OCM, the ACE Demonstration, and BPCI Model 2 were incorporated into the design of the CCJR model is discussed later in this proposed rule.

5. Overlap With Ongoing CMS Efforts

We propose to exclude from participation in CCJR certain hospitals participating in the risk-bearing phase of BPCI Models 2 and 4 for LEJR episodes, as well as acute care hospitals participating in BPCI Model 1. We propose not to exclude beneficiaries in CCJR model episodes from being included in other Innovation Center models or CMS programs, such as the Medicare Shared Savings Program, as detailed later in this proposed rule. We propose to account for overlap, that is, where CCJR beneficiaries are also included in other models and programs to ensure the financial policies of CCJR are maintained and results and spending reductions are attributed to the correct model or program.

6. Quality Measures and Reporting Requirements

We are proposing to adopt three hospital-level quality of care measures for the CCJR model. Those measures

include a complication measure, readmission measure, and a patient experience survey measure. We propose to use these measures to test the success of the model in achieving its goals under section 1115A of the Act and to monitor for beneficiary safety. We intend to publicly report this information on the Hospital Compare Web site. Additionally, we are proposing and requesting public feedback on possible voluntary submission of data to support the development of a hospital-level measure of patient-reported outcomes following an elective Primary Total Hip (THA) or Total Knee Arthroplasty (TKA).

7. Data Sharing Process

We propose to share data with participant hospitals upon request throughout the performance period of the CCJR model to the extent permitted by the HIPAA Privacy Rule and other applicable law. We propose to share upon request both raw claims-level data and claims summary data by service line with participants. This approach would allow participant hospitals without prior experience analyzing claims to use summary data to receive useful information, while allowing those participant hospitals who prefer raw claims-level data the opportunity to analyze claims. We propose to provide hospitals with up to 3 years of retrospective claims data upon request that will be used to develop their target price, as described in section III.C of this proposed rule. In accordance with the HIPAA Privacy Rule, we would limit the content of this data set to the minimum data necessary for the participant hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population.

8. Beneficiary Protections

Under the CCJR model, beneficiaries retain the right to obtain health services from any individual or organization qualified to participate in the Medicare program. Under the CCJR model, eligible beneficiaries who receive services from a participant hospital would not have the option to opt out of inclusion in the model. We propose to require participant hospitals to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice. We will also make a robust effort to reach out to beneficiaries and their advocates to help them understand the CCJR model.

We also propose to use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. Beneficiary protections are discussed in greater depth in section III.E. of this proposed rule.

9. Financial Arrangements and Program Policy Waivers

We propose to hold participant hospitals financially responsible for CCJR LEJR episodes as participants in the model as discussed in section III.C.10.a. of this proposed rule. Specifically, only these hospital participants would be directly subject to the requirements of this proposed rule for the CCJR model. Participant hospitals would be responsible for ensuring that other providers and suppliers collaborating with the hospital on LEJR episode care redesign are in compliance with the terms and conditions of the model.

Several of the proposed Medicare program policy waivers outline the conditions under which skilled nursing facilities (SNFs) and physicians could furnish and bill for certain services furnished to CCJR beneficiaries where current Medicare programs rules would not permit such billing. We draw the attention of SNFs and physicians to these proposals that are included in section III.C.10.b.(5). of this proposed rule.

C. Summary of Economic Effects

As shown in our impact analysis, we expect the proposed model to result in savings to Medicare of $153 million over the 5 years of the model. More specifically, in performance year 1 of the model, we estimate a Medicare cost of approximately $23 million, as we have proposed that hospitals will not be subject to downside risk in the first year of the model. As we introduce downside risk beginning in performance year 2 of the model, we estimate Medicare savings of approximately $29 million. In performance year 3 of the model, we estimate Medicare savings of $43 million. In performance years 4 and 5 of the model, as we have proposed to move from target episode pricing that is based on a hospital's experience to target pricing based on regional experience, we estimate Medicare savings of $50 million and $53 million, respectively.

Additionally, hospitals must meet or exceed specific thresholds on performance on certain quality of care measures in order to be eligible for a reconciliation payment and as the performance threshold increases in performance years 4 through 5, we estimate additional savings. As a result, we estimate the net savings to Medicare to be $153 million over the 5 years of the model. We anticipate there would be a broader focus on care coordination and quality improvement for LEJR episodes among hospitals and other providers within the Medicare program that would lead to both increased efficiency in the provision of care and improved quality of the care provided to beneficiaries.

We note that under section 1115A(b)(3)(B) of the Act, the Secretary is required to terminate or modify a model unless certain findings can be made with respect to savings and quality after the model has begun. If during the course of testing the model it is determined that termination or modification is necessary, such actions would be undertaken through rulemaking.

II. Background

This proposed rule proposes the implementation of a new innovative health care payment model under the authority of section 1115A of the Act. Under the model, called the CCJR model, acute care hospitals in certain selected geographic areas will receive bundled payments for episodes of care where the diagnosis at discharge includes a lower extremity joint replacement or reattachment of a lower extremity that was furnished by the hospital. We are proposing that the bundled payment will be paid retrospectively through a reconciliation process; hospitals and other providers and suppliers will continue to submit claims and receive payment via the usual Medicare FFS payment systems. All related care covered under Medicare Part A and Part B within 90 days after the date of hospital discharge from the joint replacement procedure will be included in the episode of care. We believe this model will further our goals of improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures.

III. Provisions of the Proposed Rule

A. Proposed Definition of the Episode Initiator and Selected Geographic Areas

1. Background

The CCJR model is different from BPCI because it would require participation of all hospitals (with limited exceptions) throughout selected geographic areas, which would result in a model that includes varying hospital types. However, a discussion of BPCI is relevant because its design informs and supports the proposed CCJR model. The BPCI model is voluntary, and under that model we pay a bundled payment for an episode of care only to entities that have

elected to participate in the model. We are interested in testing and evaluating the impact of an episode payment approach for LEJRs in a variety of other circumstances, including among those hospitals that have not chosen to voluntarily participate because we have not tested bundled payments for these hospitals previously. This would allow CMS and participants to gain experience testing and evaluating episode-based payment for LEJR procedures furnished by hospitals with a variety of historic utilization patterns; roles within their local markets; volume of services provided; access to financial, community, or other resources; and population and health care provider density. Most importantly, participation of hospitals in selected geographic areas will allow CMS to test bundled payments without introducing selection bias such as the selection bias inherent in the BPCI model due to self-selected participation.

2. Proposed Definition of Episode Initiator

In BPCI Model 2, LEJR episode initiators are either acute care hospitals where the LEJR procedure is performed or physician group practices whose physician members are the admitting or operating physician for the hospital stay. Thus, under BPCI, it is possible that only some Medicare cases that could potentially be included in an LEJR episode at a specific hospital are actually being tested in BPCI. For example, if the hospital itself is not participating as an episode initiator under BPCI, yet some physicians who admit patients to the hospital are members of physician group practices participating in BPCI, not all of the hospital's possible LEJR episodes are tested and paid under BPCI.

Under the proposed CCJR model, as described further in section III.B of this proposed rule, episodes would begin with admission to an acute care hospital for an LEJR procedure that is paid under the IPPS through Medical Severity Diagnosis-Related Group (MS–DRG) 469 (Major joint replacement or reattachment of lower extremity with MCC) or 470 (Major joint replacement or reattachment of lower extremity without MCC) and end 90 days after the date of discharge from the hospital. For the CCJR model, we propose that hospitals would be the only episode initiators. For purposes of CCJR, the term ''hospital'' means a hospital as defined in section 1886(d)(1)(B) of the Act. This statutory definition of hospital includes only acute care hospitals paid under the IPPS. Under this proposal, all acute care hospitals in Maryland would be excluded from CCJR. The state of Maryland entered into an agreement with CMS, effective January 1, 2014, to participate in CMS' new Maryland All-Payer Model. In order to implement the Maryland All-Payer Model, CMS waived certain requirements of the Act, and the corresponding implementing regulations, as set forth in the agreement between CMS and Maryland. Specifically, under the Maryland All-Payer Model, Maryland acute care hospitals are not paid under the IPPS or OPPS but rather are paid under rates set by the state. Following the model's performance period, Maryland will transition to a new model that incorporates the full spectrum of care, not just hospital services. As such, with respect to Maryland hospitals, CMS intends to test and develop new payment and delivery approaches that can incorporate non-hospital services in a manner that accounts for Maryland's unique hospital rate setting system and permit Maryland to develop its own strategy to incentivize higher quality and more efficient care across clinical situations within and beyond hospitals, including but not limited to LEJR episodes of care. We are proposing that payments to Maryland hospitals would be excluded in the regional pricing calculations as described in section III.C.4 of this proposed rule. We seek comment on this proposal and whether there are potential approaches for including Maryland acute care hospitals in CCJR. In addition, we seek comment on whether Maryland hospitals should be included in CCJR in the future upon any termination of the Maryland All-Payer Model.

We propose to designate IPPS hospitals as the episode initiators to ensure that all Medicare FFS LEJR services furnished by participant hospitals in selected geographic areas to beneficiaries who do not meet the exclusion criteria specified in section III.B.3 of this proposed rule and are not BPCI episodes that we are proposing to exclude as outlined in this section and also in section III.C.7 of this proposed rule are included in the CCJR model. We are proposing certain exceptions to the inclusion of hospitals in the CCJR Model, as discussed in section III.C. of this proposed rule. Given that our proposal to initiate the LEJR episode begins with an admission to a hospital paid under the IPPS that results in a discharge assigned to MS–DRG 469 or 470, we believe that utilizing the hospital as the episode initiator is a straightforward approach for this model because the hospital furnishes the LEJR procedure. In addition, we are interested in testing a broad model in a number of hospitals under the CCJR model in order to examine results from a more generalized payment model. Thus, we believe it is important that, in a model where hospital participation is not voluntary, all Medicare FFS LEJR episodes that begin at the participant hospital in a selected geographic area are included in the model for beneficiaries that do not meet the exclusion criteria specified in section III.B.3 of this proposed rule and are not BPCI episodes that we are proposing to exclude as outlined in this section and also in section III.C.7 of this proposed rule. This is best achieved if the hospital is the episode initiator. Finally, as described in the following sections that present our proposed approach to geographic area selection, this geographic area selection approach relies upon our definition of hospitals as the entities that initiate episodes. We seek comment on our proposal to define the episode initiator as the hospital under CCJR.

3. Financial Responsibility for the Episode of Care

BPCI Model 2 participants that have entered into agreements with CMS to bear financial responsibility for an episode of care include acute care hospitals paid under the IPPS, health systems, physician-hospital organizations, physician group practices, and non-provider business entities that act as conveners by coordinating multiple health care providers' participation in the model. Thus, our evaluation of BPCI Model 2 will yield information about how results for LEJR episodes may differ based on differences in which party bears financial responsibility for the episode of care.

For the CCJR model, we propose to make hospitals financially responsible for the episode of care for several reasons. We recognize that ideally all of the providers involved in the continuum of care for Medicare beneficiaries in a 90-day post-discharge LEJR episode would work together to determine the best structure for managing the LEJR episode, develop an efficient process that leads to high quality care, track information across the episode about quality and Medicare expenditures, and align financial incentives using a variety of approaches, including gainsharing. However, because the proposed CCJR model is testing a more generalizable model by including hospitals that might not participate in a voluntary model and includes episodes initiated at a wide variety of hospitals, we believe it is

most appropriate to identify a single type of provider to bear financial responsibility for making repayment to CMS under the model.

Hospitals play a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing LEJR procedures. Moreover, the episode always begins with an acute care hospital stay, IPPS payments for LEJRs comprise about 50 percent of Medicare payments for a 90-day episode, and the beneficiary's recovery from surgery begins during the hospital stay. Most hospitals already have some infrastructure related to health information technology, patient and family education, and care management and discharge planning. This includes post-acute care (PAC) coordination infrastructure and resources such as case managers, which hospitals can build upon to achieve efficiencies under this episode payment model. Many hospitals also have recently heightened their focus on aligning their efforts with those of community providers to provide an improved continuum of care due to the incentives under other CMS models and programs, including Accountable Care Organization (ACO) initiatives such as the Medicare Shared Savings Program (MSSP), and the Hospital Readmissions Reduction Program (HRRP), establishing a base for augmenting these efforts under the CCJR model.

In view of our proposal that hospitals be the episode initiators under this model, we believe that hospitals are more likely than other providers to have an adequate number of episode cases to justify an investment in episode management for this model. We also believe that hospitals are most likely to have access to resources that would allow them to appropriately manage and coordinate care throughout the LEJR episode. Finally, the hospital staff is already involved in discharge planning and placement recommendations for Medicare beneficiaries, and more efficient PAC service delivery provides substantial opportunities for improving quality and reducing costs under CCJR.

We considered requiring treating physicians (orthopedic surgeons or others) or their associated physician group practices, if applicable, to be financially responsible for the episode of care under the CCJR Model. We expect that every Medicare beneficiary discharged with a diagnosis grouped under MS–DRG 469 or 470 would have an operating physician and an admitting physician for the hospital stay. However, the services of providers other than the hospital where the acute care hospital stay for the LEJR procedure (hereinafter ''the anchor hospitalization'') occurs would not necessarily be furnished in every LEJR episode. For example, that physicians of different specialties play varying roles in managing patients during an acute care hospitalization for a surgical procedure and during the recovery period, depending on the hospital and community practice patterns and the clinical condition of the beneficiary and could not be assumed to be included in every LEJR episode. This variability would make requiring a particular physician or physician group practice to be financially responsible for a given episode very challenging.

If we were to assign financial responsibility to the operating physician, it is likely that there would be significant variation in the number of relevant episodes that could be assigned to an individual person. Where the physician was included in a physician group practice, episodes could be aggregated to this group level but this would not be possible for all cases and would likely still have low volume concerns. We believe that the small sample sizes accruing to individual physician and physician group practices would make systematic care redesign inefficient and more burdensome, given that we are proposing to test all episodes occurring at hospitals selected for participation for beneficiaries that do not meet the exclusion criteria specified in section III.B.3 of this proposed rule and are not BPCI episodes that we are proposing to exclude as outlined in this section and also in section III.C.7 of this proposed rule.

Finally, we note that although the BPCI initiative includes the possibility of a physician group practice as a type of initiating participant, the physician groups electing to participate in BPCI have done so because their practice structure supports care redesign and other infrastructure necessary to bear financial responsibility for episodes and is not necessarily representative of the typical group practice. In addition, most of the physician group practices in BPCI are not bearing financial responsibility, but are participating in BPCI as partners with convener organizations (discussed later in this section), which enter into agreements with CMS, on behalf of health care providers such as physician group practices, through which they accept financial responsibility for the episode of care. The infrastructure necessary to accept financial responsibility for episodes is not present across all physician group practices, and thus we do not believe it would be appropriate to designate physician group practices to bear the financial responsibility for making repayments to CMS under the proposed CCJR model. We seek comment on our proposal to require the hospital to bear the financial responsibility for the episodes of care under CCJR.

We are proposing that hospitals will bear the financial responsibility for LEJR episodes of care under CCJR. However, because there are LEJR episodes currently being tested in BPCI Model 1, 2, 3 or 4, we believe that participation in CCJR should not be required if it would disrupt testing of LEJR episodes already underway in BPCI models. Therefore, we are proposing that IPPS hospitals located in an area selected for the model that are active Model 1 BPCI participant hospitals as of July 1, 2015 or episode initiators for LEJR episodes in the risk-bearing phase of Model 2 or 4 of BPCI as of July 1, 2015, would be excluded from participating in CCJR during the time that their qualifying episodes are included in one of the BPCI models. Likewise, we are proposing that if the participant hospital is not an episode initiator for LEJR episodes under BPCI Model 2, then LEJR episodes initiated by other providers or suppliers under BPCI Model 2 or 3 (where the surgery takes place at the participant hospital) would be excluded from CCJR. Otherwise qualifying LEJR episodes (that is, those that are not part of a Model 3 BPCI LEJR episode or a Model 2 physician group practice-initiated LEJR episode) at the participant hospital would be included in CCJR.

While we propose that the participant hospital be financially responsible for the episode of care under CCJR, we also believe that effective care redesign for LEJR episodes requires meaningful collaboration among acute care hospitals, PAC providers, physicians, and other providers and suppliers within communities to achieve the highest value care for Medicare beneficiaries. We believe it may be essential for key providers to be aligned and engaged, financially and otherwise, with the hospitals, with the potential to share financial responsibility with those hospitals. We note that all relationships between and among providers and suppliers must comply with all relevant laws and regulations, including the fraud and abuse laws and all Medicare payment and coverage requirements unless otherwise specified further later in this section and in section III.C.10 of this proposed rule. Depending on a hospital's current degree of clinical integration, new and different contractual relationships among hospitals and other health care

providers may be important, although not necessarily required, for CCJR model success in a community. We acknowledge that financial incentives for other providers may be important aspects of the model in order for hospitals to partner with these providers and incentivize certain strategies to improve episode efficiency.

In the BPCI initiative, participants have entered a variety of relationships with entities above the hospital level. Some of these relationships are ones where the financial risk is borne by the entity other than the hospital, such as a parent organization (known as awardee conveners) and others have managerial or other responsibility relationships with other organizations (known as facilitator conveners) but financial responsibility remains with the episode initiator . We acknowledge the important role that conveners play in the BPCI initiative with regard to providing infrastructure support to hospitals and other entities initiating episodes in BPCI. The convener relationship (where another entity assumes financial responsibility) may take numerous forms, including contractual (such as a separate for-profit company that agrees to take on a hospital's financial risk in the hopes of achieving financial gain through better management of the episodes) and through ownership (such as when risk is borne at a corporate level within a hospital chain).

However, we are proposing that for the CCJR model, we would hold only the participant hospitals financially responsible for the episode of care. This is consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based reimbursement arrangements. If conveners were included as participants in CCJR, we may not gain the knowledge of how a variety of hospitals can succeed in relationship with CMS in which they bear financial risk for the episode of care. We acknowledge that CCJR hospitals may wish to enter into relationships with other entities in order to manage the episode of care or distribute risk. We do not intend to restrict the ability of hospitals to enter into administrative or risk sharing arrangements related to this model. We refer readers to section III.C.10 of this proposed rule for further discussion of model design elements that may outline financial arrangements between participant hospitals and other providers and suppliers.

4. Proposed Geographic Unit of Selection and Exclusion of Selected Hospitals

In determining which hospitals to include in the CCJR model, we considered whether the model should be limited to hospitals where a high volume of LEJRs are performed, which would result in a more narrow test on the effects of an episode-based payment, or whether to include all hospitals in particular geographic areas, which would result in testing the effects of an episode-based payment approach more broadly across an accountable care community seeking to coordinate care longitudinally across settings. Selecting certain hospitals where a high volume of LEJRs are performed may allow for fewer hospitals to be selected as model participants, but still result in a sufficient number of CCJR episodes to evaluate the success of the model. However, there would be more potential for behavioral changes that could include patient shifting and steering between hospitals in a given geographic area that could impact the test. Additionally, this approach would provide less information on testing episode payments for LEJR procedures across a wide variety of hospitals with different characteristics. Selecting geographic areas and including all IPPS hospitals in those areas not otherwise excluded due to BPCI overlap as previously described and in section III.C.7 of this proposed rule as model participants would help to minimize the risk of participant hospitals shifting higher cost cases out of the CCJR model. Moreover, in selecting geographic areas we could choose certain characteristics, stratify geographic areas according to these characteristics, and randomly select geographic areas from within each stratum. Such a stratified random sampling method based on geographic area would allow us to observe the experiences of hospitals with various characteristics, such as variations in size, profit status, and episode utilization patterns, and examine whether these characteristics impact the effect of the model on patient outcomes and Medicare expenditures within episodes of care. Stratification would also substantially reduce the extent to which the selected hospitals will differ from non-selected hospitals on the characteristics used for stratification, which would improve the statistical power of the subsequent model evaluation, improving our ability to reach conclusions about the model's effects on episode costs and the quality of patient care. Therefore, given the authority in section 1115A(a)(5) of the Act, which allows the Secretary to elect to limit testing of a model to certain geographic areas, we propose to use a stratified random sampling method to select geographic areas and require all hospitals paid under the IPPS in those areas to participate in the CCJR model and be financially responsible for the cost of the episode, with certain exceptions as previously discussed and in sections III.B.3 and III.C.7 of this proposed rule.

a. Overview and Options for Geographic Area Selection

In determining the geographic unit for the geographic area selection for this model, we considered using a stratified random sampling methodology to select (1) certain counties based on their Core-Based Statistical Area (CBSA) status, (2) certain zip codes based on their Hospital Referral Regions (HRR) status or (3) certain states. We address each geographic unit in turn.

We considered selecting certain counties based on their CBSA status. The general concept of a CBSA is that of a core area containing a substantial population nucleus, together with adjacent communities having a high degree of economic and social integration within that core. Counties are designated as part of a CBSA when the county or counties or equivalent entities are associated with at least one core (urbanized area or urban cluster) of at least 10,000 in population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties associated with the core. There are 929 CBSAs currently used for geographic wage adjustment purposes across Medicare payment systems.[4] The 929 CBSAs include 388 Metropolitan Statistical Areas (MSAs), which have an urban core population of at least 50,000, and the 541 Micropolitan Statistical Areas (μSA), which have an urban core population of at least 10,000 but less than 50,000. CBSAs may be further combined into a Combined Statistical Area (CSA) which consists of two or more adjacent CBSAs (MSAs or μSAs or both) with substantial employment interchange. Counties not classified as a CBSA are typically categorized and examined at a state level.

[4] As stated in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552) and final rule (78 FR 50586), on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for MSAs, μSAs, and CSAs, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.*

The choice of a geographical unit based on CBSA status could mean selection of a CBSA, an MSA, or a CSA. We propose basing the selection on an MSA, which we will discuss later in this section.

In determining which geographic areas will be potentially subject to selection, we focused on MSAs, which is a subcategory within CBSA characterized by counties associated with an urban core population of at least 50,000. It is our intention at this time that counties not in an MSA would not be subject to the selection process. These counties not subject to selection would include the μSA counties and the counties without a core urban area of at least 10,000. These areas are largely rural areas and have a limited number of qualifying LEJR cases. Relatively few of these areas would be able to qualify for inclusion based on the minimum number of LEJR episodes in year requirement discussed later in this section.

We considered, but ultimately decided against, using CSA designation instead of MSAs as a potential unit of selection. Under this scenario, we would look at how OMB classifies counties. We would first assess whether a county has been identified as belonging to a CSA, a unit which consists of adjacent MSAs or μSAs or both. If the county was not in a CSA, we would determine if it was in an MSA that is not part of a larger CSA. Counties not associated with a CSA or an MSA would be unclassified and excluded from selection. These unclassified areas would include the counties in a state that were either not a CBSA (no core area of at least 10,000) or associated with a μSA (core area of between 10,000 and 50,000) but unaffiliated with a CSA.

Whether to select on the basis of CSA/MSAs or just on MSAs was influenced by a number of factors including an assessment with respect to the anticipated degree to which LEJR patients would be willing to travel for their initial hospitalization, the extent to which surgeons are expected to have admitting privileges in multiple hospitals located in different MSAs and considerations related to the degree to which we desire to include hospitals within μSAs that are part of a larger CSA. It was believed that the anticipated risk for patient shifting and steering between MSAs within a CSA was not severe enough to warrant selecting CSAs. However, for these same reasons, we believe that selecting complete MSAs is preferable to selecting metropolitan divisions of MSAs for inclusion in the CCJR model. We use the metropolitan divisions to set wage indices for its prospective payment systems. Of the 388 MSAs, there are 11 MSAs that contain multiple metropolitan divisions. For example, the Boston-Cambridge-Newton, MA–NH MSA is divided into the following metropolitan divisions:

- Boston, MA.
- Cambridge-Newton-Framingham, MA.
- Rockingham County-Strafford County, NH.

The Seattle-Tacoma-Bellevue, WA MSA is divided into the following metropolitan divisions:

- Seattle-Bellevue-Everett, WA.
- Tacoma-Lakewood, WA.

We propose selecting entire MSAs rather than sub-divisions within an MSA.

We next considered selecting hospital referral regions (HRRs). HRRs represent regional health care markets for tertiary medical care. There are 306 HRRs with at least one city where both major cardiovascular surgical procedures and neurosurgery are performed. HRRs are defined by determining where the majority of patients were referred for major cardiovascular surgical procedures and for neurosurgery.[5] Compared to MSAs, HRRs are classified based on where the majority of beneficiaries within a zip code receive their hospital services for selected tertiary types of care. The resulting HRRs represent the degree to which people travel for tertiary care that generally requires the services of a major referral center and not the size of the referral network for more routine services, such as knee and hip arthroplasty procedures. In addition, because HRRs are defined based on referrals for cardiovascular surgical procedures and neurosurgery, they may not reflect referrals for orthopedic procedures. Therefore, we believe that MSAs as a geographic unit are preferable over HRRs for this model.

We also considered selecting states for the CCJR model. However, we concluded that MSAs as a geographic unit are preferable over states for the CCJR model. As mentioned in section III.A.4.b of this proposed rule, we anticipate that hospitals that would otherwise be required to participate in the CCJR model would be excluded from the model because their relevant LEJR episodes are already being tested in BPCI. If we were to select states as the geographic unit, there is a potential that an entire state would need to be excluded because a large proportion of hospitals in that state are episode initiators of LEJR episodes in BPCI. In contrast, if we excluded a specific MSA due to BPCI participation, as discussed in the next section, we could still select another MSA within that same state. Likewise, if we chose states as the geographic unit, we would automatically include hospitals in all rural areas within the state selected. If MSAs are selected for the geographic unit, we anticipate that fewer small rural hospitals would be included in the model. Using a unit of selection smaller than a state would allow for a more deliberate choice about the extent of inclusion of rural or small population areas. Selecting states rather than MSAs would also greatly reduce the number of independent geographic areas subject to selection under the model, which would decrease the statistical power of the model evaluation. Finally, MSAs straddle state lines where providers and Medicare beneficiaries can easily cross these boundaries for health care. Choosing states as the geographic unit would potentially divide a hospital market and set up a greater potential for patient shifting and steering to different hospitals under the model. The decision that the MSA-level analysis was more analytically appropriate was based on the specifics of this model and not meant to imply that other levels of selection would not be appropriate in a different model such as the proposed Home Health Value Based Purchasing (HHVBP) model.

For the reasons previously discussed, we propose to require participation in the CCJR model of all hospitals, with limited exceptions as previously discussed in section III.A.2.of this proposed rule, paid under the IPPS that are physically located in a county in an MSA selected through a stratified random sampling methodology, outlined in section III.A.3.b in this proposed rule, to test and evaluate the effects of an episode-based payment approach for an LEJR episodes. We propose to determine that a hospital is located in an area selected if the hospital is physically located within the boundary of any of the counties in that MSA as of the date the selection is made. Although MSAs are revised periodically, with additional counties added or removed from certain MSAs, we propose to maintain the same cohort of selected hospitals throughout the 5 year performance period of the model with limited exceptions as described later in this section. Thus, we propose not to add hospitals to the model if after the start of the model new counties are added to one of the selected MSAs or

[5] The Dartmouth Atlas of Healthcare, *http://www.dartmouthatlas.org/data/region/*. Accessed on April 9, 2015.

remove hospitals from the model if counties are removed from one of the selected MSAs. We believe that this approach will best maintain the consistency of the participants in the model, which is crucial for our ability to evaluate the results of the model. However, we retain the possibility of adding a hospital that is opened or incorporated within one of the selected counties after the selection is made and during the period of performance. (See section III.C.of this proposed rule for discussion of how target prices will be determined for such hospitals.) Although we considered including hospitals in a given MSA based on whether the hospitals were classified into the MSA for IPPS wage index purposes, this process would be more complicated, and we could not find any compelling reasons favoring this approach. For example, we assign hospitals to metro divisions of MSAs when those divisions exist. See our previous discussion of this issue. In addition, there is the IPPS process of geographic reclassification by which a hospital's wage index value or standardized payment amount is based on a county other than the one where the hospital is located. For the purpose of this model, it is simpler and more straightforward to use the hospital's physical location as the basis of assignment to a geographic unit. This decision would have no impact on a hospital's payment under the IPPS. We seek comment on our proposal to include participant hospitals for the CCJR model based on the physical location of the hospital in one of the counties included in a selected MSA.

b. MSA Selection Methodology

We propose to select the MSAs to include in the CCJR model by stratifying all of the MSAs nationwide according to certain characteristics.

(1) Exclusion of Certain MSAs

Prior to assigning an MSA to a selection stratum, we examined whether the MSA met specific proposed exclusion criteria. MSAs were evaluated sequentially using the following 4 exclusion criteria: First, MSAs in which fewer than 400 LEJR episodes (determined as we propose to determine episodes included in this model, as discussed in section III.B.2) occurred from July 1, 2013 through June 30, 2014 were removed from possible selection. The use of the 400 LEJR cases in a year was based on a simple one-sided power calculation to assess the number of episodes that would be needed to detect a 5 percent reduction in episode expenditures. Accordingly, cases in hospitals paid under either the critical access hospital (CAH) methodology or the Maryland All-Payer Model are not included in the count of eligible episodes. This criterion removed 156 MSAs from possible selection.

Second, MSAs were removed from possible selection if there were fewer than 400 non-BPCI LEJR episodes in the MSA in the reference year. For the purposes of this exclusion, the number of BPCI episodes was estimated as the number of potentially eligible cases during the reference year that occurred in acute care hospitals participating in BPCI Model 1, or in phase 2 of BPCI Models 2 or 4 as of July 1, 2015 and the number of LEJRs in 2013 and 2014 associated with these hospitals was examined. This criterion removed an additional 24 MSAs from potential selection.

Third, MSAs were also excluded from possible selection if the MSA was dominated by BPCI Models 1, 2, 3, or 4 episodes to such a degree that it would impair the ability of participants in either the CCJR model or the BPCI models to succeed in the objectives of the initiative or impair the ability to set accurate and fair prices. We anticipate that some degree of overlap in the two programs will be mutually helpful for both models. There are two steps to this exclusion. First, we looked at the number of LEJR episodes at BPCI Model 1, 2 or 4 initiating hospitals and second, the number of LEJR episodes among BPCI Model 3 SNF and HHA episode initiators. We set the first cut off for this exclusion if, within an MSA, more than 50 percent of otherwise qualifying proposed CCJR episodes were in Phase 2 of BPCI Model 2 or 4 with hospital initiators. We set the second cut off for BPCI Model 3, based on if either SNF or HHA BPCI Model 3 initiating providers accounted for more than 50 percent of LEJR referrals to that provider type, the MSA would be eliminated from the possibility of selection. As a result of this third criterion, 4 additional MSAs were removed from possible selection. No MSAs were excluded based on Skilled Nursing Facility (SNF) or Health Home Agency (HHA) participation in Model 3.

Finally, MSAs were removed if, after applying the previous 3 criteria they remained eligible for selection, but more than 50 percent of estimated eligible episodes during the reference year were not paid under the IPPS system. Please refer to the appenda for this proposed rule for the status of each MSA based on these exclusion criteria, available at *http://innovation.cms.gov/initiatives/ccjr/*. After applying these four exclusions, 196 MSAs remained to be stratified for purposes of our proposed selection methodology.

(2) Proposed Selection Strata

Numerous variables were considered as potential strata for classifying MSAs included in the model. However, our proposal is intended to give priority to transparency and understandability of the strata. We propose creating selection strata based on the following two dimensions: MSA average wage-adjusted historic LEJR episode payments and MSA population size.

(a) MSA Average Wage-adjusted Historic LEJR Episode Payments.

We were interested in being able to classify and divide MSAs according to their typical patterns of care associated with LEJR episodes. As a straightforward measure of LEJR patterns of care, we selected the mean MSA episode payment, as defined in this proposed rule. MSAs vary in their average episode payments. The average episode payments in an area may vary for a variety of reasons including—1) in response to the MS–DRG mix and thus the presence of complicating conditions; 2) readmission rates; 3) practice patterns associated with type of PAC provider(s) treating beneficiaries; 4) variations of payments within those PAC providers, and 5) the presence of any outlier payments.

The measure of both mean episode payments and median episode payments within the MSA was considered. We propose to stratify by mean because it would provide more information on the variation in episode payments at the high end of the range of payments. We are interested in the lower payment areas for the purpose of informing decisions about potential future model expansion. However, the CCJR model is expected to have the greatest impact in areas with higher average episode payments.

The average episode payments used in this analysis were calculated based on the proposed episode definition for CCJR using Medicare claims accessed through the Chronic Conditions Warehouse for 3 years with admission dates from July 1, 2011 through June 30, 2014. Episode payments were wage-adjusted using the FY 2014 hospital wage index contained in the FY 2014 IPPS Final Rule, downloaded at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Data-Files.html.* The adjusted payment was calculated by dividing the unadjusted payment by a factor equal to the sum of 0.3 plus the

multiplicative product of 0.7 and the wage index value of the hospital where the LEJR was performed. Episodes in the database with IPPS payments less than $4,000 for the DRG 469 or 470 case were deleted as indicating that the hospital did not receive full payment for the LEJR procedure. We also truncated the episode payment at the 99.9th percentile of the distribution ($135,000) to limit the impact of extreme outliers.

(b) MSA Population Size

The second dimension proposed for the CCJR selection strata is the number of persons in the MSA. In deciding how best to incorporate the dimensions of urban density and availability of medical resources, a variety of measures were considered, including overall population in the included counties, overall population in the core area of the MSA, population over the age of 65 in the MSA, the number of hospital beds and the number of Medicare FFS LEJR procedures in a year. The reason we decided to include this dimension in the strata definition is that these factors are believed to be associated with the availability of resources and variations in practice and referral patterns by the size of the healthcare market. When examined, these alternative measures were all very highly correlated with one another, which allowed the use of one of these measures to be able to substitute for the others in the definition of the stratum. From these alternative approaches, we choose to use MSA population.

In operationalizing this measure, MSAs were classified according to their 2010 census population.

(c) Analysis of Strata

The two proposed domains, MSA population and MSA historic LEJR episode spending, were examined using a K-Means factor analysis. The purpose of this factor analysis was to inform the process of which cut points most meaningfully classify MSAs. Factor analysis attempts to identify and isolate the underlying factors that explain the data using a matrix of associations. Factor analysis is an interdependence technique. Essentially, variables are entered into the model and the factors (or clusters) are identified based on how the input variables correlate to one another. The resulting clusters of MSAs produced by this methodology suggested natural cut points for average episode payments at $25,000 and $28,500. While not intentional, these divisions correspond roughly to the 25th and 75th percentiles of the MSA distribution. Cut points based on these percentiles seemed reasonable from statistical and face validity perspectives in the sense that they created groups that included an adequate number of MSAs and a meaningful range of costs.

As a result of this analysis, we propose to classify MSAs according to their average LEJR episode payment into four categories based the on the 25th, 50th and 75th percentiles of the distribution of the 196 potentially selectable MSAs. This approach ranks the MSAs relative to one another and creates four equally sized groups of 49. The population distribution was divided at the median point for the MSAs eligible for potential selection. This resulted in MSAs being divided into two equal groups of 98. The characteristics of the resulting strata are shown in Table 1.

TABLE 1—SUMMARY POPULATION AND EPISODE PAYMENT STATISTICS BY MSA GROUP

	Payment in lowest quarter	Payment in 2nd lowest quarter	Payment in 3rd lowest quarter	Payment in highest quarter	Total eligilble
MSAs with population less than median:					
Number of Eligible MSAs	33	19	22	24	98
Average of Population	251,899	238,562	268,331	254,154	253,554
Minimum MSA Population	96,275	55,274	106,331	96,024	55,274
Maximum MSA Population	425,790	416,257	424,858	428,185	428,185
Average Episode Payments ($)	$22,994	$25,723	$27,725	$30,444	$26,410
Minimum Episode Payments	$18,440	$24,898	$26,764	$29,091	$18,440
Maximum Episode Payments	$24,846	$26,505	$28,679	$32,544	$32,544
MSAs with population more than median:					
Number of Eligible MSAs	16	30	27	25	98
Average of Population	1,530,083	1,597,870	1,732,525	2,883,966	1,951,987
Minimum MSA Population	464,036	436,712	434,972	439,811	434,972
Maximum MSA Population	4,335,391	5,286,728	12,828,837	19,567,410	19,567,410
Average Episode Payments ($)	$23,192	$25,933	$27,694	$30,291	$27,082
Minimum Episode Payments	$16,504	$25,091	$26,880	$28,724	$16,504
Maximum Episode Payments	$24,819	$26,754	$28,659	$33,072	$33,072
Total Eligible MSAs	49	49	49	49	.....

Note: Population and episode payment means are un-weighted averages of the MSA values within each of the eight MSA groups.

Please refer to the addenda for this proposed rule for information on the non-excluded MSAs, their wage adjusted average LEJR episode spending, their population and their resultant group assignment at: *http://innovation.cms.gov/initiatives/ccjr/*.

(3) Factors Considered but Not Used in Creating Proposed Strata

In addition to the two dimensions we are proposing to use for the selection groups previously discussed, a variety of possible alternative measures and dimensions were considered. Many of these variables are considered to be important but it was believed that it was important to have a fairly straightforward and easily understandable stratum definition. Simplicity, by definition, required that only the most important variables would be used. If a market characteristic under consideration was correlated with one of the chosen dimensions or it was believed that variations in the characteristic could be adequately captured by random selection within the strata, is was not prioritized for inclusion.

Some of the factors considered that we are not proposing as dimensions are—

- Measures associated with variation in practice patterns associated with LEJR episodes. In considering how to operationalize this measure, a number of alternatives were considered including total PAC LEJR payments in

an MSA, percent of LEJR episodes with a SNF claim in an MSA, percent of LEJR episodes with an initial discharge to HHA, percent of LEJR episodes with an IRF claim, and percent of LEJR episodes with claims for two or more types of PAC providers;

- Measures associated with relative market share of providers with respect to LEJR episodes;
- Healthcare supply measures of providers in the MSA including counts of IRF beds, SNF beds, hospital beds, and number of orthopedic surgeons;
- MSA level demographic measures such as; average income, distributions of population by age, gender or race, percent dually eligible, percent of population with specific health conditions or other demographic composition measures; and
- Measures associated with the degree to which a market might be more capable or ready to implement care redesign activities. Examples of market level characteristics that might be associated with anticipated ease of implementation include the MSA-level EHR meaningful use levels, managed care penetration, ACO penetration and experience with other bundling efforts.

It should be noted that, while these measures are proposed to be part of the selection stratus, we acknowledge that these and other market-level factors may be important to the proper understanding of the evaluation of the impact of CCJR. It is the intention that these and other measures will be considered in determining which MSAs are appropriate comparison markets for the evaluation as well as considered for possible subgroup analysis or risk adjustment purposes. The evaluation will include beneficiary, provider, and market level characteristics in how it examines the performance of this proposed model.

(4) Sample Size Calculations and the Number of Selected MSAs

Analyses of the necessary sample size led us to conclude that we need to select 75 MSAs of the 384 MSAs with eligible LEJR episodes to participate in CCJR. The number and method of selection of these 75 MSAs from the 8 proposed groups is addressed in the following section. In coming to the decision to target 75 MSAs, we are proposing a conservative approach. Going below this threshold would jeopardize our ability to be confident in our results and to be able to generalize from the model to the larger national context. We discuss the assumptions and modeling that went into our proposal to test the model in 75 MSAs later in this section.

In calculating the necessary size of the model, a key consideration was to have sufficient power to be able to detect the desired size impact. The larger the anticipated size of the impact, the fewer MSAs we would have to sample in order to observe it. However, a model sized to be able to only detect large impacts runs the risk of not being able to draw conclusions if the size of the change is less than anticipated. The measure of interest used in estimating sample size requirements for the CCJR model was wage-adjusted total episode spending. The data used for the wage-adjusted total episode spending is the 3 year data pull previously described that covers LEJR episodes with admission dates from July 1, 2011 through June 30, 2014. For the purposes of the sample size calculation the impact estimate assumed we wanted to be able to detect a 2 percent reduction in wage adjusted episode spending after 1 year of experience. This amount was chosen because it is the anticipated amount of the discount we propose to apply to target prices in CCJR.

The next consideration in calculating the necessary sample size is the degree of certainty we will need for the statistical tests that will be performed. In selecting the right sample size, there are two types of errors that need to be considered ''false negatives'' and ''false positives''. A false positive occurs if a statistical test concludes that the model was successful (the model saved money) when it was, in fact, not. A false negative occurs if a statistical test fails to find statistically significant evidence that the model was successful, but it was, in fact, successful. In considering the minimum sample size needs of a model, a standard guideline in the statistical literature suggests calibrating statistical tests to generate no more than a 5 percent chance of a false positive and selecting the sample size to ensure no more than a 20 percent chance of a false negative. In contrast, the proposed sample size for this project was based on a 20 percent chance of a false positive and a 30 percent chance of a false negative in order to be as conservative as was practicable.

A third consideration in the sample size calculation was the appropriate unit of selection and whether it is necessary to base the calculation on the number of MSAs, the number of hospitals, or the number of episodes. As discussed later in this section, we are proposing to base the sample size calculation at the MSA level.

The CCJR model is a nested comparative study, which has two key features. First, the unit of assignment (to treatment and comparison groups) is an identifiable group; such groups are not formed at random, but rather through some physical, social, geographic, or other connection among their members. Second, the units of observation are members of those groups. In such designs, the major analytic problem is that there is an expectation for a positive correlation (intra-class correlation (ICC)) among observations of members of the same group (MSA). That ICC reflects an extra component of variance attributable to the group above and beyond the variance attributable to its members. This extra variation will increase the variance of any aggregate statistic beyond what would be expected with random assignment of beneficiaries or hospitals to the treatment group.

In determining the necessary sample size, we need to take into consideration the degrees of freedom. As part of this process, we examined the number of beneficiaries, the number of hospitals, and the number of MSAs and the level of correlation in episode payments between each level. For example, while each beneficiary has their own episode expenditure level, there are commonalities between those expenditure amounts at the hospital level, based on hospital-specific practice and referral patterns. The number of degrees of freedom needed for any aggregate statistic is related to the number of groups (MSAs or hospitals), not the number of observations (beneficiary episodes). If we were to base the determination of the size of the model on beneficiary episodes where correlation exists, we would have an inflated false positive error rate and would overstate the impact of the model. We empirically examined the level of correlation between beneficiaries and hospitals and between hospitals and MSAs and determined that the correlation was high enough to be of concern and necessitate a MSA level unit of selection.

Using the aforementioned assumptions, a power calculation was run which indicated we would need between 50 and 150 treatment MSAs to be able to reliably detect a 2 percent reduction in payments after 1 year. The lower end of this range assumes the ability of evaluation models to substantially reduce variation through risk adjustment and modeling. We anticipate that we will be able to use the conservative end of this range, but assuming that evaluation modeling can achieve ''best'' results poses a real risk to our ability to draw conclusions. We want to allow for some degree of flexibility and are thus proposing proceeding with 75 MSAs. The 75 MSA

number is at the 25th percentile between the 50 and 150 treatment MSA range. We narrowed the acceptable range to between 50 and 100, based on the assumption that we will be able substantial improve our estimates through modeling, and then chose a number in the middle of this reduced range.

(5) Method of Selecting MSAs

As previously discussed, we are seeking to choose 75 MSAs from our proposed 8 selection groups. We examined and considered a number of possible approaches including equal selection in each of the eight groups, equal selection in the four payment groups, selection proportionate to the number of MSAs in each group, and a number of approaches that differentially weighted the payment categories.

After consideration, it was decided that a methodology that proportionally under-weighted more efficient MSAs and over-weighted more expensive MSAs was the most appropriate approach to fulfilling the overall priorities of this model to increase efficiencies and savings for LEJR cases while maintaining or improving the overall quality of care. This approach would make it less likely for the MSAs in the lowest spending category to be selected for inclusion. We thought this appropriate because the MSAs in the lowest expenditure areas have the least room for possible improvement and are already performing relatively efficiently compared to other geographic areas, which means that experience with the model in these areas may be relatively less valuable for evaluation purposes. At the same time, we believed it was important to include some MSAs in this group in order to assess the performance of this model in this type of circumstance. We also believe it is appropriate for higher payment areas to be disproportionately included because they are most likely to have significant room for improvement in creating efficiencies. We expect more variation in practice patterns among the more expensive areas. There are multiple ways an MSA can be more relatively expensive, including through outlier cases, higher readmission rates, greater utilization of physician services, or through PAC referral patterns. A larger sample of MSAs within the higher payment areas will allow for us to observe the impact of the CCJR model on areas with these various practice patterns in the baseline period.

The proposed method of disproportionate selection between the strata is to choose 30 percent of the MSAs in the two groups in the bottom quarter percentile of the payment distribution, 35 percent of the MSAs in the two groups in the second lowest quartile, 40 percent in the third quartile, and 45 percent in the highest episode payment quartile. This proportion works out to an average of 38 percent overall, which corresponds to 75 selected MSAs out of the 196 eligible. The number of MSAs to be chosen in the eight selection groups is shown in Table 2.

TABLE 2—NUMBER OF MSAS TO BE CHOSEN FROM THE EIGHT SELECTION GROUPS

	Payment in lowest quarter	Payment in 2nd lowest quarter	Payment in 3rd lowest quarter	Payment in highest quarter	Total eligible MSAs
Selection Proportion	30%	35%	40%	45%	
Less Than Median Population (Group #)	(1)	(2)	(3)	(4)	
Number Eligible MSAs	33	19	22	24	98
Proportion x Number	9.9	6.65	8.8	10.8	
Number to be selected from group	10	7	9	11	37
More Than Median Population (Group #)	(5)	(6)	(7)	(8)	
Number Eligible MSAs	16	30	27	25	98
Proportion x Number	4.8	10.5	10.8	11.25	
Number to be selected from group	5	11	11	11	38
Total Eligible MSAs	49	49	49	49	196
Number to be selected	15	18	20	22	75

We selected the proposed MSAs for the CCJR model through random selection. In the proposed method of selection, each MSA was assigned to one of the eight selection groups previously identified. Based on this sampling methodology, SAS Enterprise Guide 7.1 software was used to run a computer algorithm designed to randomly select MSAs from each strata. SAS Enterprise Guide 7.1 and the computer algorithm used to conduct selection represents an industry-standard for generating advanced analytics and provides a rigorous, standardized tool by which to satisfy the requirements of randomized selection. The key SAS commands employed include a ''PROC SURVEYSELECT'' statement coupled with the ''METHOD=SRS'' option used to specify simple random sampling as the sample selection method. A random number seed was generated for each of the eight strata by using eight number seeds corresponding to birthdates and anniversary dates of parties present in the room. The random seeds for stratum one through eight were as follows: 907, 414, 525, 621, 1223, 827, 428, 524. Note that no additional stratification was used in any of the eight groupings so as to produce an equal probability of selection within each of the eight groups. For more information on this procedure and the underlying statistical methodology, please reference SAS support documentation at: *http://support.sas.com/documentation/cdl/en/statug/63033/HTML/default/viewer.htm#statug_surveyselect_sect003.htm/*. We also considered a potential alternative approach to this random selection in which we would generate a starting number within SAS and then choose every third MSA within a group starting at this point until the relevant number of MSAs were chosen. We opted to not utilize this feature for simplicity's sake and alignment with other randomization methodologies used for CMS models.

The selection of an MSA means that all hospitals that are physically located anywhere within the counties that make up the MSA are included. By definition, the entire county is included in an MSA and hospitals that are in the relevant counties will be impacted even if they are not part of the core urban area.

The MSAs selected may change if the methodology changes in response to comments on the proposed methodology. Should the methodology we propose in this rule change as a result of comments received during the rulemaking process, it could result in different areas being selected for the model. In such an event, we would

apply the final methodology and announce the selected MSAs in the final rule. Therefore we seek comment from all interested parties in every MSA on the randomized selection methodology proposed in this section.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the new proposed part 510 of the Code of Federal Regulations.

TABLE 3—PROPOSED MSAS INCLUDED IN THE CCJR MODEL

MSA	MSA Name
10420	Akron, OH.
10740	Albuquerque, NM.
11700	Asheville, NC.
12020	Athens-Clarke County, GA.
12420	Austin-Round Rock, TX.
13140	Beaumont-Port Arthur, TX.
13900	Bismarck, ND.
14500	Boulder, CO.
15380	Buffalo-Cheektowaga-Niagara Falls, NY.
16020	Cape Girardeau, MO-IL.
16180	Carson City, NV.
16740	Charlotte-Concord-Gastonia, NC-SC.
17140	Cincinnati, OH-KY-IN.
17820	Colorado Springs, CO.
17860	Columbia, MO.
18580	Corpus Christi, TX.
19500	Decatur, IL.
19740	Denver-Aurora-Lakewood, CO.
20020	Dothan, AL.
20500	Durham-Chapel Hill, NC.
21780	Evansville, IN-KY.
22420	Flint, MI.
22500	Florence, SC.
22660	Fort Collins, CO.
23540	Gainesville, FL.
23580	Gainesville, GA.
24780	Greenville, NC.
25420	Harrisburg-Carlisle, PA.
26300	Hot Springs, AR.
26900	Indianapolis-Carmel-Anderson, IN.
28140	Kansas City, MO-KS.
28660	Killeen-Temple, TX.
29820	Las Vegas-Henderson-Paradise, NV.
30700	Lincoln, NE.
31080	Los Angeles-Long Beach-Anaheim, CA.
31180	Lubbock, TX.
31540	Madison, WI.
32780	Medford, OR.
32820	Memphis, TN-MS-AR.
33100	Miami-Fort Lauderdale-West Palm Beach, FL.
33340	Milwaukee-Waukesha-West Allis, WI.
33700	Modesto, CA.
33740	Monroe, LA.
33860	Montgomery, AL.
34940	Naples-Immokalee-Marco Island, FL.
34980	Nashville-Davidson—Murfreesboro—Franklin, TN.
35300	New Haven-Milford, CT.
35380	New Orleans-Metairie, LA.

TABLE 3—PROPOSED MSAS INCLUDED IN THE CCJR MODEL—Continued

MSA	MSA Name
35620	New York-Newark-Jersey City, NY-NJ-PA.
35980	Norwich-New London, CT.
36260	Ogden-Clearfield, UT.
36420	Oklahoma City, OK.
36740	Orlando-Kissimmee-Sanford, FL.
37860	Pensacola-Ferry Pass-Brent, FL.
38300	Pittsburgh, PA.
38940	Port St. Lucie, FL.
38900	Portland-Vancouver-Hillsboro, OR-WA.
39340	Provo-Orem, UT.
39740	Reading, PA.
40060	Richmond, VA.
40420	Rockford, IL.
40980	Saginaw, MI.
41860	San Francisco-Oakland-Hayward, CA.
42660	Seattle-Tacoma-Bellevue, WA.
42680	Sebastian-Vero Beach, FL.
43780	South Bend-Mishawaka, IN-MI.
41180	St. Louis, MO-IL.
44420	Staunton-Waynesboro, VA.
45300	Tampa-St. Petersburg-Clearwater, FL.
45780	Toledo, OH.
45820	Topeka, KS.
46220	Tuscaloosa, AL.
46340	Tyler, TX.
47260	Virginia Beach-Norfolk-Newport News, VA-NC.
48620	Wichita, KS.

B. Episode Definition for the Comprehensive Care for Joint Replacement (CCJR) Model

1. Background

Coordinated Quality Care-Joint Replacement is an episode payment model, focused on incentivizing health care providers to improve the efficiency and quality of care for an episode of care as experienced by a Medicare beneficiary by bundling payment for services furnished to the beneficiary for an episode of care for a specific clinical condition over a defined period of time. Key policies of such a model include the definition of episodes of care. Episodes of care have two significant dimensions—(1) a clinical dimension that describes what clinical conditions and associated services comprise the episode; and (2) a time dimension that describes the beginning, middle, and end of an episode. We present our proposals for these two dimensions of CCJR episodes in this section.

2. Clinical Dimension of Episodes of Care

a. Definition of the Clinical Conditions Included in the Episode

As discussed previously in section I.A. of this proposed rule, we have identified LEJR episodes, primarily hip and knee replacements, as the focus of this model. We believe that a straightforward approach for hospitals and other providers to identify Medicare beneficiaries in this payment model is important for the care redesign that is required for model success, as well as to operationalize the proposed payment and other model policies.

The vast majority of lower extremity joint replacements (LEJRs) are furnished in the inpatient hospital setting, with a small fraction of partial knee replacements occurring in the hospital outpatient department (HOPD) setting. Most of the Current Procedural Terminology (CPT) codes that physicians report for LEJR are on the hospital Outpatient Prospective Payment System (OPPS) inpatient only list. The CY 2015 OPPS inpatient only list is Addendum E of the CY 2015 Hospital Outpatient Prospective Payment–Final Rule with Comment Period, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1613-FC.html*. Thus, under current FFS payment policy, Medicare pays hospitals for the facility services required for LEJR only when those procedures are furnished in the inpatient hospital setting. Therefore, we believe an episode payment model most appropriately focuses around an inpatient hospitalization for these major surgical procedures, as there is little opportunity for shifting the procedures under this model to the outpatient setting.

We note further that LEJRs are paid for under the IPPS through the following two Medicare Severity-Diagnosis Related Groups (MS–DRGs):

- MS–DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)).
- MS–DRG 470 (Major joint replacement or reattachment of lower extremity without MCC).

Multiple ICD–9–CM procedure codes that describe LEJR procedures and other less common lower extremity procedures group to these MS–DRGs, with their percentage distribution within the IPPS MS–DRGs 469 and 470 for the past 4 years outlined in Table 4.

TABLE 4—DISTRIBUTION OF HOSPITAL CLAIMS FOR PROCEDURE CODES MAPPING TO MS–DRGS 469 AND 470

ICD–9–CM procedure code	Code descriptor	FY 2014 %	FY 2013 %	FY 2012 %	FY 2011 %
81.54	Total knee replacement	57	58	58	58
81.51	Total hip replacement	30	29	29	28
81.52	Partial hip replacement	12	13	13	14
81.56	Total ankle replacement	0	0	0	0
00.85	Resurfacing hip, total, acetabulum and femoral head	0	0	0	0
00.86	Resurfacing hip, partial, femoral head	0	0	0	0
00.87	Resurfacing hip, partial, acetabulum	0	0	0	0
84.27	Lower leg or ankle reattachment	0	N/A	N/A	N/A
84.28	Thigh reattachment	N/A	N/A	N/A	0

Note: Percentages or claim counts with "N/A" had no claims. percentages of 0% represent less than 0.5% of total claims.

Additionally, we note that there are various types of claims-based information available to CMS, hospitals, and other providers, that could be used to identify beneficiaries in the model who receive LEJRs, including the MS–DRGs for the acute care hospitalization for the procedure, the ICD–9–CM procedure code on the hospital claim, or the CPT code(s) reported by the orthopedic surgeon who furnishes the surgical procedure. While we could utilize ICD–9–CM procedure codes or CPT codes to identify beneficiaries included in the model, over 85 percent of procedures that group to MS–DRGs 469 and 470 are hip or knee replacements. Additionally, the hospitals that would be participating in this model receive payment under the IPPS, which is not determined by CPT codes and is based on clinical conditions and procedures that group to MS–DRGs. Finally, our review of the other low volume procedures that group to these same MS–DRGs, aside from total or partial hip and knee replacements, does not suggest that there is significant clinical or financial heterogeneity within these two MS–DRGs such that we would need to define care for included beneficiaries by ICD–9–CM procedure codes.

Therefore, we propose that an episode of care in the CCJR model is triggered by an admission to an acute care hospital stay (hereinafter ''the anchor hospitalization'') paid under MS–DRG 469 or 470 under the IPPS during the model performance period. This approach offers operational simplicity for providers and CMS, and is consistent with the approach taken by the BPCI initiative to identify beneficiaries whose care is included in the LEJR episode for that model. We seek public comments on this proposal to define the clinical conditions that are the target of CCJR.

b. Definition of Related Services Included in the Episode

For purposes of this model, as in BPCI, given the frequent comorbidities experienced by Medicare beneficiaries and the generally elective nature of LEJR, we are interested in testing inclusive episodes to incentivize comprehensive, coordinated patient-centered care for the beneficiary throughout the episode. We propose to exclude only those Medicare items and services furnished during the episode that are unrelated to LEJR procedures based on clinical justification. During our experience with BPCI implementation, we reviewed a number of narrow episode definitions for LEJR episodes that were recommended by BPCI participants and other interested parties during the design phase for this project. We concluded that these narrow definitions commonly exclude many services that may be linked to the LEJR, as LEJR beneficiaries, on average, are at higher risk for more clinical problems than Medicare beneficiaries who have not recently undergone such procedures.

Therefore, we propose that all CCJR episodes, beginning with the admission for the anchor hospitalization under MS–DRG 469 or 470 through the end of the proposed episode, include all items and services paid under Medicare Part A or Part B with the exception of certain exclusions as proposed in this section that are excluded because they are unrelated to the episode. The items and services ultimately included in the episode after the exclusions are applied are called related items and services. As proposed in sections III.C.4 and III.C.6 of this proposed rule, Medicare spending for related items and services would be included in the historical data used to set target prices, as well as in the calculation of actual episode spending that would be compared against the target price to assess the performance of participant hospitals. In contrast, Medicare spending for unrelated items and services (excluded from the episode definition) would not be included in the historical data used to set target prices or in the calculation of actual episode spending.

Related items and services included in CCJR episodes would be the following items and services paid under Medicare Part A or Part B, after the exclusions are applied:

- Physicians' services.
- Inpatient hospital services (including readmissions), with certain exceptions proposed later in this section.
- Inpatient psychiatric facility (IPF) services.
- LTCH services.
- IRF services.
- SNF services.
- HHA services.
- Hospital outpatient services.
- Independent outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment (DME).
- Part B drugs.
- Hospice.

We note that under our proposed definition of related services included in the episode, the episode could include certain per-member-per-month model payments, as discussed in section III.C of this proposed rule.

We propose to exclude from CCJR drugs that are paid outside of the MS–DRG, specifically hemophilia clotting factors (§ 412.115), identified through HCPCS code, diagnosis code, and revenue center on IPPS claims. Hemophilia clotting factors, in contrast to other drugs that are administered during an inpatient hospital stay and paid through the MS–DRG, are paid separately by Medicare in recognition that clotting factors are costly and essential to appropriate care for certain beneficiaries. Thus, we believe there are no efficiencies to be gained in the variable use of these high cost drugs when particular beneficiaries receive

LEJR procedures who have significantly different medical needs for clotting factors under an episode payment model, so we propose to exclude these high cost drugs from the actual historical episode expenditure data used to set target prices and from the hospital's episode actual spending that is reconciled to the target price. Similarly, we propose to exclude IPPS new technology add-on payments for drugs, technologies, and services from CCJR episodes, excluding them from both the actual historical episode expenditure data used to set target prices and from the hospital's actual episode spending that is reconciled to the target price. This proposal would apply to both the anchor hospital stay and any related readmissions during the episode. New technology add-on payments are made separately and in addition to the MS–DRG payment under the IPPS for specific new drugs technologies, and services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid otherwise under the MS–DRG system. Medicare pays a marginal cost factor of 50 percent for the costs to hospitals of the new drugs, technologies, or services. We do not believe it would be appropriate for the CCJR model to potentially hamper beneficiaries' access to new technologies that are receiving new technology add-on payments or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward episode actual expenditures. In addition, because new drugs, technologies, or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions, we believe we should exclude IPPS new technology add-on payments from CCJR episodes.

We followed a number of general principles in determining other proposed excluded services from the CCJR episodes in order to promote coordinated, high-quality, patient-centered care. Based on the broad nature of these episodes, we propose to identify excluded (unrelated) services rather than included (related) services based on the rationale that all Part A and Part B services furnished during the episode are related to the episode, unless they are unrelated based on clinical justification as described in more detail later in this section. In developing our proposals for exclusions for this model, we believe that no Part A services, other than certain excluded hospital readmissions during the episode as described in this section, furnished post-hospital discharge during the episode should be excluded, as post-hospital discharge Part A services are typically intended to be comprehensive in nature. We also believe that no claims for services with diagnosis codes that are directly related to the LEJR procedure itself (for example, loosening of the joint prosthesis) based on clinical judgment, and taking into consideration coding guidelines, should be excluded. Furthermore, we believe that no claims for diagnoses that are related to the quality and safety of care furnished during the episode, especially the anchor hospitalization under MS–DRG 469 or 470, should be excluded, such as direct complications of post-surgical care during the anchor hospitalization. Examples of diagnoses that would not be excluded on this basis include surgical site infection and venous thromboembolism. Finally, we believe that no claims for services for diagnoses that are related to preexisting chronic conditions such as diabetes, which may be affected by care furnished during the episode, should be excluded. However, severe exacerbations of chronic conditions (for example, some surgical readmissions) that are unlikely to be affected by care furnished during the episode should be excluded; thus, when a beneficiary is admitted to the hospital during the episode for these circumstances, we would not consider it to be a related readmission for purposes of CCJR. We also believe that services for clinical conditions that represent acute clinical conditions not arising from an existing chronic clinical condition or complication of LEJR surgery occurring during an episode of care, which would not be covered by the previous principles about included services, should be excluded.

To operationalize these principles for CCJR, we propose to exclude unrelated inpatient hospital admissions during the episode by identifying MS–DRGs for exclusion. We propose to exclude unrelated Part B services based on the ICD–9–CM diagnosis code (or their ICD–10–CM equivalents when ICD–10–CM codes are implemented) that is the principal diagnosis code reported on claims for services furnished during the episode. More specifically, we propose to exclude specific inpatient hospital admissions and services consistent with the LEJR episode definition (also triggered by MS–DRGs 469 and 470) that is currently used in BPCI Model 2. We note that the list of exclusions was initially developed over 2 years ago for BPCI through a collaborative effort of CMS staff, including physicians from medical and surgical specialties, coding experts, claims processing experts, and health services researchers. The list has been shared with thousands of entities and individuals participating in one or more phases of BPCI, and has undergone refinement over that time in response to stakeholder input about specific diagnoses or MS–DRGs for exclusion, resulting in only minimal changes over the last 2 years. Thus, the BPCI list of exclusions for LEJR procedures has been vetted broadly in the health care community; refined based on input from a wide variety of providers, researchers and other stakeholders; and successfully operationalized in the BPCI models. We are proposing its use in CCJR based on our confidence related to our several of years of experience that this definition is reasonable and workable for LEJR episodes, for both providers and CMS.

With respect to the proposed inpatient hospital admission exclusions for this model, we propose that all medical MS–DRGS for readmissions be included in CCJR episodes as related services, with the exception of oncology and trauma medical MS–DRGs. We propose that admissions for oncology and trauma medical MS–DRGs be excluded from CCJR episodes. Readmissions for medical MS–DRGs are generally linked to the hospitalization for the LEJR procedure as a complication of the illness that led to the surgery, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of care. We refer readers to section III.D. of this proposed rule for background and discussion of the complication rate measure proposed for CCJR that includes common medical complications resulting from the aforementioned circumstances following LEJR procedures and that may result in related hospital readmissions. For readmissions for medical MS–DRGs, the selection of the primary diagnosis code is not clear-cut, so we generally believe they all should be included, and we strongly believe that providers should focus on comprehensive care for beneficiaries during episodes. We propose to include all disease-related surgical MS–DRGs for readmissions, such as hip/knee revision, in CCJR episodes. We also propose to include readmissions for all body system-related surgical MS–DRGs as they are generally related to complications of the LEJR procedures. An example of a readmission of this type would be for an inferior vena cava filter placement for

treatment of thromboembolic complications of the LEJR. We propose to exclude hospital admissions for chronic disease surgical MS–DRGs, such as prostatectomy (removal of the prostate gland), as they are unrelated to the clinical condition that led to the LEJR nor would they have been precipitated by the LEJR. Finally, we propose that hospital admissions for acute disease surgical MS–DRGs, such as appendectomy, be excluded because they are highly unlikely to be related to, or precipitated by, LEJR procedures and would not be affected by LEJR episode care redesign.

With respect to the LEJR proposed diagnosis code exclusions for Part B services for this model, we propose that ICD–9–CM codes be excluded or included as a category and as identified by code ranges. We propose that disease-related diagnoses, such as osteoarthritis of the hip or knee, are included. We also propose that body system-related diagnoses are included because they relate to complications that may arise from interactions with the health care system. An example of this would be pressure pre-ulcer skin changes. Additionally, we propose that all common symptom diagnoses are included because providers have significant discretion to select these as principal diagnosis codes. We propose that acute disease diagnoses, such as severe head injury, are excluded. Finally, we propose that chronic disease diagnoses be included or excluded based on specific clinical and coding judgment as described previously with respect to the original development of the exclusions for LEJR episodes under BPCI, taking into consideration whether the condition was likely to have been affected by the LEJR procedure and recovery period and whether substantial services were likely to have been provided for the chronic condition during the episode. Thus, chronic kidney disease and cirrhosis would be included in the episode, but glaucoma and chemotherapy would be excluded.

Exclusions from CCJR episodes are based on care for unrelated clinical conditions represented by MS–DRGs for readmissions during the episode and ICD–9 CM codes for Part B services furnished during the episode after discharge from the anchor hospitalization. The complete lists of proposed excluded MS–DRGs for readmissions and proposed excluded ICD–9–CM codes for Part B services is posted on the CMS Web site at *http://innovation.cms.gov/initiatives/ccjr/.*

We note that as CMS moves to implement ICD–10–CM we will make the CCJR exclusions that would map to the final ICD–9–CM exclusions for CCJR available in the ICD–10–CM format as well. We propose that all Part A and B-covered items and services that would not be excluded based on the exclusions list are included in the episode. Furthermore, we propose to update the exclusions list without rulemaking on an annual basis, at a minimum, to reflect annual changes to ICD–CM coding and annual changes to the MS–DRGs under the IPPS, as well as to address any other issues that are brought to our attention by the public throughout the course of the model test.

We would first develop potential exclusions list revisions of MS–DRGs for readmissions and ICD–9 (or ICD–10, as applicable) diagnosis codes for Part B services based on our assessment against the following standards:

- We would not exclude any items or services that are—

++ Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism); and

++ For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

- We would exclude items and services for—

++ Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode; and

++ Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

We would post the potential revised exclusions, which could include additions to or deletions from the exclusions list, to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the exclusions list with posting to the CMS Web site of the final revised exclusions list after our consideration of the public input.

We seek comment on our proposals for identifying excluded readmissions and Part B-covered items and services, as well as our proposed process for updating the exclusions list.

3. Duration of Episodes of Care

a. Beginning the Episode and Beneficiary Care Inclusion Criteria

While we propose to identify LEJR episodes by an acute care hospitalization for MS–DRG 469 and 470, we recognize that the beneficiary's care for an underlying chronic condition, such as osteoarthritis, which ultimately leads to the surgical procedure, typically begins months to years prior to the surgical procedure. Because of the clinical variability leading up to the joint replacement surgery and the challenge of identifying unrelated services given the multiple chronic conditions experienced by many beneficiaries, we do not propose to begin the episode prior to the anchor hospitalization (that is, the admission that results in a discharge under MS–DRG 469 or 470). We believe the opportunities for care redesign and improved efficiency prior to the inpatient hospital stay are limited for an episode payment model of this type that focuses on a surgical procedure and the associated recovery once the decision to pursue surgery has been made, rather than an episode model that focuses on decision-making and management of a clinical condition itself (such as osteoarthritis).

We propose to begin the episode with an inpatient anchor hospitalization for MS–DRG 469 or MS–DRG 470 in accordance with the methodology described. This proposal to begin the episode upon admission for the anchor hospitalization is consistent with LEJR episode initiation under Model 2 of BPCI. While we are not proposing to begin the episode prior to the inpatient hospital admission, we note that our proposed episode definition includes all services that are already included in the IPPS payment based on established Medicare policies, such as diagnostic services (including clinical diagnostic laboratory tests) and nondiagnostic outpatient services related to a beneficiary's hospital admission provided to a beneficiary by the admitting hospital, or by an entity wholly owned or wholly operated by the admitting hospital (or by another entity under arrangements with the admitting hospital), within 3 days prior to and including the date of the beneficiary's admission. For more

information on the 3-Day Payment Window payment policies, see CMS Pub. 100–04, Chapter 3, section 40.3 and Chapter 4, section 10.12.

We propose that the defined population of Medicare beneficiaries whose care will be included in CCJR meet the following criteria upon admission to the anchor hospitalization. We note that these criteria are also consistent with Model 2 of BPCI, as well as most other Innovation Center models that do not target a specific subpopulation of beneficiaries. The LEJR episodes for all beneficiaries in the defined population will be included in CCJR (although certain episodes may be canceled for purposes of determining actual episode payments for reasons discussed later in this proposed rule), and we refer readers to section I.B.8 of this proposed rule for further discussion of beneficiary notification and a beneficiary's ongoing right under CCJR to obtain health services from any individual or organization qualified to participate in the Medicare program.

- The beneficiary is enrolled in Medicare Part A and Part B throughout the duration of the episode.
- The beneficiary's eligibility for Medicare is not on the basis of End Stage Renal Disease.
- The beneficiary must not be enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost-based health maintenance organizations).
- The beneficiary must not be covered under a United Mine Workers of America health plan, which provides healthcare benefits for retired mine workers.
- Medicare must be the primary payer.

Our proposal for inclusion of beneficiaries in CCJR is as broad as feasible, representing all those LEJR episodes for which we believe we have comprehensive historical Medicare payment data that allow us to appropriately include Medicare payment for all related services during the episode in order to set appropriate episode target prices. For beneficiaries whose care we propose to exclude from the model, we are unable to capture or appropriately attribute to the episode the related Medicare payments because of Medicare's payment methodology. For example, if a beneficiary is enrolled in a Medicare Advantage plan, Medicare makes capitated payments (and providers do not submit complete claims data to CMS), so we would not have a way to identify and attribute the portion of those payments related to an LEJR episode. More information on setting bundled payment target prices for episodes under CCJR is available in section III.C.4.b of this proposed rule. Including the broadest feasible array of Medicare beneficiaries' admissions in the model would provide CMS with the most robust information about the effects of this model on expenditures and quality for beneficiaries of the widest variety of ages and comorbidities, and allow the participant hospitals the greatest opportunity to benefit financially from systematic episode care redesign because most Medicare beneficiaries undergoing an LEJR procedure will be included in the model and, therefore, subject to the policies we propose.

We seek comment on our proposal on when to begin the CCJR episode, as well as to identify the care included for beneficiaries.

b. Middle of the Episode

We propose that once the episode begins for a beneficiary whose care is included, the episode continues until the end as described in the next section of this proposed rule, unless the episode is cancelled because the beneficiary no longer meets the same inclusion criteria proposed for the beginning of the episode at any point during the episode. When an episode is cancelled, the services furnished to beneficiaries prior to and following the episode cancellation will continue to be paid by Medicare as usual but we will not calculate actual episode spending that would otherwise under CCJR be reconciled against the target price for the beneficiary's care (see section III.C.6 of this proposed rule). As discussed in section III.C.10.a.(3) of this proposed rule with comment period, waivers of program rules applicable to beneficiaries in CCJR episodes would apply to the care of beneficiaries who are in CCJR episodes at the time when the waiver is used to bill for a service that is furnished to the beneficiary, even if the episode is later cancelled.

We believe it would be appropriate to cancel the episode when a beneficiary's status changes during the episode such that they no longer meet the criteria for inclusion because the episode target price reflects full payment for the episode, yet we would not have full Medicare episode payment data for the beneficiary to reconcile against the target price.

In addition, we propose that the following circumstances would also cancel the episode:

- The beneficiary is readmitted to an acute care hospital during the episode and discharged under MS–DRG 469 or 470 (in this case, the first episode would be cancelled and a new LEJR episode would begin for the beneficiary).
- The beneficiary dies during the anchor hospitalization.
- The beneficiary initiates an LEJR episode under BPCI Models 1, 2, 3 or 4.

In the case of beneficiary death during the anchor hospitalization, we believe it would be appropriate to cancel the episode as there are limited efficiencies that could be expected during the anchor hospital stay itself. In the case of beneficiary readmission during the first CCJR episode for another LEJR (typically a planned staged second procedure), we do not believe it would be appropriate to include two episodes in the model with some time periods overlapping, as that could result in attribution of the Medicare payment for 2 periods of PAC to a single procedure.

We seek comment on our proposals to cancel episodes once they have begun but prior to their end.

c. End of the Episode

LEJR procedures are typically major inpatient surgical procedures with significant associated morbidity and a prolonged recovery period that often is marked by significant PAC needs, potential complications of surgery, and more intense management of chronic conditions that may be destabilized by the surgery. In light of the course of recovery from LEJRs for Medicare beneficiaries, we propose that an episode in the CCJR model end 90 days after discharge from the acute care hospital in which the anchor hospitalization (for MS–DRG 469 or 470) took place. Hereinafter, we refer to the proposed CCJR model episode duration as the ''90-day post-discharge'' episode. To the extent that a Medicare payment for included services spans a period of care that extends beyond the episode duration, these payments would be prorated so that only the portion attributable to care during the fixed duration of the episode is attributed to the episode spending.

We note for the vast majority of beneficiaries undergoing a hip or knee joint replacement, a 90-day post-discharge episode duration encompasses the full transition from acute care and PAC to recovery and return to activities. We believe the 90-day post-discharge episode duration encourages acute care hospitals, physicians, and PAC providers to promote coordinated, quality care as the patient transitions from the inpatient to outpatient settings and the community.

In proposing the 90-day post-discharge duration for LEJR episodes in CCJR, we took into consideration the literature regarding the clinical

experiences of patients who have undergone THA or TKA procedures. In 2007–2008, the 30-day all-cause readmission rate for primary THA among Medicare beneficiaries was 8.5 percent, while the 90-day all-cause readmission rate was 11.9 percent, indicating that while the rate of readmission begins to taper after 30 days, readmissions continue to accrue throughout this 90 day window.[6] In single center studies, Schairer et al found unplanned 30-day hospital readmission rates were 3.5 percent and 3.4 percent and unplanned 90-day hospital admission rates were 4.5 percent and 6 percent for primary THA and TKA, respectively, demonstrating that the risk of readmission remains significantly elevated from 30 through 90 days post-hospital discharge.[7] [8] Further exploring the reasons for unplanned admission for TKAs within 90 days of a knee replacement procedure, Schairer et al found that 75 percent were caused by surgical causes such as arthrofibrosis and surgical site infection. Additional information on the common reasons for hospital readmission following TKA or THA can be obtained from The American College of Surgeons National Surgical Quality Improvement Program.[9] These data identified the top ten reasons for readmission within 30 days of a hip or knee arthroplasty:

- Surgical site infections (18.8 percent).
- Prosthesis issues (7.5 percent).
- Venous thromboembolism (6.3 percent).
- Bleeding (6.3 percent).
- Orthopedic related (5.1 percent).
- Pulmonary (3.2 percent).
- Cardiac (2.4 percent).
- CNS or CVA (2.4 percent).
- Ileus or Obstruction (2.3 percent).
- Sepsis (2.1 percent).

In addition, the authors concluded that ''readmissions after surgery were associated with new post-discharge complications related to the procedure and not exacerbation of prior index hospitalization complications, suggesting that readmissions after surgery are a measure of post-discharge complications.'' Finally, with regard to the potential for readmission for joint replacement revision within a 90-day post-discharge episode, in a twelve-year study on Medicare patients conducted by Katz, et al., the risk of revision after THA remained elevated at approximately 2 percent per year for the first eighteen months and then 1 percent per year for the remainder of the follow-up period.[10] This study suggests that a longer episode, as opposed to a shorter episode, is more likely to simulate the increased risk of revision LEJR patients face.

In order to address the complication rates associated with elective primary total hip or knee arthroplasty, we developed an administrative claims-based measure (for a detailed description of the measure see section III.D of this proposed rule). During the development of the Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA or TKA or both, complications of elective primary total hip or knee replacement were identified to occur within specific timeframes.[11] For example, analyses done during the development of the measure as well as Technical Expert Panel opinion found that—(1) mechanical complications and periprosthetic joint infection/wound infection are still attributable to the procedure for the 90 days following admission for surgery; (2) death, surgical site bleeding, and pulmonary embolism are still likely attributable to the hospital performing the procedure for up to 30 days; and (3) medical complications of acute myocardial infarction (AMI), pneumonia, and sepsis/septicemia/shock are more likely to be attributable to the procedure for up to 7 days.

Other factors further supporting a 90-day post-discharge episode duration are the elevated risk of readmission throughout this time period, as well as the fact that treatment for pneumonia is considered by American Thoracic Society guidelines to be ''health care-associated'' if it occurs up to 90 days following an acute care hospitalization of at least 2 days.[12] According to the American Academy of Orthopedic Surgeons, patients undergoing total hip replacement should be able to resume most normal light activities of daily living within 3 to 6 weeks following surgery.[13] In a small randomized controlled trial of two approaches to hip arthroplasty, average time to ambulation without any assistive device was 22–28 days.[14] According to a 2011 systematic review of studies evaluating physical functioning following THA, patients have recovered to about 80 percent of the levels of controls by 8 months after surgery.[15]

We also refer readers to a study by the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S Department of Health and Human Services that assessed the mean payments for acute care, PAC, and physician services grouped in the MS–DRG 470.[16] In this study, CMS payment for services following an MS–DRG 470 hospitalization were concentrated within the first 30 days following discharge, with plateauing of payments between 60- or 90-days post-discharge.

[6] Cram P, Lu X, Kates SL, Singh JA, Li Y, Wolf BR. Total Knee Arthroplasty Volume, Utilization, and Outcomes Among Medicare Beneficiaries, 1 991–2010. JAMA. 2012;308(12):1227–1236. doi:10.1001/2012.jama.11153.

[7] Schairer WW, et al. Causes and frequency of unplanned hospital readmission after total hip arthroplasty. Clin Orthop Relat Res. 2014 Feb;472(2):464–70. doi: 1 0.1007/s11999–013–3121–5.

[8] Schairer WW, et al. What are the rates and causes of hospital readmission after total knee arthroplasty? Clin Orthop Relat Res. 2014 Jan;472(1):181–7. doi: 1 0.1007/s11999–013–3030–7.

[9] Merkow RP, Ju MH, Chung JW, et al. Underlying Reasons Associated With Hospital Readmission Following Surgery in the United States. JAMA. 2015;313(5):483–495. doi:10.1001/jama.2014.18614.

[10] Katz JN, et al. Twelve-Year Risk of Revision After Primary Total Hip Replacement in the U.S. Medicare Population. J Bone Joint Surg Am. 2012 Oct 1 7; 94(20): 1 825–1832. doi: 1 0.2106/JBJS.K.00569

[11] Hospital Quality Initiatives. Measure Methodology. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* See Hip and Knee Arthroplasty Complications zip file under downloads. Accessed on April 10, 2015.

[12] Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. American Thoracic Society, Infectious Diseases Society of America. Am J Respir Crit Care Med. 2005;171(4):388.

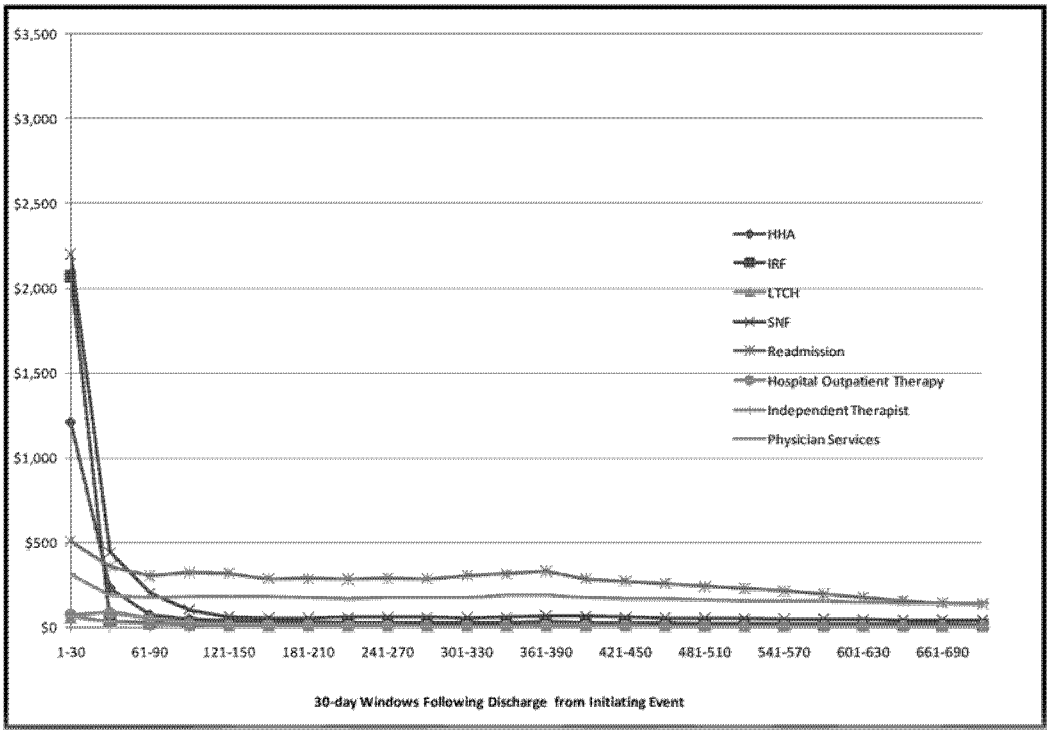
[13] *http://orthoinfo.aaos.org/topic.cfm?topic=A00377.*

[14] Taunton MJ, et al. Direct Anterior Total Hip Arthroplasty Yields More Rapid Voluntary Cessation of All Walking Aids: A Prospective, Randomized Clinical Trial The Journal of Arthroplasty. Volume 29, Issue 9, Supplement, September 2014, Pages 169–172.

[15] Vissers MM, et al. Recovery of Physical Functioning After Total Hip Arthroplasty: Systematic Review and Meta-Analysis of the Literature. Physical Therapy May 2011 vol. 91 no. 5 615–629.

[16] Post-Acute Care Episodes Expanded Analytic File. Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. April 2011.

Mean Acute, PAC, and Physician Payments Per PAC User Following Discharge From an Acute Initiating Event, by Type of Claim, MS-DRG 470, "Major Joint Replacement or Reattachment of Lower Extremity w/o MCC"



Note: All initiating events occurred in 2006. Twenty-four 30-day windows were constructed following discharge from the initiating event to follow service use for 2 years.

Source: RTI analysis of 2006, 2007, and 2008 Medicare claims (M3MM181).

Finally, payment and length of stay analyses found the average length of stay in PAC during a 90-day post-discharge episode for MS–DRG 470 to be 47.3 days, indicating that a longer period post-discharge of 90 days is reasonable as a proposal to end the episode of care.[17] We note that these analyses did not include any time between hospital discharge and the start of PAC.

TABLE 5—COST AND LENGTH OF STAY STATISTICS FOR MS–DRG 470 FOR VARIOUS EPISODE DURATIONS

Statistics for DRG 470 (2006 data)	30-day episode	60-day episode	90-day episode
Mean Medicare spending per hospital discharge (acute+PAC+physician)	$18,838	$20,343	$21,125
Mean payment for anchor hospitalization	10,463	10,463	10,463
Mean payment for PAC	6,835	8,339	9,122
Mean payment for physicians (during anchor hospitalization)	1,540	1,540	1,540
Mean payment for readmission (includes all PAC users, even if no readmission occurs during the episode).	550	929	1,242
Mean length of stay (LOS) for PAC	25.5 days	39.6 days	47.3 days

Note: Data are per PAC user (88% of beneficiaries hospitalized under MS–DRG 470 are discharged to PAC). PAC users are defined as beneficiaries discharged to SNF, IRF, or LTCH within 5 days of discharge from the index acute hospitalization, or discharged to HHA or hospital outpatient therapy within 14 days of discharge from the index acute hospitalization. Mean LOS for PAC does not include any gap between hospital discharge date and start of PAC.

Other tests of bundled payment models for hip and knee replacement have used 90-day post-discharge episodes.[18] We also note that despite BPCI Model 2 allowing participants a choice between 30-, 60-, or 90-day post-discharge episodes, over 86 percent of participants have chosen the 90-day post-discharge episode duration for the LEJR episode. Further, a 90-day post-discharge episode duration aligns with the 90-day global period included in the Medicare Physician Fee Schedule payment for the surgical procedure.

We also considered proposing a 60-day post-discharge episode duration, but the full transition of care following LEJR would exceed this window for some beneficiaries, especially those who are discharged to an institutional post-acute provider initially and then

[17] Analysis of Post Acute Care Episode Definitions File. *http://innovation.cms.gov/initiatives/bundled-payments/learning-area.html.*

[18] -Ridgely MS, et al. Bundled Payment Fails To Gain A Foothold In California: The Experience Of The IHA Bundled Payment Demonstration. Health Affairs, 33, no.8 (2014):1345–1352.

transition to home health or outpatient therapy services for continued rehabilitation. According to a report from ASPE on Medicare beneficiaries receiving PAC following major joint replacement in 2006, 13 percent first receive SNF services and then receive HHA services—with a total mean episode duration of 56.8 days.[19] An additional 9.2 percent receive HHA services first and then receive outpatient therapy services—with a total mean episode duration of 78.7 days. Finally, 6.7 percent receive IRF services first and then HHA services (total mean length of stay 55.3 days), and 4.8 percent receive SNF services first and then outpatient therapy services (total mean length of stay 71.5 days). The remainder only receives one type of PAC.

Therefore, in order to be inclusive of most possible durations of recovery, and services furnished to reach recovery, we propose the 90-day post-discharge episode duration for CCJR. We believe that beneficiaries will benefit from aggressive management and care coordination throughout this episode duration, and hospitals will have opportunities under CCJR to achieve efficiencies from care redesign during the 90-day post-discharge episode period.

We seek comment on our proposal to end the episode 90 days after the date of discharge from the anchor hospitalization, as well as on the alternative we considered of ending the CCJR episode 60 days after the date of discharge.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the new proposed Part 510.

C. Proposed Methodology for Setting Episode Prices and Paying Model Participants under the CCJR Model

1. Background

As described in section II.B of this proposed rule, we propose to use the CCJR episode payment model to incentivize participant hospitals to work with other health care providers to improve quality of care for Medicare beneficiaries undergoing LEJR procedures and post-operative recovery, while enhancing the efficiency with which that care is provided. We propose to apply this incentive by paying participant hospitals or holding them responsible for repaying Medicare based on their CCJR episode quality and Medicare expenditure performance. The following sections describe our proposals for—

- How CCJR episodes would be attributed to a participant hospital;
- How the reconciliation of Medicare expenditures based on actual episode spending in relation to the target price would be structured and operationalized;
- How Medicare actual episode payments under existing payment systems would be compared against episode target prices;
- How hospital quality of care for CCJR episodes would be compared against quality thresholds Medicare establishes under this model;
- How payments to or repayment amounts from participant hospitals would be determined so that, on average, the episode target prices are paid by Medicare for CCJR episodes; and
- What protections from excessive risk due to high payment cases would be in place for participant hospitals.

2. Performance Years, Retrospective Episode Payment, and Two-sided Risk Model

a. Performance Period

We propose that the CCJR model would have 5 performance years. The performance years would align with calendar years, beginning January 1, 2016. Table 6 includes details on which episodes would be included in each of the 5 performance years.

TABLE 6—PERFORMANCE YEARS FOR CCJR MODEL

Performance year	Calendar year	Episodes included in performance year
1	2016	Episodes that start on or after January 1, 2016, and end on or before December 31, 2016.
2	2017	Episodes that end between January 1, 2017, and December 31, 2017, inclusive.
3	2018	Episodes that end between January 1, 2018, and December 31, 2018, inclusive.
4	2019	Episodes that end between January 1, 2019, and December 31, 2019, inclusive.
5	2020	Episodes that end between January 1, 2020, and December 31, 2020, inclusive.

All episodes tested in this model will begin on or after January 1, 2016 and end on or before December 31, 2020. We note that this definition results in performance year 1 being shorter than the later performance years in terms of the length of time over which an anchor hospitalization could occur under the model. We also note that some episodes that begin in a given calendar year may be captured in the following performance year due to the episodes ending after December 31st (for example, episode beginning in December 2016 and ending in March 2017 would be part of performance year 2). We believe 5 years would be sufficient time to test the CCJR model and gather sufficient data to evaluate whether it improves the efficiency and quality of care for an LEJR episode of care. Having fewer than 5 performance years may not provide sufficient time or data for evaluation. The 5-year performance period is consistent with the performance period used for other CMMI models (for example, the Pioneer Accountable Care Organization (ACO) Model).

b. Proposed Retrospective Payment Methodology

As described in section III.B of this proposed rule, we propose that an episode in the CCJR model begins with the admission for an anchor hospitalization and ends 90 days post-discharge from the anchor hospitalization, including all related services covered under Medicare Parts A and B during this timeframe, with limited exclusions and adjustments, as described in sections III.B, III.C.3, and III.C.7 of this proposed rule. The

[19] Examining Post Acute Care Relationships in an Integrated Hospital. Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. February 2009.

episodes would be attributed to the participant hospital where the anchor hospitalization occurred.

We propose to apply the CCJR episode payment methodology retrospectively. Under this proposal, all providers and suppliers caring for Medicare beneficiaries in CCJR episodes would continue to bill and be paid as usual under the applicable Medicare payment system. After the completion of a CCJR performance year, Medicare claims for services furnished to beneficiaries in that year's non-cancelled episodes would be grouped into episodes and aggregated, and participant hospitals' CCJR episode quality and actual payment performance would be assessed and compared against episode quality thresholds and target prices, as described in sections III.C.5 and III.C.4 of this proposed rule, respectively. After the participant hospitals' actual episode performance in quality and spending are compared against the aforementioned episode quality thresholds and target prices, we would determine if Medicare would make a payment to the hospital (reconciliation payments), or if the hospital owes money to Medicare (resulting in Medicare repayment). The possibility for hospitals to receive reconciliation payments or be subject to repayment (note: participant hospitals would not be subject to repayment for performance year 1) is further discussed in section III.C.2.c. of this proposed rule.

We considered an alternative option of paying for episodes prospectively by paying one lump sum amount to the hospital for the expected costs of the 90-day episode. However, we believe such an option would be challenging to implement at this time given the payment infrastructure changes for both hospitals and Medicare that would need to be developed to pay and manage prospective CCJR episode payments. We note that a retrospective episode payment approach is currently being utilized under BPCI Model 2. We believe that a retrospective payment approach can accomplish the objective of testing episode payment in a broad group of hospitals, including financial incentives to streamline care delivery around that episode, without requiring core billing and payment changes by providers and suppliers, which would create substantial administrative burden. However, we seek comment on potential ways to implement a prospective payment approach for CCJR in future performance years of the model.

c. Proposed Two-Sided Risk Model

We propose to establish a two-sided risk model for hospitals participating in the CCJR model. We propose to provide episode reconciliation payments to hospitals that meet or exceed quality performance thresholds and achieve cost efficiencies relative to CCJR target prices established for them, as defined later in sections III.C.4 and III.C.5 of this proposed rule. Similarly, we propose to hold hospitals responsible for repaying Medicare when actual episode payments exceed their CCJR target prices in each of performance years 2 through 5, subject to certain proposed limitations discussed in section III.C.8 of this proposed rule. Target prices would be established for each participant hospital for each performance year.

We propose that hospitals will be eligible to receive reconciliation payments from Medicare based on their quality and actual episode spending performance under the CCJR model in each of CCJR performance years 1 through 5. Additionally, we propose to phase in the responsibility for hospital repayment of episode actual spending if episode actual spending exceeds their target price starting in performance year 2 and continuing through performance year 5. Under this proposal in performance year 1, participant hospitals would not be required to pay Medicare back if episode actual spending is greater than the target price.

We considered an episode payment structure in which, for all 5 performance years of the model, participant hospitals would qualify for reconciliation payments if episode actual spending was less than the episode target price, but would not be required to make repayments to Medicare if episode actual spending was greater than the episode target price. However, we believe not holding hospitals responsible for repaying excess episode spending would reduce the incentives for hospitals to improve quality and efficiency. We also considered starting the CCJR payment model with hospital responsibility for repaying excess episode spending in performance year 1 to more strongly align participant hospital incentives with care quality and efficiency. However, we believe hospitals may need to make infrastructure, care coordination and delivery, and financial preparations for the CCJR episode model, and that those changes can take several months or longer to implement. With this consideration in mind, we propose to begin hospitals' responsibility for repayment of excess episode spending beginning in performance year 2 to afford hospitals time to prepare, while still beginning some incentives earlier (that is, reconciliation payments in year 1) to improve quality and efficiency of care for Medicare beneficiaries. We solicit comment on the proposed incentive structure for CCJR.

In an effort to further ensure hospital readiness to assume responsibility for circumstances that could lead to a hospital repaying to Medicare actual episode payments that exceed the episode target price, we propose to begin to phase in this responsibility for performance year 2, with full responsibility for excess episode spending (as proposed in this rule) applied for performance year 3 through performance year 5. To carry out this ''phase in'' approach, we propose during the first year of any hospital financial responsibility for repayment (performance year 2) to set an episode target price that partly mitigates the amount that hospitals would be required to repay (see section III.C.4.b of this proposed rule), as well as more greatly limits (as compared to performance years 3 through 5) the maximum amount a hospital would be required to repay Medicare across all of its episodes (see section III.C.8 of this proposed rule).

3. Adjustments to Payments Included in Episode

Medicare payments during the model's performance year for Parts A and B claims for services included in the episode definition, as discussed in section III.B of this proposed rule, would be summed together for each non-cancelled CCJR episode that occurred to create the actual episode payment amount. We propose three adjustments to this general approach for—(1) special payment provisions under existing Medicare payment systems; (2) payment for services that straddle the end of the episode; and (3) high payment episodes. We note there would be further adjustments to account for overlaps with other Innovation Center models and CMS programs; we refer readers to section III.C.7 of this proposed rule.

We do not propose to adjust hospital-specific or regional components of target prices for any Medicare repayment or reconciliation payments made under the CCJR model; CCJR repayment and reconciliation payments would be not be included per the proposed episode definition in section III.B of this proposed rule. Including reconciliation payments and Medicare repayments in target price calculations would perpetuate the initial set of target prices

once CCJR performance years are captured in the 3- historical-years of data used to set target prices, as proposed in section III.C.4. of this proposed rule, beginning with performance year 3 when performance year 1 would be part of the 3-historical-years. Including any prior performance years' reconciliations or repayments in target price calculations would approximately have the effect (excluding impact of the proposed adjustments for high payment episodes (see section III.C.3.c. of this proposed rule) and proposed limits or adjustments to hospital financial responsibility (see section III.C.8. of this proposed rule)) of Medicare paying hospitals the target price, regardless of whether the hospital went below, above, or met the target price in the prior performance years before accounting for the reconciliation payments or repayments. We intend for target prices to be based on historical patterns of service actually provided, so we do not propose to include reconciliation payments or repayments for prior performance years in target price calculations.

a. Proposed Treatment of Special Payment Provisions Under Existing Medicare Payment Systems

Many of the existing Medicare payment systems have special payment provisions that have been created by regulation or statute to improve quality and efficiency in service delivery. IPPS hospitals are subject to incentives under the HRRP, the Hospital Value-Based Purchasing (HVBP) Program, the Hospital-Acquired Condition (HAC) Reduction Program, and the Hospital Inpatient Quality Reporting Program (HIQR) and Outpatient Quality Reporting Program (OQR). IPPS hospitals and CAHs are subject to the Medicare EHR Incentive Program. Additionally, the majority of IPPS hospitals receive additional payments for Medicare Disproportionate Share Hospital (DSH) and Uncompensated Care, and IPPS teaching hospitals can receive additional payments for Indirect Medical Education (IME). IPPS hospitals that meet a certain requirements related to low volume Medicare discharges and distance from another hospital receive a low volume add-on payment. As mentioned in section III.B.2.b of this proposed rule, acute care hospitals may receive new technology add-on payments to support specific new technologies or services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid otherwise under the MS–DRG system. Also, some IPPS hospitals qualify to be sole community hospitals (SCHs) or Medicare-dependent hospitals (MDHs), and they may receive enhanced payments based on cost-based hospital-specific rates for services; whether a SCH or MDH receives enhanced payments may vary year to year, in accordance with §§ 419.43(g) and 412.108(g), respectively.

Medicare payments to providers of post-acute services, including IRFs, SNFs, IPFs, HHAs, LTCHs, and hospice facilities, are conditioned, in part, on whether the provider satisfactorily reports certain specified data to CMS: the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP), the Skilled Nursing Facility Quality Reporting Program (SNF QRP), the Inpatient Psychiatric Facility Quality Reporting Program (IPF QRP), the Home Health Quality Reporting Program (HH QRP), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), and the Hospice Quality Reporting Program. Additionally, IRFs located in rural areas receive rural add-on payments, IRFs serving higher proportions of low-income beneficiaries receive increased payments according to their low-income percentage (LIP), and IRFs with teaching programs receive increased payments to reflect their teaching status. SNFs receive higher payments for treating beneficiaries with human immunodeficiency virus (HIV). HHAs located in rural areas also receive rural add-on payments.

Ambulatory Surgical Centers have their own Quality Reporting Program (ASC QRP). Physicians also have a set of special payment provisions based on quality and reporting: the Medicare EHR Incentive Program for Eligible Professionals, the Physician Quality Reporting System (PQRS), and the Physician Value-based Modifier Program.

The intent of the CCJR model is not to replace the various existing incentive programs or add-on payments, but instead to test further episode payment incentives towards improvements in quality and efficiency beyond Medicare's existing policies. Therefore, we propose that the hospital performance and potential reconciliation payment or Medicare repayment be independent of, and not affect, these other special payment provisions.

We propose to exclude the special payment provisions as discussed previously when calculating actual episode payments, setting episode target prices, comparing actual episode payments with target prices, and determining whether a reconciliation payment should be made to the hospital or funds should be repaid by the hospital.

Not excluding these special payment provisions would create incentives that are not aligned with the intent of the CCJR model. Not excluding the quality and reporting-related special payment provisions could create situations where a high-quality or reporting compliant hospital or both receiving incentive payments, or those hospitals that discharge patients to PAC providers that receive incentives for being reporting compliant, may appear to be ''high episode payment'' under CCJR. Conversely, lower quality or hospitals not complying with reporting programs or both that incur payment reduction penalties, or hospitals that discharge to PAC providers that are not reporting compliant, may appear to be ''low episode payment'' under CCJR. Such outcomes would run counter to CCJR's goal of improving quality. Also, not excluding add-on payments for serving more indigent patients, having low Medicare hospital volume, being located in a rural area, supporting greater levels of provider training, choosing to use new technologies, and having a greater proportion of CCJR beneficiaries with HIV from CCJR actual episode payment calculations may inappropriately result in hospitals having worse episode payment performance. Additionally, not excluding enhanced payments for MDHs and SCHs may result in higher or lower target prices just because these hospitals received their enhanced payments in one historical year but not the other, regardless of actual utilization. We believe the proposed approach of excluding special payment provisions would ensure a participant hospital's actual episode payment performance is not artificially improved or worsened because of payment reduction penalties or incentives or enhanced or add-on payments, the effects of which we are not proposing to test with CCJR.

In addition to the various incentive, enhanced, and add on payments, sequestration came into effect for Medicare payments for discharges on or after April 1, 2013, per the Budget Control Act of 2011 and delayed by the American Taxpayer Relief Act of 2012. Sequestration applies a 2 percent reduction to Medicare payment for most Medicare FFS services. Similar to the previously discussed incentive, enhanced, and add-on payments, we intend CCJR to be independent of the introduction and potential future elimination of sequestration. We do not intend to have participant hospitals' episodes appear to be ''low payment''

episodes relative to historical data, for part of which sequestration may not have been in effect, just because of an across-the-board Medicare payment reduction through sequestration. Therefore, we propose to account for the effects of sequestration when calculating actual episode payments, setting episode target prices, comparing actual episode payments with target prices, and determining whether a reconciliation payment should be made to the hospital or hospitals should repay Medicare.

In order to operationalize the exclusion of the various special payment provisions in calculating episode expenditures, we propose to apply the CMS Price (Payment) Standardization Detailed Methodology described on the QualityNet Web site at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.* This pricing standardization approach is the same as used for the HVBP program's Medicare spending per beneficiary metric.

We solicit comment on this proposed approach to treating special payment provisions in the various Medicare payment systems.

b. Proposed Treatment of Payment for Services That Extend Beyond the Episode

As we proposed a fixed 90-day post-discharge episode as discussed in section III.B of this proposed rule, we believe there would be some instances where a service included in the episode begins during the episode but concludes after the end of the episode and for which Medicare makes a single payment under an existing payment system. An example would be a beneficiary in a CCJR episode who is admitted to a SNF for 15 days, beginning on Day 86 post-discharge from the anchor CCJR hospitalization. The first 5 days of the admission would fall within the episode, while the subsequent 10 days would fall outside of the episode.

We propose that, to the extent that a Medicare payment for included episode services spans a period of care that extends beyond the episode, these payments would be prorated so that only the portion attributable to care during the episode is attributed to the episode payment when calculating actual Medicare payment for the episode. For non-IPPS inpatient hospital (for example, CAH) and inpatient PAC (for example, SNF, IRF, LTCH, IPF) services, we propose to prorate payments based on the percentage of actual length of stay (in days) that falls within the episode window. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.C.8.e. of this proposed rule. In the prior example, one-third of the days in the 15-day length of stay would fall within the episode window, so under the proposed approach, one-third of the SNF payment would be included in the episode payment calculation, and the remaining two-thirds (because the entirety of the remaining payments fall within the 30 days after the episode ended) would be included in the post-episode payment calculation.

For HHA services that extend beyond the episode, we propose that the payment proration be based on the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that fall within the CCJR episode. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.C.8.e of this proposed rule. For example, if the patient started receiving services from an HHA on day 86 after discharge from the anchor CCJR hospitalization and the last billable home health service date was 55 days from the start of home health care date, the HHA claim payment amount would be divided by 55 and then multiplied by the days (5) that fell within the CCJR episode. The resulting, prorated HHA claim payment amount would be considered part of the CCJR episode. Services for the prorated HHA service would also span the entirety of the 30 days after the CCJR episode spends, so the result of the following calculation would be included in the 30-day post-episode payment calculation: HHA claim payment amount divided by 55 and then multiplied by 30 days (the number of days in the 30-day post-episode period that fall within the prorated HHA service dates).

There may also be instances where home health services begin prior to the CCJR episode start date, but end during the CCJR episode. In such instances, we would also prorate HHA payments based on the percentage of days that fell within the episode. Because these services end during the CCJR episode, prorated payments for these services would not be included in the 30-day post-episode payment calculation discussed in section III.C.8.e. of this proposed rule. For example, if the patient's start of care date for a home health 60-day claim was February 1, the anchor hospitalization was March 1 through March 4 (with the CCJR episode continuing for 90 days after March 4), and the patient resumed home care on March 5 with the 60-day home health claim ending on April 1 (that is, April 1 was the last billable service date), we would divide the 60-day home health claim payment amount by 60 and then multiply that amount by the days from the CCJR admission through April 1 (32 days) to prorate the HHA payment. This proposed prorating method for HHA claims is consistent with how partial episode payments (PEP) are paid for on home health claims.

For IPPS services that extend beyond the episode (for example, readmissions included in the episode definition), we propose to separately prorate the IPPS claim amount from episode target price and actual episode payment calculations as proposed in section III.C.8 of this proposed rule, called the normal MS–DRG payment amount for purposes of this proposed rule. The normal MS–DRG payment amount would be pro-rated based on the geometric mean length of stay, comparable to the calculation under the IPPS PAC transfer policy at §§ 412.4(f) and as published on an annual basis in Table 5 of the IPPS/LTCH PPS Final Rules. Consistent with the IPPS PAC transfer policy, the first day for a subset of MS–DRGs (indicated in Table 5 of the IPPS/LTCH PPS Final Rules) would be doubly weighted to count as 2 days to account for likely higher hospital costs incurred at the beginning of an admission. If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode. If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode. If the full amount is not allocated to the episode, any remainder amount would be allocated to the 30 day post-episode payment calculation discussed in section III.C.8.e of this proposed rule. The proposed approach for prorating the normal MS–DRG payment amount is consistent with the IPPS transfer per diem methodology.

The following is an example of prorating for IPPS services that extend beyond the episode. If beneficiary has a readmission for MS–DRG 493—lower extremity and humerus procedures except hip, foot, and femur, with complications—into an IPPS hospital on the 89th day after discharge from a CCJR anchor hospitalization, and is subsequently discharged after a length of stay of 5 days, Medicare payment for this readmission would be prorated for inclusion in the episode. Based on Table

5 of the IPPS/LTCH PPS Final Rule for FY 2015, the geometric mean for MS–DRG 493 is 4 days, and this MS–DRG is indicated for double-weighting the first day for proration. This readmission has only 2 days that falls within the episode, which is less than the MS–DRG 493 geometric mean of 4 days. Therefore, the normal MS–DRG payment amount associated with this readmission would be divided by 4 (the geometric mean) and multiplied by 3 (the first day is counted as 2 days, and the second day contributes the third day), and the resulting amount is attributed to the episode. The remainder one-fourth would be captured in the post-episode spending calculation discussed in section III.C.8 of this proposed rule. If the readmission occurred on the 85th day after discharge from the CCJR anchor hospitalization, and the length of stay was 7 days, the normal MS–DRG payment amount for the admission would be included in the episode without proration because length of stay for the readmission falling within the episode (6 days) is greater than or equal to the geometric mean (4 days) for the MS–DRG.

We considered an alternative option of including the full Medicare payment for all services that start during the episode, even if those services did not conclude until after the episode ended, in calculating episode target prices and actual payments. Previous research on bundled payments for episodes of PAC services noted that including the full payment for any claim initiated during the fixed episode period of time will capture continued service use. However, prorating only captures a portion of actual service use (and payments) within the bundle. [20] As discussed in section III.B of this proposed rule, the CCJR model proposes an episode length that extends 90 days post-discharge, and Table 5 in section III.B.3.c. of this proposed rule demonstrates that the average length of stay in PAC during a 90-day episode with a MS–DRG 470 anchor hospitalization is 47.3 days. Therefore, the length of the episode under CCJR (90 days) should be sufficient to capture the vast majority of service use within the episode, even if payments for some services that extend beyond the episode duration are prorated and only partly attributed to the episode.

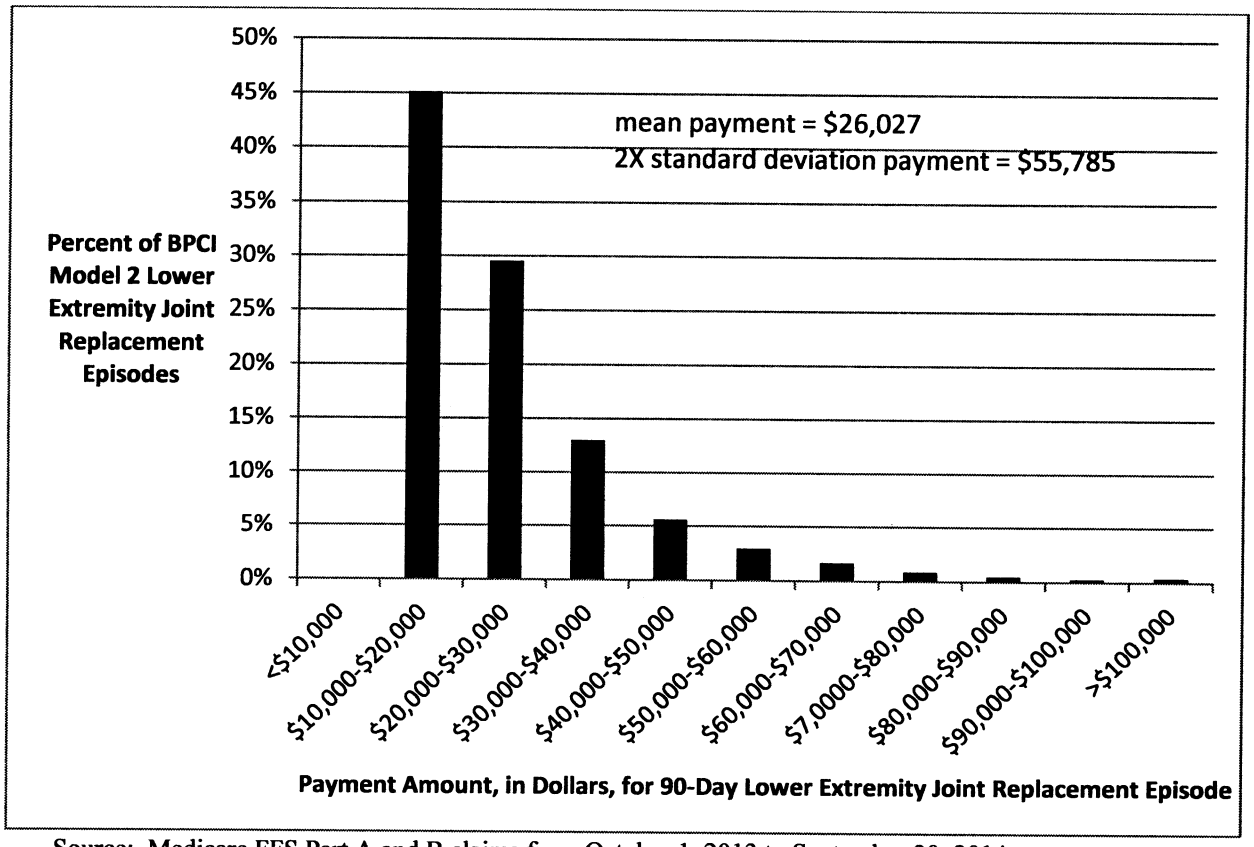
c. Proposed Pricing Adjustment for High Payment Episodes

Given the broad proposed LEJR episode definition and 90-day post-discharge episode duration proposed for CCJR, we want to ensure that hospitals have some protection from the variable repayment risk for especially high payment episodes, where the clinical scenarios for these cases each year may differ significantly and unpredictably. We do not believe the opportunity for a hospital's systematic care redesign of LEJR episodes has significant potential to impact the clinical course of these extremely disparate high payment cases.

The BPCI Model 2 uses a generally similar episode definition as proposed for CCJR and the vast majority of BPCI episodes being tested for LEJR are 90 days in duration following discharge from the anchor hospitalization. Similarly, we believe the BPCI distribution of Model 2 90-day LEJR episode payment amounts as displayed in Figure 1 provides information that is relevant to policy development regarding CCJR episodes.

[20] *http://aspe.hhs.gov/health/reports/09/pacepifinal/report.pdf.*

FIGURE 2: ESTIMATED NATIONAL DISTRIBUTION OF BPCI MODEL 2 LEJR 90-DAY EPISODE PAYMENT AMOUNTS [1 2]



Source: Medicare FFS Part A and B claims from October 1, 2013 to September 30, 2014.
1. Assumes no changes in volume or utilization pattern.
2. Payment reflects wage index removal.

As displayed, the mean episode payment amount is approximately $26,000. Five percent of all episodes are paid at two standard deviations above the mean payment or greater, an amount that is slightly more than 2 times the mean episode payment amount. While these high payment cases are relatively uncommon, we believe that incorporation of the full Medicare payment amount for such high payment episodes in setting the target price and correspondingly in Medicare's aggregate actual episode payment that is compared to the target price for the episode may lead in some cases to excessive hospital responsibility for these episode expenditures. This may be especially true when hospital responsibility for repayment of excess episode spending is introduced in performance year 2. The hospital may have limited ability to moderate spending for these high payment cases. Our proposal to exclude IPPS new technology add-on payments and separate payment for clotting factors for the anchor hospitalization from the episode definition limits excessive financial responsibility under this model of extremely high inpatient payment cases that could result from costly hospital care furnished during the anchor hospitalization. However, we believe an additional pricing adjustment in setting episode target prices and calculating actual episode payments is necessary to mitigate the hospital responsibility for the actual episode payments for high episode payment cases resulting from very high Medicare spending within the episode during the period after discharge from the anchor hospitalization, including for PAC, related hospital readmissions, and other items and services related to the LEJR episode.

Thus, in order to limit the hospital's responsibility for the aforementioned high episode payment cases, we propose to utilize a pricing adjustment for high payment episodes that would incorporate a high payment ceiling at two standard deviations above the mean episode payment amount in calculating the target price and in comparing actual episode payments during the performance year to the target prices.

Specifically, when setting target prices, we would first identify for each anchor MS–DRG in each region (discussed further in section III.C.4 of this proposed rule) the episode payment amount that is two standard deviations above the mean payment in the historical dataset used (discussed further in section III.C.4 of this proposed rule). Any such identified episode would have its payment capped at the MS–DRG anchor and region-specific value that is two standard deviations above the mean, which would be the ceiling for purposes for calculating target prices. We note that the calculation of the historical episode high payment ceiling for each region and MS–DRG anchor would be performed after other steps, including removal of effects of special payment

provisions and others described in section III.C.4.c. of this proposed rule.

When comparing actual episode payments during the performance year to the target prices, episode payments for episodes in the performance year would also be capped at two standard deviations above the mean. The high episode payment ceiling for episodes in a given performance year would be calculated based on MS–DRG anchor-specific episodes in each region. We discuss further how the high episode payment ceiling would be applied when comparing episode payments during the performance year to target prices in section III.C.6. of this proposed rule.

While this approach generally lowers the target price slightly, it provides a basis for reducing the hospital's responsibility for actual episode spending for high episode payment cases during the model performance years. When performing the reconciliation for a given performance year of the model, we would array the actual episode payment amounts for all episodes being tested within a single region, and identify the regional actual episode payment ceiling at two standard deviations above the regional mean actual episode payment amount. If the actual payment for a hospital's episode exceeds this regional ceiling, we would set the actual episode payment amount to equal the regional ceiling amount, rather than the actual amount paid by Medicare, when comparing a hospital's episode spending to the target price. Thus, a hospital would not be responsible for any actual episode payment that is greater than the regional ceiling amount for that performance year. We propose to adopt this policy for all years of the model, regardless of the reconciliation payment opportunity or repayment responsibility in a given performance year, to achieve stability and consistency in the pricing methodology. We believe this proposal provides reasonable protection for hospitals from undue financial responsibility for Medicare episode spending related to the variable and unpredictable course of care of some Medicare beneficiaries in CCJR episodes, while still fully incentivizing increased efficiencies for approximately the 95 percent of episodes for which we estimate actual episode payments to fall below this ceiling.[21] We seek comment on our proposal to apply a pricing adjustment in setting target prices and reconciling actual episode payments for high payment episodes.

4. Proposed Episode Price Setting Methodology

a. Overview

Whether a participant hospital receives reconciliation payments or is made responsible to repay Medicare for the CCJR model will depend on the hospital's quality and actual payment performance relative to episode quality thresholds and target prices. Quality performance and thresholds are further discussed in section III.C.5. of this proposed rule, and the remainder of this section will discuss the proposed approach to establishing target prices.

We propose to establish CCJR target prices for each participant hospital. For episodes beginning in performance years 1, 3, 4, and 5, a participant hospital would have eight target prices, one for each of the following:

- MS–DRG 469 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital successfully submits data on the voluntary patient reported outcome measure proposed in section III.C.5. of this proposed rule.
- MS–DRG 470 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital does not successfully submit data on the voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.

For episodes beginning in performance year 2, a participant hospital would have 16 target prices. These would include the same combinations as for the other 4 performance years, but one set for determining potential reconciliation payments, and the other for determining potential Medicare repayment amounts, as part of the phasing in of two-sided risk discussed later in this section. Further discussion on our proposals for different target prices for MS–DRG 469 versus MS–DRG 470 anchored episodes, for episodes initiated between January 1 and September 30 versus October 1 and December 31, and for participant hospitals that do and do not successfully submit data on the proposed patient-reported outcome measure can be found in sections III.C.4.b and III.C.5. of this proposed rule.

We intend to calculate and communicate episode target prices to participant hospitals prior to the performance period in which they apply (that is, prior to January 1, 2017, for target prices covering episodes initiated between January 1 and September 30, 2017; prior to October 1, 2017 for target prices covering episodes initiated between October 1 and December 31, 2017). We believe prospectively communicating prices to hospitals will help them make any infrastructure, care coordination and delivery, and financial refinements they may deem appropriate to prepare for the new episode target prices.

The proposed approach to setting target prices incorporates the following features:

- Set different target prices for episodes anchored by MS–DRG 469 versus MS–DRG 470 to account for patient and clinical variations that impact hospitals' cost of providing care.
- Use 3 years of historical Medicare payment data grouped into episodes of care according to the episode definition proposed in section III.B. of this proposed rule, hereinafter termed historical CCJR episodes. The specific set of 3- historical-years used would be updated every other performance year.

[21] Medicare FFS Parts A and B claims, CCJR episodes as proposed, between October 1, 2013 and September 30, 2014.

• Apply Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, PFS, etc.) updates to the historical episode data to ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Because different Medicare payment system updates become effective at two different times of the year, we would calculate separate target prices for episodes initiated between January 1 and September 30 versus October 1 and December 31.

• Blend together hospital-specific and regional historical CCJR episode payments, transitioning from primarily provider-specific to completely regional pricing over the course of the 5 performance years, to incentivize both historically efficient and less efficient hospitals to furnish high quality, efficient care in all years of the model. Regions would be defined as each of the nine U.S. Census divisions.

• Normalize for provider-specific wage adjustment variations in Medicare payment systems when combining provider-specific and regional historical CCJR episodes. Wage adjustments would be reapplied when determining hospital-specific target prices.

• Pool together CCJR episodes anchored by MS DRGs 469 and 470 to use a greater historical CCJR episode volume and set more stable prices.

• Apply a discount factor to serve as Medicare's portion of reduced expenditures from the CCJR episode, with any remaining portion of reduced Medicare spending below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred.

Further discussion on each of the individual features can be found in section III.C.4.b. of this proposed rule. In section III.C.4.c. of this proposed rule, we also provide further details on the proposed sequential steps to calculate target prices and how each of the pricing features would fit together.

b. Proposed Pricing Features

(1) Different Target Prices for Episodes Anchored by MS–DRG 469 Versus MS–DRG 470

For each participant hospital we propose to establish different target prices for CCJR episodes initiated by MS–DRG 469 versus MS–DRG 470. MS–DRGs under the IPPS account for some of the clinical and resource variations that exist and that impact hospitals' cost of providing care. Specifically, MS–DRG 469 is defined to identify, and provide hospitals a higher Medicare payment to reflect the higher hospital costs for, hip and knee procedures with major complications or comorbidities. Therefore, we propose to calculate separate target prices for each participant hospital for CCJR episodes with MS–DRG 469 versus MS–DRG 470 anchor hospitalizations.

We considered adjusting the episode target prices by making adjustments or setting different prices based on patient-specific clinical indicators (for example, comorbidities). However, we do not believe there is a sufficiently reliable approach that exists suitable for CCJR episodes beyond MS–DRG-specific pricing, and there is no current standard on the best approach. At the time of developing this proposed rule Tennessee, Ohio, and Arkansas are launching multi-payer (including Medicaid and commercial payers, excluding Medicare) bundles and include hip and knee replacement as an episode [22] [23] [24]. These states' hip and knee episode definitions and payment models are consistent with, though not the same as, the proposed CCJR episode described in this proposed rule. However, each of these three states uses different risk adjustment factors. This variation across states supports our belief that there is currently no standard risk adjustment approach widely accepted throughout the nation that could be used under CCJR, a model that would apply to hospitals across multiple states. Therefore, we are not proposing to make adjustments based on patient-specific clinical indicators.

We also considered making price adjustments based on the participant hospital's average Hierarchical Condition Category (HCC) score for patients with anchor CCJR hospitalizations. The CMS–HCC risk adjustment model quantifies a beneficiary's risk by examining the beneficiary's demographics and historical claims data and predicting the beneficiary's total expenditures for Medicare Parts A and B in an upcoming year. However, the CMS–HCC risk adjustment model's intended use is to pay Medicare Advantage (MA) plans appropriately for their expected relative costs. For example, MA plans that disproportionately enroll the healthy are paid less than they would have been if they had enrolled beneficiaries with the average risk profile, while MA plans that care for the sickest patients are paid proportionately more than if they had enrolled beneficiaries with the average risk profile. The CMS–HCC risk adjustment model is prospective. It uses demographic information (that is, age, sex, Medicare/Medicaid dual eligibility, disability status) and a profile of major medical conditions in the base year to predict Medicare expenditures in the next year.[25] As previously noted, the CMS–HCC risk adjustment model is used to predict total Medicare expenditures in an upcoming year, and may not be appropriate for use in predicting expenditures over a shorter period of time, such as the CCJR episode, and may not be appropriate in instances where its use is focused on lower extremity joint replacements. Therefore, since we have not evaluated the validity of HCC scores for predicting Medicare expenditures for shorter episodes of care or for specifically lower extremity joint replacement beneficiaries, we are not proposing to risk adjust the target prices using HCC scores for the CCJR model.

We also considered making adjustments or setting different prices for different procedures, such as different prices or adjustments for hip versus knee replacements, but we do not believe there would be substantial variation in episode payments for these clinical scenarios to warrant different prices or adjustments. Moreover, Medicare IPPS payments, which account for approximately 50 percent [26] of CCJR episode expenditures, do not differentiate between hip and knee procedures, mitigating procedure-specific variation for the anchor hospitalization. Furthermore, there are no widely accepted clinical guidelines to suggest that PAC intensity would vary significantly between knee and hip replacements. We seek comment on our proposal to price episodes based on the MS–DRG for the anchor hospitalization, without further risk adjustment.

[22] Tennessee Health Care Innovation Initiative. *http://www.tn.gov/HCFA/strategic.shtml.* Accessed on April 16, 2015.

[23] Ohio Governor's Office of Health Transformation. Transforming Payment for a Healthier Ohio, June 8, 2014. *http://www.healthtransformation.ohio.gov/LinkClick.aspx?fileticket=TDZUpL4a-SI%3d&tabid=138,* Accessed on April 16, 2014.

[24] Total Joint Replacement Algorithm Summary, Arkansas Health Care Payment Improvement Initiative, November 2012. *http://www.paymentinitiative.org/referenceMaterials/Documents/TJR%20codes.pdf.* Accessed on April 17, 2015.

[25] Pope, C. et al., Evaluation of the CMS–HCC Risk Adjustment Model Final Report. Report to the Centers for Medicare & Medicaid Services under Contract Number HHSM–500–2005–00029I. RTI International. Research Triangle Park, NC. March, 2011.

[26] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

(2) Three Years of Historical Data

We propose to use 3 years of historical CCJR episodes for calculating CCJR target prices. The set of 3-historical-years used would be updated every other year. Specifically—

- Performance years 1 and 2 would use historical CCJR episodes that started between January 1, 2012 and December 31, 2014;
- Performance years 3 and 4 would use historical episodes that started between January 1, 2014 and December 31, 2016; and
- Performance year 5 would use episodes that started between January 1, 2016 and December 31, 2018. We considered using fewer than 3 years of historical CCJR episode data, but we are concerned with having sufficient historical episode volume to reliably calculate target prices. We also considered not updating the historical episode data for the duration of the model. However, we believe that hospitals' target prices should be regularly updated on a predictable basis to use the most recent available claims data, consistent with the regular updates to Medicare's payment systems, to account for actual changes in utilization. We are not proposing to update the data annually, given the uncertainty in pricing this could introduce for participant hospitals. We also note that the effects of updating hospital-specific data on the target price could be limited as the regional contribution to the target price grows, moving to two-thirds in performance year 3 when the first historical episode data update would occur.

(3) Proposed Trending of Historical Data to the Most Recent Year of the Three

We acknowledge that some payment variation may exist in the 3 years of historical CCJR episodes due to updates to Medicare payment systems (for example, IPPS, OPPS, IRF PPS, SNF PPS, etc.) and national changes in utilization patterns. Episodes in the third of the 3 historical years may have higher average payments than those from the earlier 2 years because of Medicare payment rate increases over the course of the 3 historical years. We do not intend to have CCJR incentives be affected by Medicare payment system rate changes that are beyond hospitals' control. In addition to the changes in Medicare payment systems, average episode payments may change year over year due to national trends reflecting changes in industry-wide practice patterns. For example, readmissions for all patients, including those in CCJR episodes, may decrease nationally due to improved industry-wide surgical protocols that reduce the chance of infections. We do not intend to provide reconciliation payments to (or require repayments from) hospitals for achieving lower (or higher) Medicare expenditures solely because they followed national changes in practice patterns. Instead, we aim to incentivize hospitals based on their hospital-specific inpatient and PAC delivery practices for LEJR episodes.

To mitigate the effects of Medicare payment system updates and changes in national utilization practice patterns within the 3 years of historical CCJR episodes, we propose to follow an approach similar to what is done in BPCI Model 2 and apply a national trend factor to each of the years of historical episode payments. Specifically, we propose to inflate the 2 oldest years of historical episode payments to the most recent year of the 3 historical years described in section III.C.4.b.(2) of this proposed rule. We propose to trend forward each of the 2 oldest years using the changes in the national average CCJR episode payments. We also propose to apply separate national trend factors for episodes anchored by MS–DRG 469 versus MS–DRG 470 to capture any MS–DRG-specific payment system updates or national utilization pattern changes. For example, when using CY 2012–2014 historical episode data to establish target prices for performance years 1 and 2, under our proposal we would calculate a national average MS–DRG 470 anchored episode payment for each of the 3 historical years. The ratio of the national average MS–DRG 470 anchored episode payment for CY 2014 to that of CY 2012 would be used to trend 2012 MS–DRG 470 anchored episode payments to CY 2014. Similarly, the ratio of the national average MS–DRG 470 anchored episode payment for CY 2014 to that of CY 2013 would be used to trend 2013 episode payments to CY 2014. The aforementioned process would be repeated for MS–DRG 469 anchored episodes. Trending CY 2012 and CY 2013 data to CY 2014 would capture updates in Medicare payment systems as well as national utilization pattern changes that may have occurred.

We considered adjusting for regional trends in utilization, as opposed to national trends. However, we believe that any Medicare payment system updates and significant changes in utilization practice patterns would not be region-specific but rather be reflected nationally.

We seek comment on our proposal to nationally trend historical data to the most recent year of the 3 being used to set the target prices.

(4) Update Historical Episode Payments for Ongoing Payment System Updates

We propose to prospectively update historical CCJR episode payments to account for ongoing Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, PFS, etc.) updates to the historical episode data and ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Medicare payment systems do not update their rates at the same time during the year. For example, IPPS, the IRF prospective payment system, and the SNF payment system apply annual updates to their rates effective October 1, while the hospital outpatient prospective payment system (OPPS) and Physician Fee Schedule (PFS) apply annual updates effective January 1. To ensure we appropriately account for the different Medicare payment system updates that go into effect on January 1 and October 1, we propose to update historical episode payments for Medicare payment system updates and calculate target prices separately for episodes initiated between January 1 and September 30 versus October 1 and December 31 of each performance year. The target price in effect as of the day the episode is initiated would be the target price for the whole episode. Note that in performance year 5, the second set of target prices would be for episodes that start and end between and including October 1 and December 31 because the fifth performance period of the CCJR model would end on December 31, 2020. Additionally, a target price for a given performance year may apply to episodes included in another performance year. For example, an episode initiated in November 2016, and ending in February 2017 would have a target price based on the second set of 2016 target prices (for episodes initiated between October 1 and December 31, 2016), and it would be captured in the CY 2017 performance year (performance year 2) because it ended between January 1 and December 31, 2017. We refer readers to section III.C.3.c. of this proposed rule for further discussion on the definition of performance years.

We propose to update historical CCJR episode payments by applying separate Medicare payment system update factors each January 1 and October 1 to each of the following six components of each hospital's historical CCJR payments:

- Inpatient acute.

- Physician.
- IRF.
- SNF.
- HHA.
- Other services.

A different set of update factors would be calculated for January 1 through September 30 versus October 1 through December 31 episodes each performance year. The six update factors for each of the aforementioned components would be hospital-specific and would be weighted by the percent of the Medicare payment for which each of the six components accounts in the hospital's historical episodes. The weighted update factors would be applied to historical hospital-specific average payments to incorporate ongoing Medicare payment system updates. A weighted update factor would be calculated by multiplying the component-specific update factor by the percent of the hospital's historical episode payments the component represents, and summing together the results. For example, let us assume 50 percent of a hospital's historical episode payments were for inpatient acute care services, 15 percent for physician services, 35 percent for SNF services, and 0.0 percent for the remaining services. Let us also assume for this example that the update factors for inpatient acute care services, physician services, and SNF services are 1.02, 1.03, and 1.01, respectively. The weighted update factor in this example would be the following: (0.5 * 1.02) + (0.15 * 1.03) + (0.35 * 1.01) = 1.018. The hospital in this example would have its historical average episode payments multiplied by 1.018 to incorporate ongoing payment system updates. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this proposed rule.

Each of a hospital's six update factors would be based on how inputs have changed in the various Medicare payment systems for the specific hospital. Additional details on these update factors will be discussed later in this section.

Region-specific update factors for each of the aforementioned components and weighted update factors would also be calculated in the same manner as the hospital-specific update factors. Instead of using historical episodes attributed to a specific hospital, region-specific update factors would be based on all historical episodes initiated at any CCJR eligible hospital within the region. For purposes of this rule, CCJR eligible hospitals are defined as hospitals that were paid under IPPS and not a participant in BPCI Model 1 or in the risk-bearing period of Models 2 or 4 for LEJR episodes, regardless of whether or not the MSAs in which the hospitals are located were selected for inclusion in the CCJR model. CCJR episodes initiated at a CCJR eligible hospital will for purposes of this rule be referred to as CCJR episodes attributed to that CCJR eligible hospital.

We considered an alternative option of trending the historical episode payments forward to the upcoming performance year using ratios of national average episode payment amounts, similar to how we propose to trend the 2 oldest historical years forward to the latest historical year for historical CCJR episode payments in section III.C.4.b.(3) of this proposed rule. Using ratios of national average episode payment amounts would have the advantage of also capturing changes in national utilization patterns in addition to payment system updates between the historical years and the performance year. However, such an approach would need to be done retrospectively, after average episode payments can be calculated for the performance year, because it would rely on the payments actually incurred in the performance period, data for which would be not be available before the performance period. While the proposed approach of using component-specific update factors may be more complicated than the aforementioned alternative, we believe the additional complication is outweighed by the value to hospitals of knowing target prices before the start of an episode for which the target price would apply. We seek comment on this proposed approach of updating historical episode payments for ongoing Medicare payment system changes.

We do not propose to separately and prospectively apply an adjustment to account for changes in national utilization patterns between the historical and performance years. If a prospective adjustment factor for national utilization pattern changes were applied, it may only be meaningful in performance years 2 and 4, when the historical data used to calculate target prices would not be updated, but another year of historical data would be available. In any of the other 3 performance years, the latest available historical year of data would already be incorporated into the target prices. Given that we propose to refresh the historical data used to calculate target prices every 2 years, we do not believe an additional adjustment factor to account for national practice pattern changes is necessary to appropriately incentivize participant hospitals to improve quality of care and reduce episode payments.

(a) Proposed Inpatient Acute Services Update Factor

The proposed inpatient acute services update factor would apply to payments for services included in the episode paid under the IPPS. This would include payments for the CCJR anchor hospitalization, but not payments for related readmissions at CAHs during the episode window. Payments for related readmissions at CAHs would be captured under the update factor for other services in section III.C.4.b.(f) of this proposed rule.

The update factor applied to the inpatient acute services component of each participant hospital and region's historical average episode payments would be based on how inputs for the Medicare IPPS have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CCJR. We propose to use changes in the following IPPS inputs to calculate the inpatient acute services update factor: IPPS base rate and average of MS–DRG weights, as defined in the IPPS/LTCH Final Rules for the relevant years. The average MS–DRG weight would be specific to each participant hospital and region to account for hospital and region-specific inpatient acute service utilization patterns. Hospital-specific and region-specific average MS–DRG weights would be calculated by averaging the MS–DRG weight for all the IPPS MS–DRGs included in the historical episodes attributed to each participant hospital and attributed to CCJR eligible hospitals in the region, respectively; including MS–DRGs for anchor admissions as well as those for subsequent readmissions that fall within the episode definition. Expressed as a ratio, the inpatient acute services adjustment factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest historical year used in the target price (TP) calculations.

Therefore, the proposed inpatient acute services update factor formula is shown as—

$$\frac{\text{Base Rate}_{PP} * \text{average MSDRG weight}_{PP}}{\text{Base Rate}_{TP} * \text{average MSDRG weight}_{TP}}$$

(b) Proposed Physician Services Update Factor

The proposed physician services update factor would apply to payments for services included in the episode paid under the Medicare PFS for physician services. We propose to use changes in the following PFS inputs to calculate the physician services update factor of each participant hospital and region's historical average episode payments: RVUs; work, practice expense, and malpractice liability geographic practice cost indices (GPCIs); and national conversion factor, as defined in the PFS Final Rule for the relevant years. Hospital-specific and region-specific RVU-weighted GPCIs would be calculated to account for hospital and region-specific physician service utilization patterns. Hospital-specific and region-specific RVU-weighted GPCIs would be calculated by taking the proportion of RVUs for work, practice expense, and malpractice liability for physician services included in the historical episodes and attributed to each participant hospital and attributed to CCJR eligible hospitals in the region, respectively, and multiplying each proportion by the relevant GPCI.

Expressed as a ratio, the physician services update factor would equal the following:

- The numerator is based on GPCI values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on GPCI applicable at the end of the latest year used in the target price (TP) calculations.

Therefore, the proposed physician services update factor formula is shown as—

$$\frac{\text{RVU} - \text{weighted GPCI}_{PP} * \text{Conversion factor}_{PP}}{\text{RVU} - \text{weighted GPCI}_{TP} * \text{Conversion factor}_{TP}}$$

(c) Proposed IRF Services Update Factor

The proposed IRF services update factor apply to payments for services included in the episode paid under the Medicare inpatient rehabilitation facility prospective payment system (IRF PPS). We propose to use changes in the IRF Standard Payment Conversion Factor, an input for the IRF PPS and defined in the IRF PPS Final Rule for the relevant years, to update Medicare payments for IRF services provided in the episode. The IRF Standard Payment Conversion Factor is the same for all IRFs and IRF services, so there is no need to account for any hospital-specific or region-specific IRF utilization patterns; each participant hospital and region would use the same IRF services update factor.

Expressed as a ratio, the IRF PPS update factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest historical year used in the target price (TP) calculations:

Therefore, the proposed IRF services update factor formula is shown as

$$\frac{\text{IRF Standard Payment Conversion factor}_{PP}}{\text{IRF Standard Payment Conversion factor}_{TP}}$$

(d) Proposed SNF Services Update Factor

The proposed SNF services update factor would apply to payments for services included in the episode and paid under the SNF PPS, including payments for SNF swing bed services. The update factor applied to the SNF services component of each participant hospital and region's historical average episode payments would be based on how average Resource Utilization Group (RUG–IV) Case-Mix Adjusted Federal Rates for the Medicare SNF PPS (defined in the SNF PPS Final Rule) have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CCJR. The average RUG–IV Case-Mix Adjusted Federal Rates would be specific to each participant hospital and region to account for hospital and region-specific SNF service utilization patterns. Hospital-specific and region-specific average RUG–IV Case-Mix Adjusted Federal Rates would be calculated by averaging the RUG–IV Case-Mix Adjusted Federal Rates for all SNF services included in the historical episodes attributed to each participant hospital and attributed to CCJR eligible hospitals in the region, respectively. We note that the RUG–IV Case-Mix Adjusted Federal Rate may vary for the same RUG, depending on whether the SNF was categorized as urban or rural.

Expressed as a ratio, the SNF services update factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest year used in the target price (TP) calculations:

Therefore, the proposed SNF services update factor formula is shown as

$$\frac{\text{Average RUG IV Case Mix Adjusted Federal Rate}_{PP}}{\text{Average RUG IV Case Mix Adjusted Federal Rate}_{TP}}$$

(e) Proposed HHA Services Update Factor

The proposed HHA services update factor would apply to payments for services included in the episode and paid under the HH PPS, but exclude payments for Low Utilization Payment Adjustment (LUPA) claims (claims with four or fewer home health visits) because they are paid differently and would instead be captured in the update factor for other services in section III.C.4.b.(f) of this proposed rule. The update factor applied to the home health services component of each participant hospital and region's historical average episode payments would be based on how inputs for the Medicare HH PPS have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CCJR. We propose to use changes in the HH PPS base rate and average of home health resource group (HHRG) case-mix weight, inputs for the HHA PPS and defined in the HHA PPS Final Rule for the relevant years, to calculate the home health services update factor. The average HHRG case-mix weights would be specific to each participant hospital and region to account for hospital and region-specific home health service utilization patterns. Hospital-specific and region-specific HHA services update factors would be calculated by averaging the HHRG case-mix weights for all home health payments (excluding LUPA claims) included in the historical episodes attributed to each participant hospital and attributed to CCJR eligible hospitals in the region, respectively.

Expressed as a ratio, the HHA adjustment factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest historical year used in the target price (TP) calculations.

Therefore, the proposed HHA services update factor formula is shown as—

$$\frac{\text{60 Day Episode Rate}_{\text{PP}} * \text{average HHRG weight}_{\text{PP}}}{\text{60 Day Episode Rate}_{\text{TP}} * \text{average HHRG weight}_{\text{TP}}}$$

(f) Proposed Other Services Update Factor

The other services update factor would apply to payments for services included in the episode and not paid under the IPPS, PFS, IRF PPS, or HHA PPS (except for LUPA claims). This component would include episode payments for home health LUPA claims and CCJR related readmissions at CAHs. For purposes of calculating the other services update factor, we propose to use the Medicare Economic Index (MEI), a measure developed by CMS for measuring the inflation for goods and services used in the provision of physician services.[27] We would calculate the other services update factor as the percent change in the MEI between the latest year used in the TP calculation and its projected value for the upcoming performance period. Because MEI is not hospital or region-specific, each participant hospital and region would use the same other services update factor.

(5) Blend Hospital-specific and Regional Historical Data

We propose to calculate CCJR episode target prices using a blend of hospital-specific and regional historical average CCJR episode payments, including CCJR episode payments for all CCJR eligible hospitals in the same U.S. Census division as discussed further in section III.C.4.b.(6) of this proposed rule. Specifically, we propose to blend two-thirds of the hospital-specific episode payments and one-third of the regional episode payment to set a participant hospital's target price for the first 2-performance years of the CCJR model (CY 2016 and CY 2017). For performance year 3 of the model (CY 2018), we propose to adjust the proportion of the hospital-specific and regional episode payments used to calculate the episode target price from two-thirds hospital-specific and one-third regional to one-third hospital-specific and two-thirds regional. Finally, we propose to use only regional historical CCJR episode payments for performance years 4 and 5 of the model (CY 2019 and CY 2020) to set a participant hospital's target price, rather than a blend between the hospital-specific and regional episode payments. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this proposed rule. We welcome comment on the appropriate blend between hospital-specific and regional episode payments and the change in that blend over time.

We considered establishing episode target prices using only historical CCJR hospital-specific episode payments for all 5 performance years of the model (that is, episode payments for episodes attributed to the participant hospital, as previously described in section III.C.2. of this proposed rule). Using hospital-specific historical episodes may be appropriate in other models such as BPCI Model 2 where participation is voluntary and setting a region-wide target price could lead to a pattern of selective participation in which inefficient providers decline to participate, undermining the model's ability to improve the efficiency and quality of care delivered by those providers, while already-efficient providers receive windfall gains even if they do not further improve efficiency. Because CCJR model participants will be required to participate in the model, solely using hospital-specific historical episode data is not necessary to avoid this potential concern. Furthermore, using only hospital-specific historical CCJR episode payments may provide little incentive for hospitals that already cost-efficiently deliver high quality care to maintain or further improve such care. These hospitals could receive a relatively low target price because of their historical performance but have fewer opportunities for achieving additional efficiency under CCJR. They would not receive reconciliation payments for maintaining high quality and efficiency, while other hospitals that were less efficient would receive reconciliation payments for improving, even if the less historically efficient hospitals did not reach the same level of high quality and efficiency as the more historically efficient hospitals. Using only hospital-specific historical CCJR episode payments may also not be sufficient to curb inefficient care or overprovision of services for hospitals with historically high CCJR episode payments. In such instances, using hospital-specific historical episode payments for the CCJR model could result in Medicare continuing to pay an excessive amount for episodes of care provided by inefficient hospitals, and inefficient hospitals would stand to

[27] Medicare Market Basket Data. *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketData.html.*

benefit from making only small improvements. Thus, we do not propose to set target prices based solely on hospital-specific data for any performance years of the model.

We considered establishing the episode target price using only historical CCJR regional episode payments for all 5 performance years of the model. Though regional target pricing would reward the most efficient hospitals for continuing to provide high quality and cost efficient care, we are concerned about providing achievable incentives under the model for hospitals with high historical CCJR average episode payments. We believe a lower regional price for such hospitals would leave them with little financial incentive in performance year 1, especially without any responsibility to repay payments in excess of the target price as described in section III.C.3. of this proposed rule. Thus, we do not propose to set target prices solely on regional data for the entire duration of the model.

Therefore, we propose initially to blend historical hospital-specific and regional-historical episode payments and then transition to using regional-only historical episode payments in establishing target prices to afford early and continuing incentives for both historically efficient and less efficient hospitals to furnish high quality, efficient care in all years of the model. Our proposal more heavily weights a hospital's historical episode data in the first 2 years of the model (two-thirds hospital-specific, one-third regional), providing a reasonable incentive for both currently efficient and less efficient hospitals to deliver high quality and efficient care in the early stages of model implementation. Beginning in performance year 3, once hospitals have engaged in care redesign and adapted to the model parameters, we propose to shift to a more heavily weighted regional contribution (one-third hospital-specific, two-thirds regional in performance year 3) and ultimately to a regional target price for performance years 4 and 5. We believe that by performance year 4, setting target prices based solely on regional historical data would be feasible because hospitals would have had 3 years under this model to more efficiently deliver high quality care, thereby reducing some of the variation across hospitals. We believe transitioning to regional only pricing in the latter years of the model would provide important information about the reduction in unnecessary variation in LEJR episode utilization patterns within a region that can be achieved.

We believe transitioning to regional-only pricing in the latter years of the model may provide valuable information regarding potential pricing strategies for successful episode payment models that we may consider for expansion in the future. As discussed previously, substantial regional and hospital-specific variation in Medicare LEJR episode spending currently exists for beneficiaries with similar demographic and health status, so we are proposing that the early CCJR model years will more heavily weight historical hospital-specific experience in pricing episode for a participant hospital. Once the hospital has substantial experience with care redesign, we expect that unnecessary hospital-specific variation in episode spending will be minimized so that regional-only pricing would be appropriate as we have proposed. We note that, like episode payment under the CCJR model, Medicare's current payment systems make payments for bundles of items and services, although of various breadths and sizes depending on the specific payment system. For example, the IPPS pays a single payment, based on national prices with geography-specific labor cost adjustments, for all hospital services furnished during an inpatient hospital stay, such as nursing services, medications, medical equipment, operating room suites, etc. Under the IPPS, the national pricing approach incentivizes efficiencies and has, therefore, led to a substantial reduction in unnecessary hospital-specific variation in resource utilization for an inpatient hospital stay. On the other hand, the episode payment approach being tested under BPCI Model 2 relies solely on provider-specific pricing over the lifetime of the model, assuming the number of episode cases is sufficient to establish a reliable episode price, an approach that has potential limitations were expansion to be considered. Thus, we believe our proposal for CCJR will provide new, important information regarding pricing for even larger and broader bundles of services once unnecessary provider-specific variation has been minimized that would supplement our experience with patterns and pricing under existing payment systems and other episode payment models. We expect that testing of CCJR will contribute further information about efficient Medicare pricing strategies that result in appropriate payment for providers' resources required to furnish high quality, efficient care to beneficiaries who receive LEJR procedures. This is essential information for any consideration of episode payment model expansion, including nationally, in the future, where operationally feasible and appropriate pricing strategies, including provider-specific, regional, and national pricing approaches would need to be considered.

We propose an exception to the blended hospital-specific and regional pricing approach for hospitals with low historical CCJR episode volume. We propose to define hospitals with low CCJR episode volume as those with fewer than 20 CCJR episodes in total across the 3-historical-years used to calculate target prices. We believe calculating the hospital-specific component of the blended target price for these historically low CCJR episode volume hospitals may be subject to a high degree of statistical variation. Therefore, for each performance year, we propose to use 100 percent regional target pricing for participant hospitals who have fewer than twenty historical CCJR episodes in the 3-historical-years used to calculate target prices, as described in section III.C.4.b.(2) of this proposed rule. We note that the 3-historical-years used to calculate target prices would change over the course of the model, as described in section III.C.4.b.(2) of this proposed rule, and when that happens, the twenty episode threshold would be applied to the new set of historical years. If all IPPS hospitals nationally participated (for estimation purposes, only) in CCJR, we estimate about 5 percent of hospitals would be affected by this proposed low historical CCJR episode volume provision.[28] A minimum threshold of twenty episodes is almost equal to the minimum number of admissions required in the Medicare HRRP. HRRP payment adjustment factors are, in part, determined by procedure/condition-specific readmission rates for a hospital. HRRP requires at least 25 procedure/condition-specific admissions to calculate the procedure/condition-specific readmission rate and to be included in the hospital's overall HRRP payment adjustment factor. Though the proposed minimum threshold of twenty episodes is slightly less than the 25 admissions required for HRRP, we believe that because we would not be calculating infrequent events such as readmissions, we can achieve a stable price with slightly fewer episodes.

We also propose an exception to the blended hospital-specific and regional

[28] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

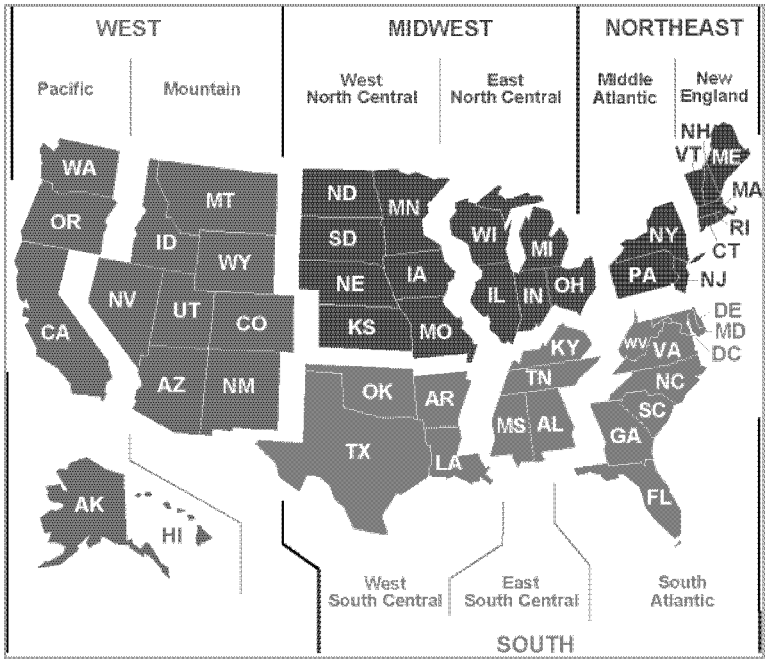
pricing approach for participant hospitals that received new CMS Certification Numbers (CCNs) during the 24 months prior to the beginning of, or during, the performance year for which target prices are being calculated. These participant hospitals with new CCNs may have formed due to a merger between or split from previously existing hospitals, or may be new hospitals altogether. As a general principle, we aim to incorporate into the target prices all the historical episodes that would represent our best estimate of CCJR historical payments for these participant hospitals with new CCNs. For participant hospitals with new CCNs that formed from a merger between or split from previously existing hospitals, we propose to calculate hospital-specific historical payments using the episodes attributed to the previously existing hospitals. These hospital-specific historical payments would then be blended with the regional historical payments according to the approach previously described in this section. For participant hospitals with new CCNs that are new hospitals altogether, we propose to use the approach previously described in this section for hospitals with fewer than 20 CCJR episodes across the 3 historical years used to calculate target prices. In other cases, due to an organizational change a hospital may experience a change to an already existing CCN during the 24 months prior to the beginning of, or during, the performance year for which target prices are being calculated. For example, one hospital with a CCN may merge with a second hospital assigned a different CCN, and both hospitals would then be identified under the single CCN of the second hospital. While there may be more than 20 CCJR episodes under the second hospital's CCN in total across the 3 historical years used to calculate target prices, in this scenario our use of only those cases under the second hospital's CCN in calculating hospital-specific historical payments would fail to meet our general principle of incorporating into target prices all the historical episodes that would represent our best estimate of CCJR historical payments for these now merged hospitals. In this scenario, we propose to calculate hospital-specific payments for the remaining single CCN (originally assigned to the second hospital only) using the historical episodes attributed to both previously existing hospitals. These hospital-specific historical payments would then be blended with the regional historical payments according to the approach previously described in this section in order to determine the episode price for the merged hospitals bearing a single CCN.

We seek comment on this proposed approach for blending hospital-specific and regional historical payments.

(6) Define Regions as U.S. Census Divisions

In all 5 performance years we propose to define ''region'' as one of the nine U.S. Census divisions [29] in Figure3.

FIGURE 3: U.S. CENSUS DIVISIONS[30]



We considered using states, HRRs, and the entire U.S. as alternative options to U.S. Census divisions in defining the region used in blending provider-specific and regional historical episode data for calculating target prices. However, HRR definitions are specifically based on referrals for cardiovascular surgical procedures and neurosurgery, and may not reflect referral patterns for orthopedic procedures. Using the entire U.S. would not account for substantial current regional variation in utilization, which is significant for episodes that often involve PAC use, such as lower extremity joint replacement procedures [31]. Finally, we considered

[29] There are four census regions—Northeast, Midwest, South, and West. Each of the four census regions is divided into two or more ''census divisions''. Source: *https://www.census.gov/geo/reference/gtc/gtc_census_divreg.html.* Accessed on April 15, 2015.

[30] *http://www.eia.gov/consumption/commercial/censusmaps.cfm.*

[31] Hussey PS, Huckfeldt P, Hirshman S, Mehrotra A. Hospital and regional variation in Medicare

using states as regions but were concerned that doing so would not allow for sufficient LEJR episode volume to set stable regional components of target prices, especially for participant hospitals in small states. We believe U.S. Census divisions provide the most appropriate balance between very large areas with highly disparate utilization patterns and very small areas that would be subject to price distortions due to low volume or hospital-specific utilization patterns.

We seek comment on our proposal to define a region as the U.S. Census division for purposes of the regional component of blended target prices under CCJR.

(7) Normalize for Provider-Specific Wage Adjustment Variations

We note that some variation in historical CCJR episode payments across hospitals in a region may be due to wage adjustment differences in Medicare's payments. In setting Medicare payment rates, Medicare typically adjusts facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative wage level in the geographic area of the facility or practitioner (or the beneficiary residence, in the case of home health and hospice services) compared to a national average wage level. Such adjustments are essential for setting accurate payments, as wage levels vary significantly across geographic areas of the country. However, having the wage level for one hospital influence the regional-component of hospital-specific and regional blended target prices for another hospital with a different wage level would introduce unintended pricing distortions not based on utilization pattern differences.

In order to preserve how wage levels affect provider payment amounts, while minimizing the distortions introduced when calculating the regional-component of blended target prices, we propose to normalize for wage index differences in historical episode payments when calculating and blending the regional and hospital-specific components of blended target prices. Calculating blended target prices from historical CCJR episodes would help ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control.

We propose to normalize for provider-specific wage index variations using the IPPS wage index applicable to the anchor hospitalization (that is, the IPPS wage index used in the calculation of the IPPS payment for the anchor hospitalization). The anchor hospitalization accounts for approximately 50 percent of the total episode expenditures, and the IPPS wage index is applied to IPPS payments in a similar manner as wage indices for other Medicare payment systems are applied to their respective payments.[32] Therefore, we propose that the IPPS wage index applicable to the anchor hospitalization for each historical episode be used to normalize for wage index variations in historical episode payments across hospitals when calculating blended target prices. We propose to specifically perform this normalization using the wage normalization factor (0.7 * IPPS wage index + 0.3) to adjust the labor-related portion of payments affected by wage indices. The 0.7 approximates the labor share in IPPS, IRF PPS, SNF, and HHA Medicare payments. We would normalize for provider-specific wage index variations by dividing a hospital's historical episode payments by the wage normalization factor.

We propose to reintroduce the hospital-specific wage variations by multiplying episode payments by the wage normalization factor when calculating the target prices for each participant hospital, as described in section III.C.4.c. of this proposed rule. When reintroducing the hospital-specific wage variations, the IPPS wage index would be the one that applies to the hospital during the period for which target prices are being calculated (for example, FY 2016 wage indices for the target price calculations for episodes that begin between January 1 and September 30, 2016). The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this proposed rule. We seek comment on our proposal to normalize for wage index differences using participant hospitals' wage indices in order to calculate blended target prices.

(8) Proposed Combination of CCJR Episodes Anchored by MS–DRGs 469 and 470

We propose to pool together CCJR episodes anchored by MS–DRGs 469 and 470 for target price calculations to use a greater historical CCJR episode volume and set more stable target prices. We note that we would still calculate separate target prices for episodes anchored by MS–DRGs 469 versus 470, described later in this section.

To pool together MS–DRG 469 and 470 anchored episodes, we propose to use an anchor factor and hospital weights. The anchor factor would equal the ratio of national average historical MS–DRG 469 anchored episode payments to national average historical MS–DRG 470 anchored episode payments. The national average would be based on episodes attributed to any CCJR eligible hospital. The resulting anchor factor would be the same for all participant hospitals. For each participant hospital, a hospital weight would be calculated using the following formula, where episode counts are participant hospital-specific and based on the episodes in the 3 historical years used in target price calculations:

$$\frac{\textit{Count of MS DRG } 469 \textit{ and MS DRG } 470 \textit{ anchored episodes}}{\textit{MS DRG } 469 \textit{ anchored episode count} * \textit{anchor factor} + \textit{MS DRG } 470 \textit{ anchored episode count}}$$

A hospital-specific pooled historical average episode payment would be calculated by multiplying the hospital's hospital weight by its combined historical average episode payment (sum of MS–DRG 469 and 470 anchored historical episode payments divided by the number of MS–DRG 469 and 470 historical episodes).

The calculation of the hospital weights and the hospital-specific pooled historical average episode payments would be comparable to how case mix indices are used to generate case mix-

payment for inpatient episodes of care [published online April 13, 2015]. JAMA Intern Med. doi:10.1001/jamainternmed.2015.0674.

[32] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

adjusted Medicare payments. The hospital weight essentially would count each MS–DRG 469 triggered episode as more than one episode (assuming MS–DRG 469 anchored episodes have higher average payments than MS–DRG 470 anchored episodes) so that the pooled historical average episode payment, and subsequently the target price, is not skewed by the hospital's relative breakdown of MS–DRG 469 versus 470 anchored historical episodes.

The hospital-specific pooled historical average payments would be modified by blending and discount factors, as described in section III.C.4.c. of this proposed rule. Afterwards, the hospital-specific pooled calculations would be ''unpooled'' by setting the MS–DRG 470 anchored episode target price to the resulting calculations, and by multiplying the resulting calculations by the hospital weight to produce the MS–DRG 469 anchored target prices.

We would calculate region-specific weights and region-specific pooled historical average payments following the same steps proposed for hospital-specific weights and hospital-specific pooled average payments. Instead of grouping episodes by the attributed hospital as is proposed for hospital-specific calculations, region-specific calculations would group together episodes that were attributed to any CCJR eligible hospital located within the region. The hospital-specific and region-specific pooled historical average payments would be blended together as discussed in section III.C.4.b.(3) of this proposed rule. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this proposed rule.

We considered an alternative option of independently setting target prices for MS–DRG 470 and 469 anchored episodes without pooling them. However, hospital volume for MS–DRG 469 was substantially less than for MS–DRG 470. In 2013 across all IPPS hospitals, there were more than 10 times as many MS–DRG 470 anchored episodes as compared to MS–DRG 469 anchored episodes. [33] In the same analysis, the median number of episodes for a hospital with at least 1 episode for the MS–DRG anchored episode was more than 80 for MS–DRG 470 anchored episodes, though fewer than 10 for MS–DRG 469 anchored episodes. Calculating target prices for MS–DRG 469 anchored episodes separately for each participant hospital may result in too few historical episodes to calculate reliable target prices. We also considered pooling together MS–DRG 469 and 470 anchored episodes without any anchor factor or hospital weights. However, internal analyses suggest that average episode payments for these two MS–DRG anchored episodes significantly differed; CCJR episodes initiated by MS–DRG 469 had payments almost twice as large as those initiated by MS–DRG 470.[34] This difference is reasonable given that Medicare IPPS payments differ for MS–DRG 469 and 470 admissions, and inpatient payments comprise approximately 50 percent of CCJR episode payments. Thus, pooling together MS–DRG 469 and 470 anchored episodes without any anchor factor or hospital weights would introduce distortions due only to case-mix differences.

(9) Discount Factor

When setting an episode target price for a participant hospital, we propose to apply a discount to a hospital's hospital-specific and regional blended historical payments for a performance period to establish the episode target price that would apply to the participant hospital's CCJR episodes during that performance period and for which the hospital would be fully, or partly, accountable for episode spending in relationship to the target price, as discussed in section III.C.3. of this proposed rule. We expect participant hospitals to have significant opportunity to improve the quality and efficiency of care furnished during episodes in comparison with historical practice, because this model would facilitate the alignment of financial incentives among providers caring for beneficiaries throughout the episode. This discount would serve as Medicare's portion of reduced expenditures from the CCJR episode, with any episode expenditure below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred. We propose to apply a 2 percent discount for performance years 1 through 5 when setting the target price. We believe that applying a 2 percent discount in setting the episode target price allows Medicare to partake in some of the savings from the CCJR model, while leaving considerable opportunity for participant hospitals to achieve further episode savings below the target price that they would be paid as reconciliation payments, assuming they meet the quality requirements as discussed in section III.C.5 of this proposed rule.

The proposed 2 percent discount is similar to the range of the discounts used for episodes in the Medicare Acute Care Episode (ACE) demonstration.[35] In the Medicare ACE, a demonstration program that included orthopedic procedures such as those included in CCJR, participant hospitals negotiated with Medicare discounts of 2.5 to 4.4 percent of all Part A orthopedic services and 0.0 to 4.4 percent of all Part B orthopedic services during the inpatient stay (excluding PAC). Hospitals received the discounted payment and reported that they were still able to achieve savings.[36] We believe there is similar, if not potentially more, opportunity for savings in the CCJR payment model because it includes acute inpatient, as well as PAC, an area of episode spending that accounts for approximately 25 percent of CCJR episode payments and exhibits more than 2 times the episode payment variation [37] than that of acute inpatient hospitalization.[38] We believe that with the proposed 2 percent discount, participant hospitals have an opportunity to create savings for themselves as well as Medicare, while also maintaining or improving quality of care for beneficiaries.

The proposed 2 percent discount also matches the discount used in the BPCI Model 2 90-day episodes, and is less than the discount used in BPCI Model 2 30-day and 60-day episodes (3 percent). Hundreds of current BPCI participants have elected to take on responsibility for repayment in BPCI Model 2 with a 2 to 3 percent discount. Because many BPCI participants volunteered to participate in a bundled payment model with a discount, we believe that a discount percent that is within, and especially a discount of 2 percent that is at the lower end of, the BPCI discount range would allow CCJR

[33] Source: CCW Part A and Part B claims for CCJR episodes beginning in CY 2013.

[34] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

[35] IMPAQ International. Evaluation of the Medicare Acute Care Episode (ACE) Demonstration: Final Evaluation Report. Columbia, MD: IMPAQ International; May 2013. *http://downloads.cms.gov/files/cmmi/ACE-EvaluationReport-Final-5-2-14.pdf.* Accessed April 1 6, 2015.

[36] IMPAQ International. Evaluation of the Medicare Acute Care Episode (ACE) Demonstration: Final Evaluation Report. Columbia, MD: IMPAQ International; May 2013. *http://downloads.cms.gov/files/cmmi/ACE-EvaluationReport-Final-5-2-14.pdf.* Accessed April 1 6, 2015.

[37] Variation for purposes of this calculation refers to standard deviation of inpatient and institutional post-acute episode payments as a percentage of average inpatient and post-acute episode payments, respectively.

[38] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

participant hospitals to create savings for both themselves and Medicare.

As mentioned previously in section III.C.3. of this proposed rule, we propose to phase in the financial responsibility of hospitals for repayment of actual episode spending that exceeds the target price starting in performance year 2. In order to help hospitals transition to taking on this responsibility, we propose to apply a reduced discount of one percent in performance year 2 for purposes of determining the hospital's responsibility for excess episode spending, but maintain the 2 percent discount for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price. For example, under this proposal in performance year 2, a hospital that achieves CCJR actual episode payments below a target price based on a 2 percent discount would retain savings below the target price, assuming the quality thresholds for reconciliation payment eligibility are met (discussed in section III.C.5. of this proposed rule) and the proposed performance year stop-gain limit (discussed in section III.C.8. of this proposed rule) does not apply. Medicare would hold responsible for repayment hospitals whose CCJR actual episode payments exceed a target price based on a one percent discount, assuming the proposed performance year 2 stop-loss limit (discussed in section III.C.8. of this proposed rule) does not apply. Hospitals that achieve CCJR actual episode payments between a 2 percent-discounted target price and 1 percent-discounted target price would neither receive reconciliation payments nor be held responsible for repaying Medicare. The decision on which percent-discounted target price applies will be made by evaluating actual episode payments in aggregate after the completion of performance year 2, and the same percent-discounted target price would apply to all episodes that are initiated in performance year 2. We propose to apply this reduced one percent discount for purposes of hospital repayment responsibility only in performance year 2 and apply the 2 percent discount for excess episode spending repayment responsibility for performance years 3 through 5. Under this proposal, the discount for determination of reconciliation payment for episode actual spending below the target price would not deviate from 2 percent through performance years 1 through 5.

In section III.C.5. of this proposed rule, we propose voluntary submission of data for a patient-reported outcome measure. We propose to incent participant hospitals to submit data on this measure by reducing the discount percentage by 0.3 percentage points for successfully submitting data, as defined in section III.D. of this proposed rule. By successfully submitting data on this metric for episodes ending in performance years 1, 2, 3, 4, and or 5, we would adjust the discount percentage in the corresponding year(s) as follows:

- For episodes beginning in performance year 2, set the discount percentage in a range from 2 percent to 1.7 percent for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price, and set the discount percentage in a range from 1 percent to 0.7 percent for purposes of determining the amount the hospital would be responsible for repaying Medicare for actual episode spending above the target price.
- For episodes beginning in performance years 3 through 5, set the discount percentage in a range from 2 percent to 1.7 percent for purposes of reconciliation payment and Medicare repayment calculations.

The determination of whether the hospital successfully submitted data on the patient-reported outcome measure cannot be made until after the performance year ends and data is reported. Therefore, participant hospitals would be provided target prices for both scenarios whether the successfully submit data or not and such determination will happen at the time of payment reconciliation (discussed further in section III.C.6. of this proposed rule).

We seek comment on our proposed discount percentage of 2 percent for CCJR episodes, our proposal to reduce the discount to 1 percent on a limited basis in performance year 2, and our proposal to reduce the discount by 0.3 percentage points for successfully reporting patient-reported outcomes data in the corresponding year.

c. Proposed Approach to Combine Pricing Features

In section III.C.4.(b) of this proposed rule we discuss the various features we propose to incorporate into our approach to set target prices. We refer readers to that section for more information on rationale and alternatives considered for each feature. In this section we discuss how the different pricing features, as well as the episode definition (section III.B. of this proposed rule) and adjustments to payments included in the episodes (section III.C.3. of this proposed rule), would fit together and be sequenced to calculate CCJR episode target prices for participant hospitals. As previously discussed in sections III.C.4.a and III.C.4.b of this proposed rule, we propose to calculate sixteen target prices for performance year 2, and eight target prices for each of the other 4 performance years. The following steps would be used to calculate MS–DRG 469 and 470 anchored episode target prices for both January 1 through September 30 and October 1 through December 31 each performance year. The output of each step would be used as the input for the subsequent step, unless otherwise noted.

- Calculate historical CCJR episode payments for episodes that were initiated during the 3- historical-years (section III.C.4.b.(2) of this proposed rule) for all CCJR eligible hospitals for all Medicare Part A and B services included in the episode. We note that specific PBPM payments may be excluded from historical episode payment calculations as discussed in section III.C.7.d. of this proposed rule.
- Remove effects of special payment provisions (section III.C.3.a. of this proposed rule).
- Prorate Medicare payments for included episode services that span a period of care that extends beyond the episode (section III.C.3.b of this proposed rule.).
- Normalize for hospital-specific wage adjustment variation by dividing the episodes outputted in step (3) by the hospital's corresponding wage normalization factor described in section III.C.4.b.(7) of this proposed rule.
- Trend forward 2 oldest historical years of data to the most recent year of historical data. As discussed in section III.C.4.b.(3) of this proposed rule, separate national trend factors would be applied to episodes anchored by MS–DRG 469 versus MS–DRG 470.
- Cap high episode payment episodes with a region and MS–DRG anchor-specific high payment ceiling as discussed in section III.C.3.c. of this proposed rule, using the episode output from the previous step.
- Calculate anchor factor and participant hospital-specific weights (section III.C.4.b.(8) of this proposed rule) using the episode output from the previous step to pool together MS–DRG 469 and 470 anchored episodes, resulting in participant hospital-specific pooled historical average episode payments. Similarly, calculate region-specific weights to calculate region-specific pooled historical average episode payments. We have posted region-specific pooled historical average

episode payments on the CCJR proposed rule Web site at *http://innovation.cms.gov/initiatives/ccjr/.*

- Calculate participant hospital-specific and region-specific weighted update factors as described in section III.C.4.b.(4) of this proposed rule. Multiply each participant hospital-specific and region-specific pooled historical average episode payment by its corresponding participant hospital-specific and region-specific weighted update factors to calculate participant hospital-specific and region-specific updated, pooled, historical average episode payments.
- Blend together each participant hospital-specific updated, pooled, historical average episode payment with the corresponding region-specific updated, pooled, historical average episode payment according to the proportions described in section III.C.4.b.(5) of this proposed rule. Participant hospitals that do not have the minimum episode volume across the historical 3 years would use 0.0 percent and 100 percent as the proportions for hospital and region, respectively.
- Reintroduce hospital-specific wage variations by multiplying the participant hospital-specific blended, updated, and pooled historical average episode payments by the corresponding hospital-specific wage normalization factor, using the hospital's IPPS wage index that applies to the hospital during the period for which target prices are being calculated (section III.C.4.b.(7) of this proposed rule).
- Multiply the appropriate discount factor, as discussed in section III.C.4.b.(9) of this proposed rule to each participant hospital's wage-adjusted, blended, updated, and pooled historical average episode payment. For performance years 1, 3, 4, and 5, two discount factors would be used, one if the hospital successfully submits data on the patient-reported outcomes measure proposed in section III.C.5 of this proposed rule, and one if the hospital does not successfully submit the data. For performance year 2, 4 discount factors would be used to account for the 4 combinations of the following: a) whether or not the hospital successfully submits data on the patient-reported outcomes measure; and b) for the different discount factors proposed for purposes of calculating reconciliation payments vs. calculating repayment amounts. The result of this calculation would be the participant hospital-specific target prices for MS–DRG 470 anchored episodes.
- Multiply participant hospitals' target prices for MS–DRG 470 anchored episodes by the anchor factor (section III.C.4.b.(8) of this proposed rule) to calculate hospitals' target prices for MS–DRG 469 anchored episodes.

The aforementioned steps would be used to calculate target prices for episodes that begin between January 1 and September 30, as well as for episodes that begin between October 1 and December 31, for each performance year. The target price calculations for the two different time periods each performance year would differ by the IPPS wage index used in step (11) and the update factors used in step (8). By following these eight steps, we would calculate eight target prices for each participant hospital for performance years 1, 3, 4, and 5, and 16 target prices for performance year 2. We refer readers to section III.C.4.b. of this proposed rule for further details on each of the specific steps.

We seek comment on the proposed approach to sequence and fit together the different pricing features, the episode definition (section III.B. of this proposed rule), and adjustments to payments included in the episodes (section III.C.3. of this proposed rule) to calculate CCJR episode target prices for participant hospitals.

5. Proposed Use of Quality Performance in the Payment Methodology

a. Background

Over the past several years Medicare payment policy has moved away from FFS payments unlinked to quality and towards payments that are linked to quality of care. Through the Affordable Care Act, we have implemented specific IPPS programs like the HVBP (subsection (o) of section 1886 of the Act), the Hospital Acquired Conditions Reduction Program (HACRP) (subsection (q) of section 1886) and the HRRP (subsection (p) of section 1886), where quality of care is linked with payment. We have also implemented the MSSP, an accountable care organization program that links shared savings payment to quality performance. Since the implementation of the HRRP in October 2012, readmission rates for various medical conditions like THA and TKA (THA/TKA) have improved. Trend analyses show a decrease in readmission rates and specifically with THA/TKA risk-standardized readmissions rates (RSRR) from 5.4 percent (July 2010-June 2011) to 4.8 percent (July 2012-June 2013).[39] Additionally, hospital THA/TKA RSCR decreased from 3.4 percent (April 2010 through March 2011) to 3.1 percent (April 2012 through March 2013). Despite the downward trend of THA/TKA RSRRs and RSCRs, the wide dispersion in these readmission rates suggests there is still room for hospitals to improve their performance on these measures as illustrated by a THA/TKA RSRR distribution of 2.8 to 9.4 percent (July 2010-June 2013) and a THA/TKA RSCR distribution of 1.5 to 6.4 percent (April 2010-March 2013). We believe that the CCJR Model provides another mechanism for hospitals to improve quality of care, while also achieving cost efficiency. Incentivizing high-value care through episode-based payments for LEJR procedures is a primary objective of CCJR. Therefore, incorporating quality performance into the episode payment structure is an essential component of the CCJR model. We also believe that the financial opportunity proposed in section III.C.3. of this proposed rule provides the appropriate incentives necessary to reward a participant hospital's achievement of episode savings when the savings are greater than the discounted target price. For the reasons stated previously, we believe it is important for the CCJR model to link the financial reward opportunity with achievement in quality of care for Medicare beneficiaries undergoing LEJR.

As discussed in section III.C of this proposed rule, which outlines the payment structure for the CCJR model, each participant hospital will have target prices calculated for MS–DRG 469 and 470 anchored episodes; each anchored episode includes an anchor hospitalization for an LEJR procedure and a 90–day period after the date of discharge from the anchor hospitalization. These episode target prices represent expected spending all related Part A and Part B spending for such episodes, with a discount. Hospitals who achieve actual episode spending below a target price for a given performance period would be eligible for a reconciliation payment from CMS, subject to the proposed stop-gain limit policy as discussed in section III.C.8. of this proposed rule.

In the next section of this proposed rule, we propose quality performance standards that must also be met in order for a hospital to be eligible to receive a reconciliation payment under CCJR. Specifically, we describe our proposal to include a performance measure result threshold on select outcomes-based quality measures as a requirement for participants to receive a reconciliation payment if actual episode spending is

[39] Hospital Quality Initiatives. CMS Hospital Quality Chartbook 2014. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf* . Accessed April 21, 2015.

less than the target price under CCJR in a performance year, in addition to a payment adjustment for successful reporting of a voluntary measure in development. Beginning in performance year one and continuing throughout the duration of the model, we propose to make reconciliation payments only to those CCJR hospital participants that meet or exceed a minimum measure result threshold. We also discuss an alternative approach to determining CCJR reconciliation payment eligibility and adjusting payment based on a quality score developed from performance on three outcomes-based quality measures and success in reporting the voluntary measurement in development.

b. Proposed Implementation of Quality Measures for Reconciliation Payment Eligibility

In section III.D. of this proposed rule we propose three measures to assess quality of care of the hospitals participating in the CCJR Model. We also propose voluntary data submission for a patient-reported outcome measure. In this section we propose using three measures to determine eligibility for a reconciliation payment, as well as propose rewarding hospitals that voluntarily submit data for the patient-reported outcome measure. We also discuss an alternative approach to determining reconciliation payment eligibility and adjusting payment based on a composite quality score calculated from the three required outcome measures and success on reporting voluntary data on the patient-reported outcome measure.

(1) General Selection of Proposed Quality Measures

The CCJR model is designed to provide financial incentives to improve coordination of care for beneficiaries that we expect to lead to avoidance of post-surgical complications and hospital readmissions, as well as to improve patient experience through care redesign and coordination. Furthermore, we acknowledge that achievement of savings while ensuring high-quality care for Medicare FFS beneficiaries in LEJR episodes will require close collaboration among hospitals, physicians, PAC providers, and other providers. In order to encourage care collaboration among multiple providers of patients undergoing THA and TKA, we propose three measures, as described in detail in section III.D.2. of this proposed rule, to determine hospital quality of care and to determine eligibility for a reconciliation payment under the CCJR model. The measures we are proposing are as follows:

- Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551), an administrative claims-based measure.
- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550), an administrative claims-based measure.
- HCAHPS Survey measure.

Beginning in performance year 1 and continuing throughout the duration of the model, we propose to make reconciliation payments only to those CCJR participant hospitals that meet or exceed a minimum performance threshold on the measures previously listed. We propose that hospitals must meet or exceed the measure reporting thresholds and other requirements described in section III.C and III.D. of this proposed rule on all three measures in order to be eligible for a reconciliation payment.

These three outcome measures were chosen due to their: (1) Alignment with the goals of the CCJR model; (2) hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including programs that tie payment to performance such as HVBP and HRRP; and (3) assessment of CMS priorities to improve the rate of LEJR complications and readmissions, while improving patient experience. We believe the three quality measures we propose for reconciliation payment eligibility reflect these goals and accurately measure hospitals' level of achievement on such goals.

(2) Proposal To Adjust the Payment Methodology for Voluntary Submission of Data for Patient-Reported Outcome Measure

During our consideration of quality metrics for the CCJR model, we examined the feasibility of linking voluntary data submission of patient-reported outcomes, beyond the current three required measures proposed in section III.D.2. of this proposed rule for use in the model, with the possibility of incentivizing participant hospitals under the episode payment model to participate in this voluntary submission of data. We specifically examined potential patient-reported outcome measures since this type of outcome measure aligns with the CCJR model goal of improving LEJR episode quality of care, including a heightened emphasis on patient-centered care where patients provide meaningful input to their care. Furthermore, the availability of patient reported outcome data would provide additional information on a participant hospital's quality performance, especially with respect to a patient's functional status, beyond the current three required measures proposed in section III.D.2. of this proposed rule for use in the model. We note that we have a measure in development, the Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary THA or TKA measure or both (hence forth referred to as ''THA/TKA patient-reported outcome-based measure''), that would support the National Quality Strategy domain of patient and family engagement, and could capture meaningful information that would not otherwise be available on patient outcomes that are related to the quality of LEJR episodes under CCJR. We believe that incorporating this measure into CCJR by adjusting the payment methodology for successful voluntary data submission on the THA/TKA patient-reported outcome-based measure (henceforth referred to as ''THA/TKA voluntary data'') would provide participant hospitals with valuable information on functional outcomes that would assist them in assessing an important patient-centered outcome, engaging other providers and suppliers in care redesign for LEJR episodes, as well as provide them with the potential for greater financial benefit from improved LEJR episode efficiencies. We do not believe it would be appropriate at this time to hold any participant hospitals financially accountable for their actual THA/TKA voluntary data, as we have proposed for the three required measures described in section III.C.5.b.(2) of this proposed rule.

Instead, we propose to adjust the episode payment methodology for participant hospitals that successfully submit THA/TKA voluntary data by reducing the discount percentage used to set the target price from 2.0 percent to 1.7 percent of expected episode spending based on historical CCJR episode data, hereinafter referred to as the voluntary reporting payment adjustment. The proposed payment policies with respect to reconciliation payment eligibility and the discount percentage based on hospital voluntary data submission are summarized in Table 7 for performance years 3 through 5 where hospitals have full repayment responsibility. The specific percentages that would apply for purposes of the repayment amount and reconciliation payment are outlined for performance years 1 and 2 in the discussion that follows.

TABLE 7—RECONCILIATION PAYMENT ELIGIBILITY AND DISCOUNT PERCENTAGE INCLUDED IN THE TARGET PRICE FOR EACH PARTICIPANT HOSPITAL BASED ON QUALITY PERFORMANCE IN PERFORMANCE YEARS 3–5

Discount percentage included in target price/reconciliation payment eligibility	Meets thresholds for all 3 required quality measures	Does not meet thresholds for one or more of 3 required quality measures
Successfully submits THA/TKA voluntary data	1.7%/eligible	1.7%/ineligible.
Does not successfully submit THA/KA voluntary data	2.0%/eligible	2.0%/ineligible.

We refer readers to section III.D.3. of this proposed rule for further discussion of the THA/TKA patient-reported outcome-based measure and our proposed definition of successful reporting. In addition, we refer readers to section III.C.4.b.(9) of this proposed rule for discussion of the proposed discount of 2.0 percent (without the voluntary reporting payment adjustment) to establish the target price. We believe that a voluntary reporting payment adjustment of 0.3 percent of expected episode spending would, on average, cover the participant hospitals' additional administrative costs of voluntarily reporting patient risk variables and patient-reported reported function for outcome calculation. We estimate the value of this discount reduction, on average, to be about $75 per LEJR episode at a participant hospital, which we believe would be sufficient to pay hospitals for the resources required to survey beneficiaries pre- and post-operatively about functional status and report this information required for measure development to CMS. We also believe that voluntary reporting on this patient-reported outcome measure is integral to implementation of the CCJR model, as it will allow us to further develop and evaluate the measure for potential use in this model in the future as a measure of quality that is important and not captured in any other available measures.

The voluntary reporting payment adjustment would be available for all years of the model, unless we find the measure to be unfeasible or have adequately developed the measure such that continued voluntary data collection is no longer needed for measure development during the course of the model. In those situations, we would notify participant hospitals that the voluntary reporting payment adjustment was no longer available as we would cease collecting the data.

When we provide the episode target price to each participant hospital at 2 times during the performance year, we would provide different target prices reflecting the 2.0 percent and 1.7 percent discounts. At the time of reconciliation for the performance year, we would determine which participant hospitals successfully reported the THA/TKA voluntary data for that performance year. The effects of this voluntary reporting payment adjustment would vary for each year of the model, depending on the proposed reconciliation payment and repayment policies for that performance year. For hospitals that achieved successful reporting of the THA/TKA voluntary data in performance year 3, 4, or 5,we would use the target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to calculate the hospital's reconciliation payment or repayment amount. Based on this comparison, consistent with the proposal described in section III.C.6. of this proposed rule, we would make a reconciliation payment if actual episode spending is less than the target price (and the thresholds for reconciliation payment eligibility are met for the three required quality measures) or make participant hospitals responsible for repaying Medicare if actual episode spending exceeds the target price. For performance year 2, when repayment responsibility is being phased-in, for participant hospitals with successful THA/TKA voluntary data reporting, we would use a target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to determine if actual episode spending was below the target price, whereupon the participant hospital would receive a reconciliation payment if the quality thresholds on the three required measures are met. In order to help hospitals transition to taking on repayment responsibility, we propose to apply a reduced discount of 0.7 percent for successful THA/TKA voluntary data reporting hospitals (compared with 1.0 percent for nonreporting or unsuccessfully reporting hospitals) in performance year 2 for purposes of determining the hospital's repayment responsibility for excess episode spending. For performance year 1, when there is no repayment responsibility, for participant hospitals with successful THA/TKA voluntary data reporting, we would use a target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to determine if actual episode spending was below the target price, whereupon the participant hospital would receive a reconciliation payment if the quality thresholds on the three required measures are met. We believe this proposed voluntary reporting payment adjustment provides the potential for increased financial benefit for participant hospitals due to a higher target price (that reflects a lower discount percentage) that successfully report the measure. Participant hospitals that successfully report the voluntary data would be subject to a lower repayment amount (except for performance year 1 when hospitals have no repayment responsibility) or a higher reconciliation payment (assuming the thresholds are met on the three required measures for reconciliation payment eligibility), than hospitals that do not successfully report the voluntary data.

In general, participant hospitals that meet the performance thresholds for the three required quality measures and reduce actual episode spending below the target price, as well as successfully report the THA/TKA voluntary data, would be eligible to retain an additional 0.3 percent of the reduced episode expenditures relative to participant hospitals that successfully report the three required quality measures but do not report voluntary data, funds which would offset additional administrative costs that the participant hospitals would incur in reporting on the measure. Additionally, for performance years 2–5 where participant hospitals have payment responsibility, participant hospitals with increased actual episode spending above the target price would not be required to repay 0.3 percent of the increased episode expenditures (relative to participant hospitals that do not report voluntary data), funds that would offset additional administrative costs that the participant hospitals would incur in reporting on the measure. These costs would include the hospital staff time required for training on the measure, as well as then gathering and reporting on multiple patient risk variables from LEJR episode

beneficiaries' medical records and locating beneficiaries and administering via phone survey questions on functional status, which would also then be reported to CMS. Thus, we expect that the proposal would encourage reporting by a number of participant hospitals, and it has the potential to benefit those hospitals that successfully report on the measure. Therefore, this proposal could financially benefit reporting hospitals that would also collect valuable information on patient functional outcomes that could inform their LEJR care redesign. While this measure remains in development from our perspective to ensure translation of data across care settings and the respective hospital communities during the 90-day post-discharge episode of care, participant hospitals would gain anecdotal, locally relevant information regarding the patient-reported outcomes of their own patients that could inform participant hospitals' continuous quality improvement efforts.

We considered two alternative options to adjust the CCJR payment methodology by modifying the required quality measure thresholds for reconciliation payment eligibility for those participant hospitals that successfully submit the THA/TKA voluntary data. First, we considered adjusting the threshold that hospitals must meet on the three required quality measures for reconciliation payment eligibility if reduced episode spending is achieved from the unadjusted 30th percentile threshold to the adjusted 20th percentile threshold for performance years 1, 2, and 3, and from the unadjusted 40th percentile to the adjusted 30th percentile for performance years 4 and 5. Second, we considered only requiring hospitals to meet the 30th percentile threshold on two of three outcome measures for performance years 1, 2, and 3, and the 40th percentile threshold on two of three outcome measures for performance years 4 and 5. These options would provide the opportunity for some participant hospitals, specifically those that missed the unadjusted percentile for one or more of the three required quality measures by a specified margin, to receive reconciliation payments if actual episode spending was less than the target price. However, these options could benefit only a subset of participant hospitals that successfully reported the THA/TKA voluntary data. For the majority of participant hospitals that we expect would meet the unadjusted thresholds for all three required measures, these options do not provide any incentive to voluntarily report the data because the hospitals would not benefit from voluntarily reporting the additional measure. We decided not to propose either of these options to adjust the CCJR payment methodology for participant hospitals that voluntarily report data on the new measure because the limited benefit could result in few hospitals choosing to report on the measure, thereby limiting our progress in developing the measure. We note that these two considered options and our proposal are not mutually exclusive.

We seek comment on the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CCJR participant hospitals that voluntarily and successfully report on the THA/TKA voluntary data. Given our interest in robust hospital participation in reporting on the THA/TKA voluntary data under CCJR, we are specifically interested in information on the additional resources and their associated costs that hospitals would incur to report THA/TKA voluntary data, as well as the relationship of these costs to the potential financial benefit participant hospitals could receive from the proposed reduced discount of 1.7 percent. Based on such information, we would consider whether a change from the proposed discount factor reduction due to successful voluntary data submission would be appropriate. We also seek comment on whether the alternative payment methodology adjustments considered, or combination of adjustments, would more appropriately incentivize CCJR participant hospitals to submit THA/TKA voluntary data. We believe that development of the THA/TKA patient-reported outcome measure would benefit from reporting by a broad array of participant hospitals, including those that currently deliver high quality, efficient LEJR episode care and those that have substantial room for improvement on quality and or cost-efficiency.

Furthermore, in light of our interest in encouraging CCJR participant hospital THA/TKA voluntary data reporting, we also considered alternative approaches to collect this information or provide hospitals with funds to help cover their associated administrative costs other than adjustments to the CCJR model payment methodology. One alternative would be for hospitals to collect and report on patient pre-operative information collected 0 to 90 days before surgery, while CMS would engage a contractor to collect and report the post-operative information collected 9 to 12 months after surgery. This approach would reduce some of the administrative burden of collection and reporting on hospitals, although participant hospitals would need to provide CMS with certain beneficiary information, including contact information that would be needed for a CMS contractor to contact the beneficiary at a later date. We seek comment on this alternative, including whether hospitals would incur significant additional administrative costs to report on the data prior to surgery and how CMS could best provide funds to offset some of those costs, through an adjustment to the CCJR payment methodology or other means. We also seek comment on the information participant hospitals would need to provide to CMS so a CMS contractor could collect and report the post-operative data, and the most efficient ways for hospitals to provide this information to us. Finally, we considered an approach that would provide hospitals with separate payment outside of an adjustment to the CCJR payment methodology to specifically assist in covering their administrative costs of reporting THA/TKA voluntary data, in order to achieve robust hospital participation in reporting. We seek comment on the hospital administrative costs that would be incurred for reporting, as well as on approaches we could take to ensure that hospitals achieved successful reporting under such an approach if separate payment was made. Finally, we are interested in comments regarding the comparative strength of these various alternatives in encouraging hospitals to participate in reporting THA/TKA voluntary data.

For a detailed description of this measure see section III.D.3 of this proposed rule

(3) Measure Risk-Adjustment and Calculations

All three proposed outcome measures are risk-adjusted and we refer readers to section III.D.2 of this proposed rule for a full discussion of these measures and risk-adjustment methodologies. We believe that risk-adjustment for patient case-mix is important when assessing hospital performance based on patient outcomes and experience and understanding how a given hospital's performance compares to the performance of other hospitals with similar case-mix.

(4) Applicable Time Period

We propose to use a 3-year rolling performance or applicable period for the

Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551) and the Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) measures. We also specifically propose to align with the HIQR program's 3-year rolling performance period for the RSSR and RSCR measures since we believe that a 3-year performance period yields the most consistently reliable and valid measure results (FY 2015 IPPS/LTCH 70 FR 50208 through 50209). For the HCAHPS Survey measure, we propose to follow the same performance period as in the HIQR program (FY 2015 IPPS/LTCH Final rule 79 FR 50259). HCAHPS scores are created from 4 consecutive quarters of survey data; publicly reported HCAHPS results are also based on 4 quarters of data. For the voluntary data collection for the proposed THA/TKA patient-reported outcome-based performance measure, the optimal reporting time period has not been determined. Therefore, we propose defining the applicable time period as 12 month intervals that may begin between July 1, 2016 and December 31, 2016, and continue in subsequent performance years for a total of four or fewer performance periods. Participant hospitals will submit required data to CMS in a mechanism similar to the data submission process for the HIQR program within sixty days of the end of each 12 month period. As described in section III.C.5.b.(3) of this proposed rule, the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CCJR participant hospitals that successfully report on the THA/TKA voluntary data would begin in year 2 and also apply to subsequent years of the model.

(5) Criteria for Applicable Hospitals and Performance Scoring

(a) Identification of Participant Hospitals for the CCJR Model

As discussed in section III.A.2 of this proposed rule, all CCJR participant hospitals would be IPPS hospitals.

(b) Methodology to Determine Performance on the Quality Measures

To determine performance on the quality measures, we propose to calculate measure results for all three measures as outlined in the Quality Measures section III.D.2 of this proposed rule. Performance on the three measures for the CCJR model participant hospitals would be compared to the national distribution of measure results for each of these measures obtained through the HIQR program. The HIQR program is an IPPS program in which public reporting is a focus of the program for the nation's acute care hospitals, and we propose using the absolute value of the CCJR model participant hospital's result to determine if that participant hospital is eligible for a reconciliation payment. In essence we intend to take the HIQR program measure results (also posted publicly) for the proposed measures, identify the threshold as outlined in section III.C.5.b.(3) of this proposed rule, and apply the thresholds also outlined in section III.C.5.b.(7) of this proposed rule. We believe it is reasonable to use the HIQR program distribution of measure results to identify a measure result threshold because—(1) the hospitals in the HIQR program represent most acute care hospitals in the nation; (2) the CCJR model participant hospitals are a subset of the hospitals in the HIQR program; and (3) the expectation that the CCJR model participant hospitals meet a measure result threshold based on a national distribution of measure results will encourage the CCJR model participant hospitals to strive to attain measure results consistent with or better than hospitals across the nation. For a detailed description of how we will determine the measure result thresholds for consideration of a reconciliation payment adjustment see section III.C.5.b.(3) and III.C.7.of this proposed rule. We would not want to encourage CCJR model participant hospitals to strive for measure results or quality of care performance that may be lower than the national measure results. Given that the CCJR participant hospitals are a subset of the HIQR program participant hospitals, they are familiar with these three measures and may have put into place processes that will help to improve quality of care in the LEJR patient population. Finally, once the measure results are calculated, we propose to use these results to determine eligibility for reconciliation payment, which is discussed in detail in the next section.

To be considered to have successfully reported the voluntary data collection and submission for the THA/TKA voluntary data, we propose that successfully reporting will mean participant hospitals must meet all of the following:

- Submit the data elements listed in section III.D.3.a.(2) of this proposed rule.
- Data elements listed in section III.D.3.a.(2) of this proposed rule must be submitted on at least 70 percent of their eligible elective primary THA/TKA patients (patients eligible for pre-operative THA/TKA voluntary data submission are those described in section III.D.3.a.(3)of this proposed rule); patients eligible for post-operative THA/TKA voluntary data submission are those described in section III.D.3.a(3) of this proposed rule and also having a THA/TKA procedure date during the anchor hospitalization at least 366 days prior to the end of the data collection period. Therefore, hospitals are not expected to collect and submit post-operative THA/TKA voluntary data on patients who are fewer than 366 days from the date of surgery.
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent 12 month period.

Hospitals meeting these three standards, and have successfully submitted THA/TKA voluntary data, will be eligible for the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CCJR participant hospitals that voluntarily and successfully report on the THA/TKA voluntary data. Encouraging collection and submission of the THA/TKA voluntary data through the CCJR model will increase availability of patient-reported outcomes to both participant hospitals that collect and submit data on their own patients in the model (and their patients as well); further development of an outcomes measure that provides meaningful information on patient-reported outcomes for THA/TKA procedures that are commonly furnished to Medicare beneficiaries; provide another quality measure that may be incorporated into the CCJR model policy linking quality to payment in future performance years, pending successful development of the measure; and inform the quality strategy of future payment models. Collecting data on at least 70 percent of hospital's eligible THA/TKA patients would provide sufficiently representative data to allow for development and testing of the THA/TKA patient-reported outcome-based performance measure.

We invite public comment on the proposal to calculate measure results for all three measures as outlined in the Quality Measures section III.D.2 of this proposed rule. We also seek public comment on our proposal for hospitals to meet three requirements, previously outlined, in order to be considered as successfully submitting THA/TKA voluntary data.

(c) Proposed Methodology To Link Quality and Payment

(i) Background

In proposing a methodology for linking payment for LEJR episodes to quality under this model, we considered several alternatives. Specifically, we considered making reconciliation payments to hospitals tied to achievement and improvement in quality performance or, alternatively, establishing minimum quality performance thresholds for selected quality measures from the beginning of the model or a later year, which would reward achievement but not necessarily improvement. While we propose in section III.C.5.b.(6)(c) of this proposed rule to establish minimum thresholds for participant hospital performance on three selected quality measures for reconciliation payment eligibility each performance year from the beginning of the model, we also discuss in detail an alternative we considered, which would make quality incentive payments related to hospital achievement and improvement on the basis of a composite quality score developed for each performance year. The composite quality score would affect reconciliation payment eligibility and change the effective discount included in the target price experienced by a participant hospital at reconciliation.

Similar to the proposal described in section III.C.5.b.(6)(c) of this proposed rule, the alternatives considered would require a determination of participant hospital performance on all three required quality measures, described in section III.D. of this proposed rule, based on the national distribution of hospital measure result performance, but instead of identifying the participant hospital's performance percentile for comparison with a threshold requirement, we would do so for purposes of assigning points toward a hospital composite quality score. Both the hospital-level 30-day, all cause Risk-Standardized Readmission Rate (RSRR) following elective primary THA and/or TKA (NQF #1551) measure and the hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA and/or TKA (NQF #1550) measure directly yield rates for which a participant hospital performance percentile could be determined and compared to the national distribution in a straightforward manner. As discussed in section III.D.2.c.of this proposed rule, we propose to use the HCAHPS Linear Mean Roll Up (HLMR) score calculated using the HCAHPS Survey (NQF #1661) measure. Once the HLMR scores are calculated, the participant hospital performance percentile could also be determined and compared to the national distribution in a straightforward manner. In addition, the alternatives considered would account for the successful submission of voluntary THA/TKA data on the patient-reported outcome measure, as discussed in section III.C.5.b.(2) of this proposed rule, in the calculation of the composite quality score.

(ii) Alternatives Considered To Link Quality and Payment

We considered assigning each participant hospital a composite quality score, developed as the sum of the individual quality measure scores described later in this section, which were set to reflect the intended weights for each of the quality measures and the successful submission of THA/TKA voluntary data in the composite quality score. The participant hospital's composite quality score would affect reconciliation payment eligibility and could also provide the opportunity for quality incentive payments under the CCJR model. Each quality measure would be assigned a weight in the composite quality score and possible scores for the measures would be set to reflect those weights. A composite quality score for each performance year would be calculated for each participant hospital based on its own performance that would affect reconciliation payment eligibility and the hospital's opportunity to receive quality incentive payments under the model. The composite quality score would also change the effective discount included in the target price experienced by the hospital at reconciliation for that performance year. We would weigh participant hospital performance on each of the three measures and successful submission of voluntary THA/TKA data according to the measure weights displayed in Table 8.

TABLE 8—QUALITY MEASURE WEIGHTS IN COMPOSITE QUALITY SCORE

Quality measure	Weight in composite quality score %
Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551)	20
Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550)	40
HCAHPS survey (NQF #1661)	30
Voluntary THA/TKA data submission on patient-reported outcome measure	10

We would assign the lowest weight of 10 percent to the successful submission of THA/TKA data on the patient-reported outcome measure because these data represent a hospital's meaningful participation in advancing the quality measurement of LEJR patient-reported outcomes but not actual outcome performance for LEJR episodes under the CCJR model. We believe the three required measures that represent LEJR outcomes deserve higher weights in the composite quality score. We would assign a modest weight of 20 percent to the readmissions measure because, while we believe that readmissions are an important quality measure for LEJR episodes, the episode payment methodology under the model already provides a strong financial incentive to reduce readmissions that otherwise would contribute significantly to greater actual episode payments. Furthermore, hospitals generally have already made significant strides over the past several years in reducing readmissions due to the inclusion of this measure in other CMS hospital programs that make payment adjustments based on performance on this measure. We believe that a higher weight than 20 percent would overvalue the contribution of readmissions performance as an indicator of LEJR episode quality in calculating the composite quality score. Furthermore, other CMS hospital programs may also make a payment adjustment based on hospital performance on the readmissions measure so we would not want this measure to also strongly influence reconciliation payment eligibility and the opportunity for quality incentive payments under the CCJR model. We would assign a higher

weight of 30 percent to the HCAHPS survey measure because we believe that incorporating this quality measure, which reflects performance regarding patients' perspectives on care, including communication, care transitions, and discharge information, is a highly meaningful outcome measure of LEJR episode quality under the CCJR model. However, we do not propose to assign the HCAHPS survey measure the highest weight of the four measures, as the measure is not specific to LEJR episode care, but rather to all clinical conditions treated by participant hospitals. Finally, we would assign the highest weight, 40 percent, to the complications measure. We believe this measure should be weighted the most because it is specific to meaningful outcomes for primary THA and TKA that are the major procedures included in LEJR episodes under the CCJR model. The measure includes important complications of LEJR episodes, such as myocardial infarction, pneumonia, surgical site bleeding, pulmonary embolism, death, mechanical joint complications, and joint infections occurring within various periods of time during the LEJR episode. LEJR episodes under the CCJR model are broadly defined so that reducing complications should be a major focus of care redesign that improves quality and efficiency under this model, yet because complications may not be as costly as readmissions, the payment incentives under the model do not as strongly target reducing complications as reducing readmissions. We seek comment on this weighting of the individual quality scores in developing a composite quality score for each participant hospital.

Under such an approach, we would first score individually each participant hospital on the Hospital-level 30-day, all-cause RSRR using the elective primary THA and/or TKA (NQF #1551) measure; Hospital-level RSCR following using the elective primary THA and/or TKA (NQF #1550) measure; and HCAPHS survey (NQF #1661) measure based on the participant hospital's performance percentile as compared to the national distribution of hospitals' measure performance, assigning scores according to the point values displayed in Table 9 These individual measure scores have been set to reflect the measure weights included in Table 9 so they can ultimately be summed without adjustment in calculating the composite quality score.

TABLE 9—INDIVIDUAL SCORING FOR THREE REQUIRED QUALITY MEASURES

Performance percentile	Complications measure quality score (points)	HCAHPS survey quality score (points)	Readmissions measure quality score (points)
≥90th	8.00	6.00	4.00
≥80th and <90th	7.40	5.55	3.70
≥70th and <80th	6.80	5.10	3.40
≥60th and <70th	6.20	4.65	3.10
≥50th and <60th	5.60	4.20	2.80
≥40th and <50th	5.00	3.75	2.50
≥30th and <40th	4.40	3.30	2.20
<30th	0.00	0.00	0.00

Given the current national distribution of hospital performance on these measures, we believe that small point increments related to higher measure performance deciles would be the most appropriate way to assign more points to reflect meaningfully higher quality performance on the measures. The absolute differences for each decile among the three measures reflect the intended weight of the measure in the composite quality score. We would assign any low volume participant hospital without a reportable value for the measure to the 50th performance percentile of the measure, so as not to disadvantage a participant hospital based on its low volume alone because that hospital may in actuality provide high quality care. These three measures are well-established measures in use under CMS hospital programs, so we do not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points for LEJR episodes under CCJR. However, we also considered reducing scores incrementally across the bottom three deciles in order to provide greater incentives for quality improvement for hospitals that may not believe they can attain the 30th performance percentile on one or more of the three measures and to avoid creating a ''cliff'' at the 30th performance percentile. We seek comment on this scoring approach to the three required quality measures.

Additionally, we would assign a measure quality score of one point for participant hospitals that successfully submit THA/TKA voluntary data and 0 points for participant hospitals that do not successfully submit these data. Because we would not use the actual THA/TKA voluntary data on the patient-reported outcome measure in assessing LEJR episode quality performance under the model, we propose this straightforward binary approach to scoring the submission of THA/TKA voluntary data for the patient-reported outcome measure development.

We note that the MSSP utilizes a similar scoring and weighting methodology, which is described in detail in the CY2011 Shared Savings Program Final Rule (see § 425.502). The HVBP and HACRP programs also utilize a similar scoring methodology, which applies weights to various measures and assigns an overall score to a hospital (79 FR 50049 and 50102).

We would sum the score on the three quality measures and the score on successful submission of THA/TKA voluntary data to calculate a composite quality score for each participant hospital. Then we would incorporate this score in the model payment methodology by first, requiring a minimum composite quality score for reconciliation payment eligibility if the participant hospital's actual episode spending is less than the target price and second, by making quality incentive payments that change the effective discount percentage included in the target price experienced by the hospital in the reconciliation process. The payment policies we would apply are displayed in Tables 10, 11, and 12 for the performance years of the model. Under the CCJR model as proposed, there is no participant hospital repayment responsibility in performance year 1 and this responsibility begins to be phased-in in

performance year 2, with full implementation in performance year 3.

TABLE 10—PERFORMANCE YEAR 1: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

Composite quality score	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment	Effective discount percentage for repayment amount
≤5.00	No	No	3.0	Not applicable.
>5.00 and ≤9.25	Yes	No	3.0	Not applicable.
>9.25 and ≤15.20	Yes	Yes	2.0	Not applicable.
>15.20	Yes	Yes	1.5	Not applicable.

TABLE 11—PERFORMANCE YEAR 2: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

Composite quality score	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment	Effective discount percentage for repayment amount
≤5.00	No	No	3.0	2.0
>5.00 and ≤9.25	Yes	No	3.0	2.0
>9.25 and ≤15.20	Yes	Yes	2.0	1.0
>15.20	Yes	Yes	1.5	0.5

TABLE 12—PERFORMANCE YEARS 3–5: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

Composite quality score	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment	Effective discount percentage for repayment amount
≤5.00	No	No	3.0	3.0
>5.00 and ≤9.25	Yes	No	3.0	3.0
>9.25 and ≤15.20	Yes	Yes	2.0	2.0
>15.20	Yes	Yes	1.5	1.5

Under this approach, the CCJR model discount included in the target price without consideration of the composite quality score would be 3.0 percent, not the 2.0 percent described under our payment proposal in section III.C.4.b.(9) of this proposed rule. We believe that a discount percentage of 3.0 percent without explicit consideration of episode quality is reasonable as it is within the range of discount percentages included in the ACE demonstration and it is the Model 2 BPCI discount factor for 30 and 60 day episodes, where a number of BPCI participants are testing LEJR episodes subject to the 3.0 percent discount factor. Hospitals that provide high quality episode care would have the opportunity to receive quality incentive payments that would reduce the effective discount percentage as displayed in Tables 10, 11, and 12. Depending on the participant hospital's actual composite quality score, quality incentive payments could be valued at 1.0 percent to 1.5 percent of the hospital's benchmark episode price (that is, of the expected episode spending prior to application of the discount factor to calculate a target price).

Under this methodology, we would require hospitals to achieve a minimum composite quality score of greater than 5.00 to be eligible for a reconciliation payment if actual episode spending was less than the target price. Participant hospitals with below acceptable quality performance reflected in a composite quality score less than or equal to 5.00 would not be eligible for a reconciliation payment if actual episode spending was less than the target price. A level of quality performance that is below acceptable would not affect participant hospitals' repayment responsibility if actual episode spending exceeds the target price. We believe that excessive reductions in utilization that lead to low actual episode spending and that could result from the financial incentives of an episode payment model would be limited by a requirement that this minimum level of LEJR episode quality be achieved for reconciliation payments to be made. This policy would encourage hospitals to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these hospitals would be ineligible to receive a reconciliation payment if actual episode spending was less than the target price.

For hospitals with composite quality scores of less than or equal to 5.00, we also considered a potential alternative approach. Under this approach, we would still permit this group of hospitals to receive reconciliation payments but would impose a quality penalty that would reduce their effective discount percentage to 4.0 percent for purposes of calculating the reconciliation payment or recoupment amount in performance years 3 through 5, 4.0 percent for calculating the reconciliation payment and 3.0 percent for calculating the repayment amount in performance year 2, and 4.0 percent for calculating the reconciliation payment in performance year 1 where participant

hospitals have no repayment responsibility. A potential advantage of this approach is that it would provide stronger incentives for quality improvement for participant hospitals with low performance on quality, even if they did not expect to be able to reduce actual episode spending below the target price. In addition, this approach would provide financial incentives to improve the efficiency of care even for hospitals that did not expect to meet the minimum quality score for reconciliation payment eligibility, while still providing strong incentives to provide high-quality care. The disadvantage of this approach is that it could provide reconciliation payments even to hospitals that did not achieve acceptable quality performance.

Participant hospitals with an acceptable composite quality score of >5.00 and ≤9.25 would be eligible for a reconciliation payment if actual episode spending was less than the target price because their quality performance was at the acceptable level established for the CCJR model. They would not be eligible for a quality incentive payment at reconciliation because their episode quality performance, while acceptable, was not good or excellent. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price.

Participant hospitals with a good composite quality score of >9.25 and ≤15.20 would be eligible for a quality incentive payment at reconciliation if actual episode spending was less than the target price because their quality performance exceeded the acceptable level required for reconciliation payment eligibility under the CCJR model. In addition, they would be eligible for a quality incentive payment at reconciliation for good quality performance that equals 1.0 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CCJR would either have less repayment responsibility (that is, the quality incentive payment would offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price and would also receive a quality incentive payment.

Finally, hospitals with an excellent composite score quality score of >15.20 would be eligible to receive a reconciliation payment if actual episode spending was less than the target price because their quality performance exceeded the acceptable level required for reconciliation payment eligibility under the CCJR model. In addition, they would be eligible for a higher quality incentive payment at reconciliation for excellent quality performance that equals 1.5 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CCJR would either have less repayment responsibility (that is, the quality incentive payment would offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price and would also receive a quality incentive payment.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.C.8 of this proposed rule would not change. We believe this approach to quality incentive payments based on the composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the CCJR model to the potential benefit of participant hospitals and their collaborators as well as CMS, although it would substantially increase the complexity of the methodology to link quality and payment. We seek comment on this alternative approach to basing reconciliation payment eligibility and quality incentive payments on the participant hospital's composite quality score under the CCJR model, as well as the composite quality scoring ranges applicable to the respective payment policies.

While we describe in detail this alternative considered to link quality to payment under CCJR, we are not proposing this methodology for several reasons. First, the MSSP and HVBP program utilize many more measures than we are proposing for the CCJR model. For example, the MSSP incorporates thirty three measures across four quality domains (79 FR 67916 and 67917). The range of measures in the MSSP and the HVBP program lends itself to a scoring approach, which can account for many measures and allows providers to achieve a high score despite performing well on some measures but achieving lower performance on others. There is a detailed description of the MSSP scoring methodology in the 2011 Shared Savings Program Final rule (76 FR 67895 through 67900). We believe that given the more limited set of measures chosen for the CCJR model, a scoring approach such as the alternative described in this section could diminish the importance of each measure. Use of a scoring approach would not allow hospital performance on two different outcomes to be easily reviewed and understood with respect to the impact of individual measure performance on Medicare's actual payment for the episode under the model. Second, we believe the measures proposed for this model represent goals of clinical care that should be achievable by all hospitals participating in the model that heighten their focus on these measures, especially the readmissions and complications measures, for LEJR episodes based on the financial incentives in the model. Finally, we believe that a methodology that assesses performance based on absolute values of a specific set of measures that are already in use, as we are proposing for the CCJR model, is the most appropriate methodology to provide achievable and predictable quality targets for participant hospitals on measures that monitor the most meaningful quality of care outcomes in a model where some acute care hospitals that might not choose to participate in a voluntary model are also included. Our proposed method as discussed in the next section reflects our expectation that hospitals achieve a certain level of performance on measures to ensure that hospitals provide high-quality care under the model.

Finally, we also considered an approach whereby participant hospitals would not be penalized with regard to their eligibility for reconciliation payments in CCJR for failure to meet the specified thresholds for the quality measures in performance year 1 of the model; in other words, we would delay the proposal described in the next

section to performance year 2 rather than beginning in performance year 1. We considered calculating participant hospital performance on the required measures for the model, and, if actual episode spending was less than the target price, the participant hospital would receive a full reconciliation payment of savings achieved beyond the target price, regardless of performance on the quality measures. However, we do not believe this would be appropriate for the CCJR model, given that two of the measures are administrative claims-based and thus impose no additional reporting burden on hospitals; rather, these two measures are established measures in existing CMS quality programs, and a central goal of the model is improving care for Medicare beneficiaries in LEJR episodes. We note that the HCAHPS survey measure is also an established measure in HIQR and would not impose additional reporting burden on hospitals.

(iii) Proposal To Link Quality and Payment Through Thresholds for Reconciliation Payment Eligibility

For the reasons outlined in the previous section, we do not propose to use similar methodologies to other CMS programs that would tie CCJR episode reconciliation payment eligibility and reconciliation payment and Medicare repayment amounts to a composite quality score on specified quality measures, but as discussed later in this section, we instead propose to simply assess performance or achievement on a quality measure by setting a measure result threshold for each measure beginning in performance year 1 of the model.

The CCJR measure result threshold would be based on the measure results from the HIQR program, a nationally-established program, and would use its national distribution of measure results. These are the same measure results posted on Hospital Compare or in the Hospital Compare downloadable database (*https://data.medicare.gov/data/hospital-compare*) for the HIQR program. We refer readers to the earlier discussion of the HIQR Program, which utilizes measures to assess most acute care hospitals in the nation. Determining the CCJR model target thresholds are discussed in the next section.

As previously described, the CCJR model proposes the following three required measures to assess LEJR episode quality of care:

- Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551).
- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550).
- HCAHPS survey (NQF #0166).

We also propose to make a voluntary reporting payment adjustment for CCJR participant hospitals who successfully and voluntarily submit data for the THA/TKA patient-reported outcome-based performance measure (henceforth referred to as ''THA/TKA voluntary data'') as described in sections III.C.5.b.(3) and III.D.3.a.(2) of this proposed rule. We propose that participant CCJR hospitals must meet or surpass a specified threshold for each required measure beginning for performance year 1 of the model in order to be eligible for a reconcilation payment if actual episode payments are less than the target price. The calculation of the HCAHPS survey measure is described in section III.D.2.c.of this proposed rule. We propose to use the individual measure results calculated as specified in section III.D. of this proposed rule for the three required measures to determine hospital eligibility for reconciliation payment for each performance year of the CCJR model. Also, as discussed in section III.C.4 of this proposed rule, which outlines the payment structure for the CCJR model, target prices for MS–DRG 470 anchored episodes and for MS–DRG 469 anchored episodes will be calculated for hospitals participating in the model for an episode of care extending 90-days after discharge from the anchor hospitalization. Participant hospitals that achieve actual episode payment below the specified target price for a given performance period would be eligible for a reconciliation payment, provided that the participant hospital also met episode quality thresholds on the three required measures for the performance period.

We propose to use the following quality criterion to determine if a participant hospital qualifies for a reconciliation payment based on the episode quality thresholds on the three required measures:

The hospital's measure result is at or above the 30th percentile of the national hospital measure results calculated for all HIQR-program participant hospitals for each of the three required measures for each performance period (for a detailed description of how we determined the performance period and reconciliation payment eligibility, see section III.C.5. of this proposed rule).

Using HIQR program's 3 year rolling period as outlined in section III.D.2.a.(6) and III.D.2.b.(6) of this proposed rule, if a participant hospital performed at or above the 30th percentile of all HIQR program hospitals for each of the three required measures and if actual episode payment was less than the target price for the specified performance year, we would make a reconciliation payment to the hospital. Failure to achieve the threshold on one or more measures would result in the participant hospital not receiving a reconciliation payment regardless of whether the actual episode payment was less than the target price for that performance period. We propose that for hospitals with insufficient volume to determine performance on an individual measure, these hospitals will be considered to be performing at the threshold level and their results will be publicly posted with all other participant hospitals' measure results (for a detailed summary of public reporting, see section III.D.5. of this proposed rule). We do not believe it would be appropriate to potentially penalize high quality, efficient hospitals due to their low volume, given that meeting the required quality measure thresholds is required for reconciliation payment eligibility.

We also propose for performance years 4 and 5 to increase the measure result threshold to the 40th percentile. We believe that increasing the measure result threshold to the 40th percentile would encourage participants to strive for continued quality improvement throughout the 5 performance years of the model. We seek comment on our proposal to make a reconciliation payment to a participant hospital that achieves actual episode spending below the target price for a performance year and performs at or above the 30th percentile of HIQR program participant hospitals for all three required quality measures in performance years 1 through 3 or the 40th percentile in performance years 4 and 5, as well as our proposal to consider low volume hospitals to be performing at the threshold level.

We propose to require hospitals to meet the threshold for all three measures for the following reasons. The measures chosen for this model are fully developed, NQF-endorsed, and implemented measures in CMS IPPS programs. These measures are also publicly reported on the Hospital Compare Web site. Hospitals are familiar with the complications and readmissions quality measures and with the HCAHPS Survey, as they are currently included in HIQR, HVBP, and HRRP (79 FR 50031, 50062, 50208, 50209 and 50259), and we believe that there is minimal additional administrative burden for hospitals. All three measures are widely utilized nationally; thus, a nationally-based

threshold is an appropriate benchmark. In addition, the goal of the CCJR model is LEJR episode care redesign that includes effective care coordination and management of care transitions. Strategies to prevent and efficiently manage post-procedure complications and hospital readmissions following an LEJR procedure are consistent with the goals of the model; a hospital cannot succeed in this model without engaging in care redesign efforts that would address aspects of care included in these measures. Failure to perform successfully on these key quality measures (defined by meeting the minimum thresholds) would indicate that hospitals are not achieving quality consistent with the goals of the model to specifically incentivize greater improvement on these measures than hospitals not participating in the CCJR model, and should not be eligible to receive a reconciliation payment from Medicare even if reduced episode spending is achieved. Finally, the approach we propose is consistent with CMS' goal of moving hospitals and other providers to value-based payment that ties payment to quality. In the 5 performance years of this model, performance on quality measures would only be applied to determining eligibility for a reconciliation payment; quality measures would not be used to determine participant hospitals' financial responsibility, except for the proposed voluntary reporting payment adjustment described in described in section III.C.5.b.(3) of this proposed rule. In essence, participant hospitals' responsibility to repay Medicare the difference between their target price and their actual episode payment, should actual episode payments exceed the target price, would not be impacted by performance on quality measures.

Finally, we propose to increase the measure result thresholds for the final 2 performance years of the model, to ensure that CCJR participant hospitals continue to maintain a high level of quality performance or improve performance on these measures as they gain experience with implementation of this payment model. More specifically, we propose that in order for a participant hospital to receive a reconciliation payment for actual episode spending that is less than the target price for performance years 4 and 5, the participant hospital's measure result must be at or above the 40th percentile of the national hospital measure results calculated for all HIQR-program participant hospitals for each of the three required measures for each performance period. As previously noted, we propose to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR. We believe that holding the participant hospitals to a set measure result threshold for the first 3 years, and increasing this threshold for performance years 4 and 5, emphasize the need to maintain and improve quality of care while cost efficiencies are pursued. We seek comment on our proposed approach to incorporating quality performance into eligibility for reconciliation payments under the CCJR model for participant hospitals.

Table 13 displays the proposed thresholds that participant hospitals must meet on the various measures over the 5 model performance years.

TABLE 13—PROPOSED THRESHOLDS FOR REQUIRED QUALITY MEASURES TO DETERMINE PARTICIPANT HOSPITAL RECONCILIATION PAYMENT ELIGILBITY OVER 5 YEARS

Measure	PY1 threshold	PY2 threshold	PY3 threshold	PY4 threshold	PY5 threshold
Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551).	30th percentile	30th percentile	30th percentile	40th percentile	40th percentile.
Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550).	30th percentile	30th percentile	30th percentile	40th percentile	40th percentile.
HCAHPS survey (NQF #0166)	30th percentile	30th percentile	30th percentile	40th percentile	40th percentile.

We seek comment on our proposed methodology to utilize quality measure performance in the payment methodology for CCJR, as well as the proposed thresholds for participant hospital reconciliation payment eligibility over the performance years of the model.

As discussed in section III.C.5.c.(3) of this proposed rule, we also believe that hospitals that choose to submit THA/TKA voluntary data should have the potential to benefit financially through an adjustment to the payment methodology of the model. We propose a voluntary reporting payment adjustment for hospitals that successfully submit the THA/TKA voluntary data by reducing the discount percentage incorporated into the target price from 2.0 percent to 1.7 percent. This voluntary reporting payment adjustment would start in performance year 1 and would be available through performance year 5 of the model for each year that the hospital successfully reports THA/TKA voluntary data. As proposed, reporting THA/TKA voluntary data would not affect eligibility for a reconciliation payment if actual episode payments are less than the target price. Participant hospitals would still need to meet the 30th or 40th percentile threshold, as applicable to the given performance year, on all three required quality measures (Table 13).

We considered, but are not proposing, two other alternatives to adjust the payment methodology for participant hospitals that successfully report the THA/TKA voluntary data as described in section III.C.5.c.(3) of this proposed rule. These alternatives would change the threshold percentile for the three required quality measures or, alternatively, reduce the number of required measures in which the threshold must be met provided that successful THA/TKA voluntary data were reported for a performance year. First, we considered reducing the threshold for reconciliation payment eligibility that participant hospitals must meet on the three required quality measures from the 30th percentile threshold to the 20th percentile threshold for performance years 1, 2, and 3, and from the 40th percentile to the 30th percentile for performance year. Second, we considered only requiring hospitals to meet the 30th percentile threshold on two of three outcome measures for performance years 1, 2, and 3, and the 40th percentile threshold on two of three outcome measures in performance years 4 and 5. Under both of these alternatives, the eligibility for reconciliation payments could change based on the THA/TKA voluntary data. We seek comment on these alternative payment methodology

adjustments that could impact reconciliation payment eligibility, unlike the proposed voluntary reporting payment adjustment. We note that the other alternative approaches to encouraging THA/TKA voluntary data reporting for CCJR beneficiaries as discussed in section III.C.5.c.(3) of this proposed rule that would not require adjustments to the CCJR payment methodology would also not affect reconciliation payment eligibility.

6. Proposed Process for Reconciliation

This section outlines our proposals on how we intend to reconcile aggregate related Medicare payments for a hospital's beneficiaries in CCJR episodes during a performance year against the applicable target price in order to determine if reconciliation payment (or Medicare repayment, beginning in performance year 2) is applicable under this model. We refer readers to section III.B of this proposed rule for our proposed definition of related services for lower extremity joint replacement episodes under CCJR, to section III.C.2.a. of this proposed rule for our proposed definition of performance years, and to section III.C.4 of this proposed rule for our proposed approach to establish target prices.

a. Net Payment Reconciliation Amount

After the completion of a performance year, we propose to retrospectively calculate a participant hospital's actual episode performance based on the episode definition. We note that episode payments for purposes of the CCJR model would exclude the effects of special payment provisions under existing Medicare payment systems (section III.C.3.a. of this proposed rule), be subject to proration for services that extend beyond the episode (section III.C.3.b. of this proposed rule), and exclude PBPM payments for programs and models specified in section III.C.7.d. of this proposed rule. Some episodes may be excluded entirely from the CCJR model due to overlap with BPCI episodes, as discussed in section III.C.7.b. of this proposed rule. Finally, actual episode payments calculated for purposes of CCJR would be capped at anchor MS–DRG and region-specific high episode payment ceilings (section III.C.3.c. of this proposed rule). We would apply the high episode payment ceiling policy to episodes in the performance year similarly to how we propose to apply it to historical episodes (section III.C.4.c. of this proposed rule). Episode payments for episodes attributed to CCJR eligible hospitals would be divided by the wage normalization factor, using the IPPS wage index applicable to the anchor admission, and for each MS–DRG anchor and region, the high episode payment ceiling would be calculated as two standard deviations above the mean. Any actual episode payment amount above the high payment ceiling would be capped at said ceiling. After applying the cap, wage variations would be reapplied to episodes by multiplying them by the same wage normalization factor, using the IPPS wage index applicable to the anchor admission.

Each participant hospital's actual episode payment performance would be compared to its target prices. We note that, as discussed in section III.C.4. of this proposed rule, a participant hospital would have multiple target prices for episodes ending in a given performance year, based on the MS–DRG anchor (MS–DRG 469 versus MS–DRG 470), the performance year when the episode was initiated, when the episode was initiated within a given performance year (January 1 through September 30 of the performance year, October 1 through December 31 of the performance year, October 1 through December 31 of the prior performance year), and whether the participant hospital successfully submitted THA/TKA voluntary data. The applicable target price for each episode would be determined using the aforementioned criteria, and the difference between each CCJR episode's actual payment and the relevant target price (calculated as target price subtracted by CCJR actual episode payment) would be aggregated for all episodes for a participant hospital within the performance year, representing the raw Net Payment Reconciliation Amount (NPRA). This amount would be adjusted per the steps discussed later in this section, creating the NPRA.

The NPRA would include adjustments to account for post-episode payment increases (section III.C.8.e. of this proposed rule). The NPRA would also include adjustments for stop-loss and stop-gain limits (section III.C.8.b. of this proposed rule), after adjustments are made for the aforementioned post-episode payment increases. Any NPRA amount greater than the proposed stop-gain limit would be capped at the stop-gain limit, and any NPRA amount less than the proposed stop-loss limit would be capped at the stop-loss limit.

We do not propose to include any CCJR reconciliation payments or repayments to Medicare under this model for a given performance year in the NPRA for a subsequent performance year. We want to incentivize providers to provide high quality and efficient care in all years of the model. If reconciliation payments for a performance year are counted as Medicare expenditures in a subsequent performance year, a hospital would experience higher Medicare expenditures in the subsequent performance year as a consequence of providing high quality and efficient care in the prior performance year, negating some of the incentive to perform well in the prior year. Therefore, we propose to not have the NPRA for a given performance year be impacted by CCJR Medicare repayments or reconciliation payments made in a prior performance year. However, as discussed in section III.C.6.b, during the following performance year's reconciliation process, we propose to account for additional claims run-out and overlap from the prior performance year, and net that amount with the subsequent performance year's NPRA to determine the reconciliation or repayment amount for the current reconciliation.

b. Payment Reconciliation

We propose to reconcile payments retrospectively through the following reconciliation process. We would reconcile a participant hospital's CCJR actual episode payments against the target price 2 months after the end of the performance year. More specifically, we would capture claims submitted by March 1st following the end of the performance year and carry out the NPRA calculation as described previously to make a reconciliation payment or hold hospitals responsible for repayment, as applicable, in quarter 2 of that calendar year.

To address issues of overlap with other CMS programs and models that are discussed in section III.C.7. of this proposed rule, we also propose that during the following performance year's reconciliation process, we would calculate the prior performance year's episode spending a second time to account for final claims run-out, as well as overlap with other models as discussed in section III.C.7 of this proposed rule. This would occur approximately 14 months after the end of the prior performance year. As discussed later in this section, the amount from this calculation, if different from zero, would be applied to the NPRA for the subsequent performance year in order to determine the amount of the payment Medicare would make to the hospital or the hospital's repayment amount. We note that the subsequent reconciliation calculation would be applied to the previous calculation of NPRA for a performance year to ensure the stop loss and stop gain limits discussed in section

III.C.8. of this proposed rule are not exceeded for a given performance year.

For the performance year 1 reconciliation process, we would calculate a participant's NPRA, as described above, and if positive, the hospital would receive the amount as a reconciliation payment from Medicare. If negative, the hospital would not be responsible for repayment to Medicare, consistent with our proposal to phase in financial responsibility beginning in performance year 2. Starting with the CCJR reconciliation process for performance year 2, in order to determine the reconciliation or repayment amount, the amount from the subsequent reconciliation calculation would be applied to the NPRA. If the amount is positive, and if the hospital meets the quality thresholds for that performance year (discussed further in section III.C.5. of this proposed rule), the hospital would receive the amount as a reconciliation payment from Medicare. If the amount is negative, Medicare would hold the participant hospital responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts. Note that given our proposal to not hold participant hospitals financially responsible for repayment for the first performance year, during the reconciliation process for performance year 2 only, the subsequent calculation amount (for performance year 1) would be compared against the performance year 1 NPRA to ensure that the sum of the NPRA calculated for performance year 1 and the subsequent reconciliation calculation for year 1 is not less than zero. For performance years 2 through 5, though, Medicare would hold the participant hospital responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts.

This reconciliation process would account for overlaps between the CCJR model and other CMS models and programs as discussed in section III.C.7 of this proposed rule, and would also involve updating performance year episode claims data. For example, for performance year 1 for the CCJR model in 2016, we would capture claims submitted by March 1st, 2017, and reconcile payments for participant hospitals approximately 6 months after the end of the performance year in quarter 2 of calendar year 2017. We would carry out the subsequent calculation in the following year in quarter 2 of calendar 2018, simultaneously with the reconciliation process for the second performance year, 2017. Table 14 provides the proposed reconciliation timeframes for the model. Lastly, we propose that the reconciliation payments to or repayments from the participant hospital would be made by the Medicare Administrative Contractor (MAC) that makes payment to the hospital under the IPPS. This approach is consistent with BPCI Model 2 operations.

We believe our proposed approach balances our goals of providing reconciliation payments in a reasonable timeframe, while being able to account for overlap and all Medicare claims attributable to episodes. We believe that pulling claims 2 months after the end of the performance year provides sufficient claims run-out to conduct the reconciliation in a timely manner, given that our performance year includes episodes ending, not beginning, by December 31st. We note that in accordance with the regulations at § 424.44 and the Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 1, Section 70, Medicare claims can be submitted no later than 1 calendar year from the date of service. We recognize that by pulling claims 2 months after the end of the performance year to conduct reconciliation, we would not have complete claims run-out. However, we believe that the 2 months of claims run out would be an accurate reflection of episode spending and consistent with the claims run-out timeframes used for reconciliation in other payment models, such as BPCI Models 2 and 3. The alternative would be to wait to reconcile until we have full claims run out 12 months after the end of the performance year, but we are concerned that this approach would significantly delay earned reconciliation payments under this model. Because we propose to conduct a second calculation to account for overlap with other CMS models and programs, we can incorporate updated claims data with 14 months run out at that time. However, we do not expect that the updated data should substantially, in and of itself, affect the reconciliation results assuming hospitals and other providers furnishing services to Medicare beneficiaries in CCJR episodes follow usual patterns of claims submission and do not alter their billing practices due to this model.

TABLE 14—PROPOSED TIMEFRAME FOR RECONCILIATION IN CCJR

Model performance year	Model performance period	Reconciliation claims submitted by	Reconciliation payment or repayment	Second calculation to address overlaps and claims run-out	Second calculation adjustment to reconciliation amount
Year 1*	Episodes ending March 31, 2016 to December 31, 2016.	March 1, 2017	Q2 2017	March 1, 2018	Q2 2018
Year 2	Episodes ending January 1, 2017 through December 31, 2017.	March 1, 2018	Q2 2018	March 1, 2019	Q2 2019
Year 3	Episodes ending January 1, 2018 through December 31, 2018.	March 1, 2019	Q2 2019	March 2, 2020	Q2 2020
Year 4	Episodes ending January 1, 2019 through December 31, 2019.	March 2, 2020	Q2 2020	March 1, 2021	Q2 2021
Year 5	Episodes ending January 1, 2020 through December 31, 2020.	March 1, 2021	Q2 2021	March 1, 2022	Q2 2022

* Note that the reconciliation for Year 1 would not include repayment responsibility from CCJR hospitals.

7. Proposed Adjustments for Overlaps With Other Innovation Center Models and CMS Programs

a. Overview

We acknowledge that there may be circumstances where a Medicare beneficiary in a CCJR episode may also be assigned to an ACO participating in the MSSP or otherwise accounted for in a payment model being tested by the Innovation Center. Current or forthcoming programs and models with potential overlap with CCJR are displayed in Table 15. For purposes of this proposed rule, ''total cost of care'' models refer to models in which episodes or performance periods include participant financial responsibility for all Part A and Part B spending, as well as some Part D spending in select cases. We use the term ''shared savings'' in this proposed rule to refer to models in which the payment structure includes a calculation of total savings and CMS and the model participants each retain a particular percentage of that savings. We note that there exists the possibility for overlap between CCJR episodes and shared savings models such as the Pioneer ACO Model, other total cost of care models such as the Oncology Care Model (OCM), other Innovation Center payment models such as BPCI, and other models or programs that incorporate per-beneficiary-per-month fees or other payment structures.

TABLE 15—CURRENT PROGRAMS AND MODELS WITH POTENTIAL OVERLAP WITH PROPOSED CCJR MODEL

Program/model	Brief description	Shared savings?	Per-beneficiary-per-month (PBPM) payments?
Pioneer	ACO shared savings program	Yes	No.
Medicare Shared Savings Program (MSSP)	ACO shared savings program	Yes	No.
Next Generation ACO	ACO shared savings program	Yes	No.
Comprehensive Primary Care initiative (CPCi)	Pays primary care providers for improved and comprehensive care management.	Yes	Yes.
Multi-payer Advanced Primary Care Practice (MAPCP)	Multi-payer model for advanced primary care practices, or ''medical homes''.	Yes	Yes.
Bundled Payments for Care Improvement (BPCI)	Bundled payment program for acute or post-acute services or both.	No	No.
Oncology Care Model (OCM)	Multi-payer model for oncology physician group practices.	No	Yes.
Comprehensive ESRD Care Initiative (CEC)	ACO for ESRD Medicare beneficiaries	Yes	No.
Million Hearts	Model targeting prevention of heart attack and stroke	No	Yes.
Medicare Care Choices Model	Hospice concurrent care model	No	Yes.

Four different issues may arise in such overlap situations that must be addressed under CCJR. First, beneficiaries in CCJR episodes could also be part of BPCI Model 2 or 3 LEJR episodes, and the clinical services provided as part of each episode may overlap entirely or in part. Second, CCJR reconciliation payments and Medicare repayments that are made under Part A and B and attributable to a specific beneficiary's episode may be at risk of not being accounted for by other models and programs when determining the cost of care under Medicare for that beneficiary. Third, some Innovation Center models make PBPM payments to entities for care coordination and other activities, either from the Part A or B Trust or both, or from the Innovation Center's own appropriation (see section 1115A(f) of the Act). These payments may occur during a CCJR episode. Finally, there could be instances when the expected Medicare savings for a CCJR beneficiary's episode is not achieved by Medicare because part of that savings is paid back to the hospital or another entity under a shared savings program or other model in which the beneficiary is also included. We seek comment on our proposals to account for overlap with other models, including those listed in Table 15 as well as other CMS models or programs.

b. CCJR Beneficiary Overlap With BPCI Episodes

BPCI is an episode payment model testing LEJR episodes, as well as 47 other episodes, in acute or PAC or both (Models 1, 2, 3 or 4). As discussed in section III.A. of this proposed rule, we propose to exclude from selection for participation in the CCJR payment model those geographic areas where 50 percent or more of LEJR episodes are initiated at acute care hospitals testing the LEJR episode in BPCI in Models 1, 2 or 4 as of July 1, 2015. In that same section, we propose that acute care hospitals in selected geographic areas participating in BPCI under Model 1 (acute care only) and those participating as episode initiators for the LEJR episode in Model 2 (acute and PAC from 30 to 90 days post-discharge) or Model 4 (prospective episode payment for the LEJR anchor hospital stay and related readmissions for 30 days post-discharge) be excluded from CCJR.

While we believe these proposals will mitigate the overlap of CCJR beneficiaries with BPCI episodes, there may still be instances of model overlap that we need to account for under CCJR. These include circumstances when a beneficiary is admitted to a participating CCJR hospital for an LEJR procedure where the beneficiary would also be in a BPCI Model 2 episode under a physician group practice that would initiate the episode under BPCI. In another example, a beneficiary discharged from an anchor hospitalization under CCJR could enter a BPCI Model 2 LEJR episode at another hospital for a phased second joint replacement procedure or enter a BPCI Model 3 LEJR episode upon initiation of PAC services at a BPCI post-acute provider episode initiator for the LEJR episode. Similarly, a beneficiary in a BPCI Model 2 or Model 3 LEJR episode could be admitted to a CCJR participant hospital for a phased second joint replacement. In all such scenarios in which there is overlap of CCJR beneficiaries with any BPCI LEJR episodes, we propose that the BPCI LEJR episode under Models 1, 2, 3, or 4 take precedence and we would cancel (or never initiate) the CCJR episode. Because the cancellation (or lack of initiation) would only occur for overlap with BPCI LEJR episodes, we expect that the participant hospital and treating physician would generally be aware of the beneficiary's care pathway that

would cancel or not initiate the CCJR episode. Therefore, we would exclude the CCJR episode from the CCJR participant hospital's reconciliation calculations where we compare actual episode payments to the target price under the CCJR model. If we were to allow both CCJR and BPCI LEJR episodes to overlap, we would have no meaningful way to apply the payment policies in two models with overlapping care redesign interventions and episodes. Participants in BPCI have an expectation that eligible episodes will be part of the BPCI model test, whereas based on our proposal CCJR participants would be aware that episodes may be canceled when there is overlap with BPCI episodes as previously discussed in this section. We aim to preserve the integrity of ongoing model tests without introducing major modifications (that is, CCJR episode precedence) that could make evaluation of existing models more challenging.

We considered that there may also be instances of overlap between CCJR and BPCI Model 3 LEJR episodes where our proposal to give precedence to all BPCI episodes could lead to undesirable patient steering because the BPCI Model 3 episode does not begin until care is initiated at an episode-initiating PAC provider. It could be possible for a participating CCJR hospital to purposefully guide a beneficiary to a BPCI Model 3 LEJR episode initiating PAC provider to exclude that beneficiary's episode from CCJR. We considered giving precedence to the CCJR episode in overlap with Model 3 beneficiaries because the CCJR episode begins with admission for the anchor hospitalization and thus includes more of the episode services. However, we believe the steering opportunities would be limited due to the preservation of beneficiary choice of provider in this model (as discussed in section III.E. of this proposed rule). As outlined in section III.E. of this proposed rule, CCJR hospitals must provide patients with a complete list of all available PAC options. Moreover, BPCI Model 3 post-acute providers are actively involved in the decision to admit patients to their facilities. As episode initiators in BPCI, such providers are subject to monitoring and evaluation under that model and would be vigilant about not engaging in steering themselves or spurred by other providers. Nevertheless, we will monitor CCJR hospitals to ensure steering or other efforts to limit beneficiary access or move beneficiaries out of the model are not occurring (see section III.F. of this proposed rule).

We seek comment on the proposed approach to address overlap between CCJR and BPCI episodes.

c. Accounting for CCJR Reconciliation Payments and Repayments in Other Models and Programs

Under CCJR, we would annually, as applicable, make reconciliation payments to or receive repayments from participating CCJR hospitals based on their quality performance and Medicare expenditures, as described in section III.C.6. of this proposed rule. While we propose that these reconciliation payments or repayments would be handled by MACs, the calculation of these amounts would be done separately before being sent through the usual Medicare claims processing systems. Nevertheless, it is important that other models and programs in which providers are accountable for the total cost of care be able to account for the full Medicare payment, including CCJR-related reconciliation payments and repayments as described in section III.C.6. of this proposed rule, for beneficiaries who are also in CCJR episodes. Accordingly, it is necessary to have beneficiary-specific information on CCJR-related reconciliation payments and repayments available when those models and programs make their financial calculations. Thus, in addition to determining reconciliation payments and repayments for the participant hospitals in the CCJR model, we propose to also calculate beneficiary-specific reconciliation payment or repayment amounts for CCJR episodes to allow for those other programs and models, as their reconciliation calculation timeframes permit, to determine the total cost of care for overlapping beneficiaries. We would perform the reconciliation calculations for CCJR hospitals and make information about the CCJR reconciliation or repayment amounts available to other programs and models, such as MSSP and Pioneer ACO, that begin reconciliation calculations after CCJR. For example, this strategy is currently in place to account for overlaps between beneficiaries aligned to Pioneer and MSSP ACOs and BPCI model beneficiaries. Beneficiary-specific reconciliation payment or repayment amounts are loaded into a shared repository for use during each program or model's respective reconciliations. However, we note that we would not make separate payments to, or collect repayments from, participating CCJR hospitals for each individual episode, but, instead, propose to make a single aggregate reconciliation payment or repayment determination for all episodes for a single performance year, as discussed in section III.C.6. of this proposed rule.

As described in section III.C.6 of this proposed rule on the Proposed Process for Reconciliation, we propose to conduct reconciliation based on claims data available 2 months after the end of the performance year and a second calculation based on claims data available 14 months after the end of a performance year to account for claims run-out and potential overlap with other models. The rationale for this reconciliation process is to be able make payments to, and recoup payments from, CCJR participant hospitals in a timely manner and to be able to account for overlaps in other models and programs. In addition, the timing of the reconciliation was determined giving consideration to when the other total cost of care models conduct their reconciliations so that when they perform their financial calculations, they will have the information necessary to account for beneficiary-specific payments/repayments made under the CCJR model. We intend to report beneficiary-specific payments and repayment amounts made for the CCJR model in the CMS Master Database Management System that generally holds payments/repayment amounts made for CMS models and programs. Other total cost of care models and programs can use the information on CCJR payment/repayment amounts reported in the Master Database Management System in their financial calculations such as in their baseline or benchmark calculations or reconciliations, to the extent that is consistent with their policies.

We seek comment on our proposed approach to ensuring that the full CCJR episode payment for a beneficiary is accounted for when performing financial calculations for other total cost of care and episode-based payment models and programs.

d. Accounting for PBPM Payments in the Episode Definition

There are currently five CMS models that pay PBPM payments to providers for new or enhanced services as displayed in Table 15. These PBPM payments vary as to their funding source (Medicare Trust Funds or Innovation Center appropriation), as well as to their payment methodology.

In general, these PBPM payments are for new or enhanced provider or supplier services that share the goal of improving quality of care overall and reducing Medicare expenditures for services that could be avoided through improved care coordination. Some of

these PBPM payments may be made for services furnished to a beneficiary that is in another Innovation Center model at the that same time that the beneficiary is in a CCJR LEJR episode, but the clinical relationship of services paid by the PBPM payments to the CCJR episode will vary. For purposes of CCJR, we consider clinically related those services paid by PBPMs that are for the purpose of care coordination and care management of any beneficiary diagnosis or hospital readmission not excluded from the CCJR episode definition, as discussed in section III.B.2 of this proposed rule.

We would determine whether the services paid by PBPM payments are excluded from the CCJR episode on a model by model basis based on their funding source and clinical relationship to CCJR episodes. If we determine a model's PBPM payments are for new or enhanced services that are clinically related to the CCJR episode and the PBPM payment is funded through the Medicare Part A or B Trust Fund, we would include the services paid by the PBPM payment to the extent they otherwise meet the proposed episode definition for the CCJR model. That is, we would include the clinically related services paid by a PBPM payment if the services would not otherwise be excluded based on the principal diagnosis code on the claim, as discussed in section III.B.2 of this proposed rule. The PBPM payments for clinically related services would not be excluded from the historical CCJR episodes used to calculate target prices when the PBPM payments are present on Part A or Part B claims, and they would not be excluded from calculation of episode actual expenditures during the performance period. PBPM model payments that we determine are clinically unrelated would be excluded, regardless of the funding mechanism or diagnosis codes on claims for those payments. We note that in the case of PBPM model payments, principal diagnosis codes on a Part B claim (which are used to identify exclusions from CCJR episodes, as discussed in section III.B.), would not denote the only mechanism for exclusion of a service from the CCJR episode. All such PBPM model payments we determine are clinically unrelated would be excluded as discussed in this proposal. Finally, all services paid by PBPM payments funded through the Innovation Center's appropriation under section 1115A of the Act would be excluded from CCJR episodes, without a specific determination of their clinical relationship to CCJR episodes. We believe including such PBPM payments funded under the Innovation Center's appropriation and not included on claims would be operationally burdensome and could significantly delay any reconciliation payments and repayments for the CCJR model. In addition, because these services are not paid for from the Medicare Part A or B Trust Fund, we are not confident that they would be covered by Medicare under existing law. Therefore, we believe the services paid by these PBPM payments are most appropriately excluded from CCJR episodes. Our proposal for the treatment of services paid through model PBPM payments in CCJR episodes would pertain to all existing models with PBPM payments, as well as future models and programs that incorporate PBPM payments. We believe that this proposal is fully consistent with our goal of including all related Part A and Part B services in the CCJR episodes, as discussed in section III.B.2. of this proposed rule.

Under this proposal, only one of the four existing models displayed in Table 15 include services paid by PBPM payments that would not be excluded from CCJR episodes. The MAPCP model makes PBPM payments that are funded through the Trust Fund for new or enhanced services that coordinate care, improve access, and educate patients with chronic illnesses. We expect these new or enhanced services to improve quality and reduce spending for services that may have otherwise occurred, such as hospital readmissions, and consider them to be clinically related to CCJR episodes because the PBPM payments would support care coordination for medical diagnoses that are not excluded from CCJR episodes. Thus, we propose that services paid by PBPM payments under the MAPCP model not be excluded from CCJR episodes to the extent they otherwise meet the proposed episode definition. While the OCM model will pay for new or enhanced services through PBPM payments funded by the Medicare Part B Trust Fund, we do not believe these services are clinically related to CCJR episodes. The OCM model incorporates episode-based payment initiated by chemotherapy treatment, a service generally reported with ICD–9–CM codes that are specifically excluded from the proposed CCJR episode definition in section III.B.2. of this proposed rule. We believe the care coordination and management services paid by OCM PBPM payments would be focused on chemotherapy services and their complications, so the services would be clinically unrelated to CCJR episodes. Therefore, we propose that services paid by PBPM payments under the OCM model be excluded from CCJR episodes. Similarly, we propose to exclude services paid by PBPM payments under the Medicare Care Choices model, because the model's focus on palliative care for beneficiaries with a terminal illness means the PBPM payments would pay for services that are clinically unrelated to CCJR episodes. The services paid by PBPM payments under this model would commonly pertain to diagnoses that are excluded from the proposed CCJR episode definition. Finally, new or enhanced services paid by PBPM payments under the Comprehensive Primary Care initiative (CPCi) are paid out of the Innovation Center's appropriation and thus would be excluded from CCJR episodes according to this proposal.

We acknowledge there may be new models not included Table 15 that could incorporate a PBPM payment for new or enhanced services. We would plan to make our determination about whether services paid by a new model PBPM payment that is funded under the Medicare Trust Funds are clinically related to CCJR episodes through the same subregulatory approach that we are proposing to use to update the episode definition (excluded MS–DRGs and ICD–9–CM diagnosis codes). We would assess each model's PBPM payment to determine if it would be primarily used for care coordination or care management services for excluded clinical conditions under the LEJR episode definition for CCJR based on the standards we propose to use to update the episode definition that are discussed in section III.B.2 of this proposed rule.

If we determine that the PBPM payment would primarily be used to pay for services to manage an excluded clinical condition, we would exclude the PBPM payment from the CCJR episode on the basis that it pays for unrelated services. If we determine that the PBPM payment could primarily be used for services to manage an included clinical condition, we would include the PBPM payment in the CCJR episode if the diagnosis code on the claim for the PBPM payment was not excluded from the episode, following our usual process for determining excluded claims for Part B services in accordance with the episode definition discussed in section III.C.2 of this proposed rule. We would post our proposed determination about whether the PBPM payment would be included in the episode to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to

the overlap list with posting to the CMS Web site of the final updated list after our consideration of the public input.

We seek comment on our proposals to account for Innovation Center model PBPM payments under CCJR.

e. Accounting for Overlap With Shared Savings Programs and Total Cost of Care Models

In addition to the Medicare Shared Savings Program (MSSP) under section 1899 of the Act, there are several ACO and other Innovation Center models that make or will make, once implemented, providers accountable for total cost of care over 6 to 12 months, including the Pioneer ACO Model, Next Generation ACO, Comprehensive ESRD Care (CEC) Model, CPCi, OCM, and the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration. Some of these are shared savings models (or programs, in the case of MSSP), while others are not shared savings but hold participating providers accountable for the total cost of care during a defined episode of care, such as OCM. Note that as discussed in section III.C.7.a. of this proposed rule, for purposes of this proposed rule, ''total cost of care'' models refer to models in which episodes or performance periods include participant financial responsibility for all Part A and Part B spending, as well as some Part D spending in select cases. Each of these payment models holds providers accountable for the total cost of care over the course of an extended period of time or episode of care by applying various payment methodologies. We believe it is important to simultaneously allow beneficiaries to participate in broader population-based and other total cost of care models, as well as episode payment models that target a specific episode of care with a shorter duration, such as CCJR. Allowing beneficiaries to receive care under both types of models may maximize the potential benefits to the Medicare Trust Funds and participating providers and suppliers, as well as beneficiaries. Beneficiaries stand to benefit from care redesign that leads to improved quality for LEJR episodes of care even while also receiving care under these broader models, while entities that participate in other models and programs that assess total cost of care stand to benefit, at least in part, from the cost savings that accrue under CCJR. For example, a beneficiary receiving an LEJR procedure may benefit from a hospital's care coordination efforts with regard to care during the inpatient hospital stay. The same beneficiary may be attributed to a primary care physician affiliated with an ACO who is actively engaged in coordinating care for all of the beneficiary's clinical conditions throughout the entire performance year, beyond the 90-day post-discharge LEJR episode.

We propose that a beneficiary could be in a CCJR episode, as defined in section III.B. of this proposed rule, by receiving an LEJR procedure at a CCJR hospital, and also attributed to a provider participating in a model or program in Table 15. For example, a beneficiary may be attributed to a provider participating in the Pioneer ACO model for an entire performance year, as well as have a CCJR episode during the ACO's performance year. Each model incorporates a reconciliation process, where total included spending during the performance period or episode are calculated, as well as any potential savings achieved by the model or program. Given that we are proposing to allow for such beneficiary overlap, we believe it is important to account for savings under CCJR and the other models and programs with potential overlap in order that CMS can apply the respective individual savings-related payment policies of the model or program, without attributing the same savings to more than one model or program.

We believe that when overlap occurs, it is most appropriate to attribute Medicare savings accrued during the CCJR time period (hospital stay plus 90 days post-discharge) to CCJR to the extent possible. The CCJR episode has a shorter duration and is initiated by a major surgical procedure, requiring an inpatient hospitalization. In contrast, the total cost of care models listed in Table 15 incorporate 6 to 12 month performance periods for participants and, in general, have a broader focus on beneficiary health. Our intention is to ensure that CCJR episodes are attributed the full expected savings to Medicare to the extent possible. As such, we propose the following policies to ensure that other models are able to account for the reconciliation payments paid to CCJR hospitals to the extent possible prior to performing their own reconciliation calculations and that, in all appropriate circumstances, the CCJR model or the other model would make an adjustment for savings achieved under the CCJR model and partially paid back through shared savings/performance payments under other initiatives to ensure that the full CCJR model savings to Medicare is realized.

We propose that the total cost of care calculations under non-ACO total cost of care models would be adjusted to the extent feasible to account for beneficiaries that are aligned to participants in the model and whose care is included in CCJR in order to ensure that the savings to Medicare achieved under CCJR (the discount percentage) are not paid back under these other models through shared savings or other performance-based payment. Thus, the non-ACO total cost of care models would adjust their calculations to ensure the CCJR discount percentage is not paid out as savings or other performance-based payment to the other model participants. As previously discussed, we believe that the efficiencies achieved during the CCJR episode should be credited to the entity that is closest to that care for the episode of care in terms of time, location, and care management responsibility, rather than the broader entity participating in a total cost of care model that spans a longer duration. We propose that the non-ACO total cost of care models to which this policy would apply would include CPCi, OCM, and MAPCP. We seek comment on our proposal to account for overlap with those non-ACO total cost of care models and any other current or forthcoming models.

We propose a different policy for accounting for overlap with MSSP and other ACO models. We note that given the operational complexities and requirements of the MSSP reconciliation process, it is not feasible for MSSP to make an adjustment to account for the discount to Medicare under a CCJR episode under existing program rules and processes. Additionally, for programmatic consistency among ACO models and programs, given that our ACO models generally are tested for the purpose of informing future potential changes to MSSP, we believe that the ACO model overlap adjustment policy should be aligned with the MSSP policy. Thus, we propose that under CCJR, we would make an adjustment to the reconciliation amount if available to account for any of the applicable discount for an episode resulting in Medicare savings that is paid back through shared savings under MSSP or any other ACO model, but only when a CCJR participant hospital also participates in the ACO and the beneficiary in the CCJR episode is also aligned to that ACO. This adjustment would be necessary to ensure that the applicable discount under CCJR is not reduced because a portion of that discount is paid out in shared savings to the ACO and thus, indirectly, back to the hospital.

However, we propose not to make an adjustment under CCJR when a

beneficiary receives an LEJR procedure at a participant hospital and is aligned to an ACO in which the hospital is not participating. While this proposal would leave overlap unaccounted for in such situations, we do not believe it would be appropriate to hold responsible for repayment the hospital that managed the beneficiary during the episode through a CCJR adjustment, given that the participant hospital may have engaged in care redesign and reduced spending during the CCJR episode. The participant hospital may be unaware that the beneficiary is also aligned to an ACO. However, we recognize that as proposed this policy would allow an unrelated ACO full credit for the Medicare savings achieved during the episode. The evaluation of the CCJR model, as discussed in section IV of this proposed rule, would examine overlap in such situations and the potential effect on Medicare savings.

We note that our proposed policy as outlined in this proposed rule would entail CCJR reclaiming from the participant hospital any discount percentage paid out as shared savings for MSSP or ACO models only when the hospital is an ACO participant and the beneficiary is aligned with that ACO, while other total cost of care models such as CPCi would adjust for the discount percentage in their calculations. While it is operationally feasible for smaller total cost of care models in testing, such as CPCi, to make an adjustment to account for any CCJR discount percentage paid out as sharing savings or other performance-based payments, the operational complexities and requirements of the large permanent Medicare ACO program, MSSP, make it infeasible for that program to make an adjustment in such cases, and we believe that other ACO models in testing that share operating principles with the MSSP should follow the same policies as the CCJR MSSP adjustment for certain overlapping ACO beneficiaries. As the landscape of CMS models and programs changes, we may revisit this policy through future rulemaking.

We seek comment on our proposals for adjustments to account for overlap between CCJR and shared savings programs and total cost of care models.

8. Proposals To Limit or Adjust Hospital Financial Responsibility

a. Overview

As discussed in section III.A of this proposed rule, we propose designating as the financially responsible providers in CCJR all acute care hospitals paid under the IPPS that are located in the selected geographic areas for this test of 90-day post-discharge LEJR episodes, with the exception of some hospitals that we propose to exclude because of participation in BPCI (Models 1, 2, or 4) for LEJR episodes. We are interested in ensuring a broad test of episode payment for this clinical condition among different types of hospitals, including those who may not otherwise choose to participate in an episode payment model. Many of the participant hospitals would likely be key service providers in their communities for a variety of medical and surgical conditions extending well beyond orthopedic procedures. We want to gain experience with this model before extending it to hospitals in uncommon circumstances. In addition, we acknowledge that hospitals designated for participation in CCJR currently vary with respect to their readiness to function under an episode payment model with regard to their organizational and systems capacity and structure, as well as their beneficiary population served. Some hospitals may more quickly be able to demonstrate high quality performance and savings than others, even though we propose that the episode target prices be based predominantly on the hospital's own historical episode utilization in the early years of CCJR.

We also note that providers may be incentivized to excessively reduce or shift utilization outside of the CCJR episode, even with the quality requirements discussed in section III.C.5 of this proposed rule. In order to mitigate any excessive repayment responsibility for hospitals or reduction or shifting of care outside the episode, especially beginning in performance year 2 of the model when we propose to begin to phase in responsibility for repaying Medicare for excess episode spending, we propose several specific policies that are also referenced in section III.C.6.b. of this proposed rule.

b. Proposed Limit on to Raw NPRA Contribution to Repayment Amounts and Reconciliation Payments

(1) Proposed Limit on Raw NPRA Contribution to Repayment Amounts

When hospital repayment responsibility begins in the second performance year of CCJR, under this proposed rule, hospitals would be required to repay Medicare for episode expenditures that are greater than the applicable target price. As discussed in the section III.C.3.c of this proposed rule regarding our proposed pricing adjustment for high payment episodes, hospitals participating in CCJR would not bear financial responsibility for actual episode payments greater than a ceiling set at two standard deviations above the mean regional episode payment. Nevertheless, hospitals would begin to bear repayment responsibility beginning in performance year 2 for those episodes where actual episode expenditures are greater than the target price up to the level of the regional episode ceiling. In aggregate across all episodes, the money owed to Medicare by a hospital for actual episode spending above the applicable target price could be substantial if a hospital's episodes generally had high payments. As an extreme example, if a hospital had all of its episodes paid at two standard deviations above the mean regional episode payment, the hospital would need to repay Medicare a large amount of money, especially if the number of episodes was large.

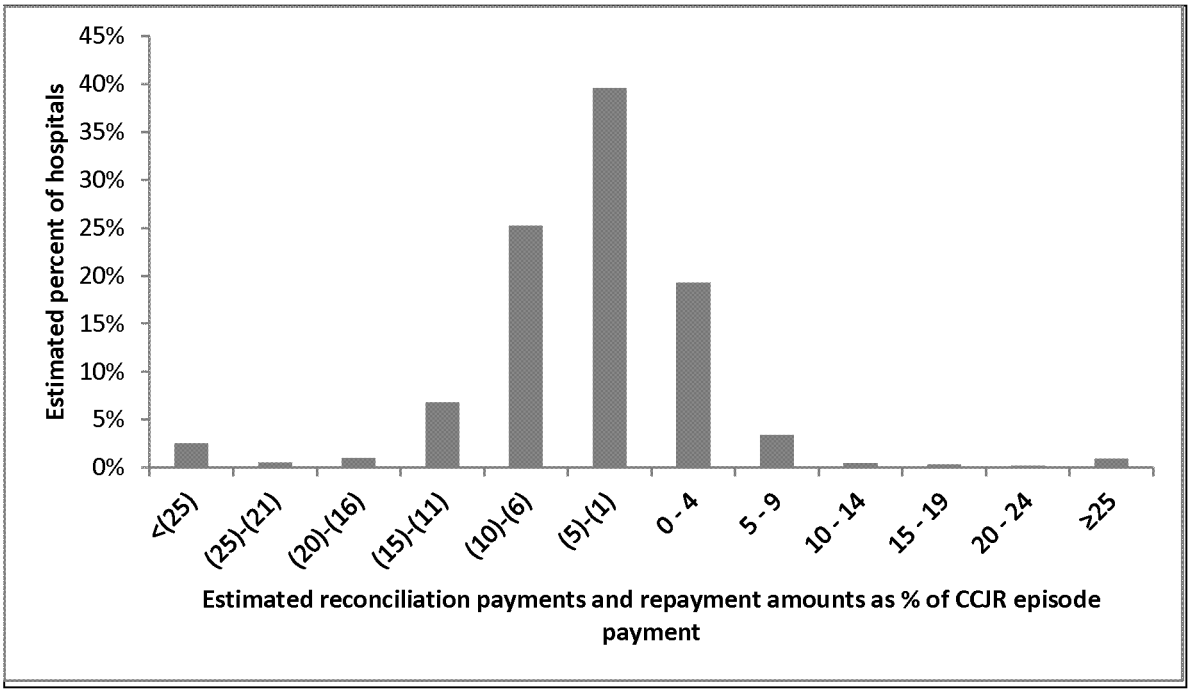
To limit a hospital's overall repayment responsibility for the raw NPRA contribution to the repayment amount under this model, we propose a 10 percent limit on the raw NPRA contribution to the repayment amount in performance year 2 and a 20 percent limit on the raw NPRA contribution to the repayment amount in performance year 3 and subsequent years. Hereinafter we refer to these proposed repayment limits as stop-loss limits. In performance year 2 as we phase in repayment responsibility, the hospital would owe Medicare under the proposed CCJR payment model no more than 10 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CCJR episodes anchored by that MS–DRG during the performance year, for each anchor MS–DRG in the model. Ten percent provides an even transition with respect to maximum repayment amounts from performance year 1, where the hospital bears no repayment responsibility, to the proposed stop-loss limit in performance years 3 through 5 of 20 percent. In performance years 3 through 5 when repayment responsibility is fully phased in, no more than 20 percent of the hospital's target price for the MS–DRG multiplied by the number of the hospital's CCJR episodes with that MS–DRG in that performance year would be owed by the hospital to Medicare under the proposed CCJR payment model. The proposed stop-loss percentage of 20 percent would be symmetrical in performance years 3 through 5 with the proposed limit on the raw NPRA contribution to reconciliation payments discussed in the following section.

We believe that a stop-loss limit of 20 percent is appropriate when the hospital bears full repayment responsibility,

based on our assessment of the changes in practice pattern and reductions in quality of care that could lead to significant repayment responsibility under the CCJR model, as compared to historical LEJR episode utilization. We estimate that the IPPS payment for the anchor hospital stay makes up approximately 50 percent of the episode target price, and we expect that the anchor hospital stay offers little opportunity for efficiencies to be achieved by reducing Medicare expenditures. In contrast, we expect significant episode efficiencies could be achieved in the 90 days following discharge from the anchor hospital stay through reductions in related hospital readmissions and increased utilization of appropriate lower intensity PAC providers, specifically increased utilization of home health services and outpatient therapy and reduced utilization of SNFs and IRFs. Hospital readmissions and facility-based PAC increase the typical Medicare episode payment by 30 to 45 percent over episodes that do not include these services. The proposed 20 percent stop-loss limit related to the total episode payment corresponds to approximately 40 percent of episode payment for the post-discharge period only, where the major opportunities for efficiency through care redesign occur. Thus, taking into consideration the historical patterns used to set target prices, we believe it is reasonable to hold participant hospitals responsible for repayment of actual episode spending that is up to 20 percent greater than the target price. If a participant hospital's repayment amount due to the raw NPRA would otherwise have exceeded the stop-loss limit of 20 percent (comparable to 40 percent of Medicare payment for the post-discharge period), the hospital's episodes would include much poorer episode efficiency as compared to the hospital's historical episodes, with large proportions of episodes including related readmissions and facility-based PAC, costly services that we do not expect to be necessary for most beneficiaries whose care is well-coordinated and appropriate throughout a high quality LEJR episode.

The following hypothetical example illustrates how the proposed stop-loss percentage would be applied in a given performance year for the episodes of a participant hospital. In performance year 3, a participant hospital had ten episodes triggered by MS–DRG 469, with a target price for these episodes of $50,000. The hospital's episode actual spending for these ten episodes was $650,000. The hospital's raw NPRA that would otherwise be $150,000 ((10 × $50,000) − $650,000) would be capped at the 20 percent stop-loss limit of $100,000 (.2 × 10 × $50,000) so the hospital would owe CMS $100,000, rather than $150,000. In performance year 3, the same participant hospital also has 100 episodes triggered by MS–DRG 470, with a target price for these episodes of $25,000. The hospital's episode actual spending for these 100 episodes was $2,800,000. The hospital's raw NPRA would be $300,000 ((100 × $25,000) − $2,800,000), an amount that would be due to CMS in full as it would not be subject to the 20 percent stop-loss limit of $500,000 (.2 × 100 × $25,000).

FIGURE 4: ESTIMATED DISTRIBUTION OF RECONCILIATION PAYMENTS AND REPAYMENT AMOUNTS UNDER PERFORMANCE YEAR 2 POLICIES, BEFORE CONSIDERATION OF CHANGES IN UTILIZATION, WITHOUT APPLICATION OF STOP-LOSS OR STOP-GAIN LIMITS, BEFORE CONSIDERATION OF QUALITY THRESHOLDS



Source: Medicare Parts A and B claims, CCJR episodes as proposed, between October 1, 2013 and September 30, 2014. Assumes no change in utilization patterns, 2% discount factor, 33%/66% regional and hospital-specific blended target price, and 20 episode threshold for using low historical volume pricing approach. Assumes all participant hospitals with actual episode spending below target prices meet minimum quality thresholds.

As illustrated in Figure 4 where we display results from our national model for the proposed CCJR performance year 2 policies when the phase-in of repayment responsibility begins and under the assumption that utilization remains constant, we estimate that the 10 percent stop-loss limit would impact the amount of repayment due to the raw NPRA for about 11 percent of hospitals. For performance year 3, the 20 percent stop-loss limit would affect significantly fewer hospitals, only about 3 percent. We note that the stop-loss limit for years 3 through 5 where repayment responsibility is fully implemented is consistent with the BPCI Model 2 policy. While Figure 3 assumes no change in utilization patterns, under the model test we expect that the proposed stop-loss limits could actually affect a smaller percentage of hospitals in each performance year because we expect LEJR episode care redesign incentivized by the model's financial opportunities to generally reduce unnecessary utilization, thereby reducing actual episode spending and, correspondingly, any associated repayment amounts due to the raw NPRA. We note that we would include any post-episode spending amount due to Medicare according to the policy proposed in section III.C.8.d of this proposed rule in assessing the total repayment amount due to the raw NPRA against the stop-loss limit for the performance year to determine a hospital's total payment due to Medicare, if applicable.

We seek comment on our proposal to adopt a 10 percent stop-loss limit in performance year 2 and 20 percent stop-loss limit in performance year 3 and beyond in CCJR as hospital repayment responsibility for excess episode spending above the target price is phased in and then maintained in the model.

(2) Proposed Limit on Raw NPRA Contribution to Reconciliation Payments

We believe a limit on reconciliation payments for CCJR would be appropriate for several reasons. Due to the proposed nature of the CCJR model during performance year 1, when hospitals have no repayment responsibility for excess episode spending above the target price, CMS bears full financial responsibility for Medicare actual episode payments for an episode that exceed the target price, and we believe our responsibility should have judicious limits. Therefore, we believe it would be reasonable to cap a hospital's reconciliation payment due to the raw NPRA as a percentage of episode payment on the basis of responsible stewardship of CMS resources. In addition, we note that beginning in performance year 1, participant hospitals would be eligible for reconciliation payments due to the NPRA if actual episode expenditures are

less than the target price, assuming the proposed quality thresholds are met. This proposal for reconciliation payments due to the NPRA provides a financial incentive to participant hospitals from the beginning of the model to manage and coordinate care throughout the episode with a focus on ensuring that beneficiaries receive the lowest intensity, medically appropriate care throughout the episode that results in high quality outcomes. Therefore, we also believe it would be reasonable to cap a hospital's reconciliation payment due to the raw NPRA based on concerns about potential excessive reductions in utilization under the CCJR model that could lead to beneficiary harm.

In determining what would constitute an appropriate reconciliation payment limit due to the raw NPRA, we believe it should provide significant opportunity for hospitals to receive reconciliation payments for greater episode efficiency that includes achievement of quality care and actual episode payment reductions below the target price, while avoiding creating significant incentives for sharply reduced utilization that could be harmful to beneficiaries. Thus, for all 5 performance years of the model, we propose a limit on the raw NPRA contribution to the reconciliation payment of no more than 20 percent of the hospital's target prices for each MS–DRG multiplied by the number of the hospital's episodes for that MS–DRG. Hereinafter we refer to this proposed reconciliation payment limit as the stop-gain limit. This proposed stop-gain limit is parallel to the 20 percent stop-loss limit proposed for performance year 3 and beyond. We believe that a parallel stop-gain and stop-loss limit is important to provide proportionately similar protections to CMS and participant hospitals for their financial responsibilities under CCJR, as well as to protect the health of beneficiaries.

As illustrated in Figure 3 where we display results from our national model for the proposed CCJR performance year 2 policies under the assumption that utilization remains constant, we estimate that the 20 percent stop-gain limit would impact the reconciliation payment amount due to the raw NPRA of almost no hospitals. We note that a stop-gain limit of 20 percent is consistent with BPCI Model 2 policy. While Figure 3 assumes no change in utilization patterns, under the model test we expect that the proposed stop-gain limit could actually affect a few hospitals in each performance year because we expect LEJR episode care redesign incentivized by the model's financial opportunities to generally reduce unnecessary utilization, thereby reducing actual episode spending and, correspondingly, increasing any associated reconciliation payment amounts due to the raw NPRA. Nevertheless, we believe the proposed stop-gain limit of 20 percent provides substantial opportunity for hospitals to achieve savings over the target price without excessive reductions in utilization, and those savings would be paid back to hospitals fully in most cases without being affected by the stop-gain limit. We seek comment on our proposal to adopt a 20 percent stop-gain limit for all performance years of CCJR.

We note that we plan to monitor beneficiary access and utilization of services and the potential contribution of the stop-gain limit to any inappropriate reduction in episode services. We refer readers to section III.F. of this proposed rule for our proposals on monitoring and addressing hospital performance under CCJR.

c. Proposed Policies for Certain Hospitals To Further Limit Repayment Responsibility

As discussed in section III.C.3. of this proposed rule, we propose that participant hospitals would be subject to repayment responsibility for episode actual spending in excess of the applicable target price beginning in performance year 2. Hospitals participating in CCJR would not be responsible for actual episode payments greater than a ceiling set at two standard deviations above the mean regional episode payment as described earlier in this section. Additionally, we propose a 10 percent limit on the raw NPRA contribution to the repayment mount in performance year 2 and a 20 percent limit on the raw NPRA contribution to the repayment amount in performance year 3 and beyond, as described in the previous section of this proposed rule.

Though our proposals provide several safeguards to ensure that participant hospitals have limited repayment responsibility due to the raw NPRA, we are proposing additional protections for certain groups of hospitals that may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes. Specifically, we are proposing additional protections for rural hospitals, SCHs, Medicare Dependent Hospitals and Rural Referral Centers (RCCs). We note that these categories of hospitals often have special payment protections or additional payment benefits under Medicare because we recognize the importance of preserving Medicare beneficiaries' access to care from these hospitals. In MedPAC's Report to the Congress in June 2012, MedPAC examined issues related to rural Medicare beneficiaries and found that ''The primary objective of rural special payments is to ensure that Medicare does its part to support the financial viability of rural providers that are necessary for beneficiaries' access to care. Some form of special payments will be needed to maintain access in areas with low population density where providers inevitably have low patient volumes and lack economies of scale.'' [40]

We propose that a rural hospital would have additional protections under the stop-loss limit proposal. For the purpose of this model, we are proposing to define a rural hospital as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103 Such rural hospitals would have additional protections under the stop-loss limit proposal. Consistent with the findings in MedPAC's June 2012 Report to the Congress, we believe rural hospitals may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes, particularly if they are the rural hospital is the only hospital in an area.

Our preliminary analysis examining national spending for MS–DRGs 469 and 470 from October 1, 2013 to September 30, 2014 showed that MS–DRGs 469 and 470 cases represent a slightly higher proportion of cases and spending for rural hospitals than the national average (for example, MS–DRG 470 episode spending represents 12 percent of IPPS spending for rural hospitals and represents 9 percent of IPPS spending nationally).[41] Additionally, our analysis on the distribution of national spending of MS–DRGs 469 and 470 episodes by service type (that is inpatient, outpatient, SNF, Home Health, Physician Part B, DME), found that on average, inpatient services account for the most spending for an MS–DRGs 469 and 470 episode (53 percent of spending for an MS–DRG 469 episode and 55 percent of spending for MS–DRG 470 episode). SNF services account for 27 percent of spending for MS–DRG 469 and 18 percent of spending for MS–DRG 470. The spending distribution for all rural IPPS hospitals also differs from the

[40] MedPAC Report to Congress June 2012, Chapter 5, page 121.

[41] Medicare FFS Parts A and B claims, CCJR episodes as proposed, between October 1, 2013 and September 30, 2014.

national average. For rural hospitals, inpatient services for CCJR episodes account for more spending than the national average (56 percent for MS–DRG 469 and 57 percent for MS–DRG 470 for rural hospitals) and SNF spending is higher than the national average (29 percent for MS–DRG 469 and 21 percent for MS–DRG 470 for rural hospitals). It is evident that this category of hospitals has different spending patterns than the national average. Furthermore, hospitals in rural areas often face other unique challenges. Rural hospitals may be the only source of healthcare services for beneficiaries living in rural areas, and beneficiaries have limited alternatives should rural hospitals be subject to financial changes under this model. Additionally, because rural hospitals may be in areas with fewer providers including fewer physicians and PAC facilities, rural hospitals may have more limited options in coordinating care and reducing spending while maintain quality of care under this model. We believe that urban hospitals may not have similar concerns as they are often in areas with many other providers and have greater opportunity to develop efficiencies under this model. Given that rural hospitals have different episode spending patterns, have different challenges in coordinating care and reducing cost than urban hospitals and serve as a primary access to care for beneficiaries, we believe that we should have a more protective stop-loss limit policy as described later in this section.

Additionally, we propose to provide additional protections for SCHs as defined in § 412.92, Medicare Dependent Hospitals as defined in § 412.108 and RRCs as defined in § 412.96. Hospitals paid under the IPPS can qualify for SCH status if they meet one of the following criteria:

- Located at least 35 miles from other like hospitals.
- Located in a rural area, located between 25 and 35 miles from other like hospitals, and no more than 25 percent of residents or Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital or the hospital has fewer than 50 beds and would meet the 25 percent criterion if not for the fact that some beneficiaries or residents were forced to seek specialized care outside of the service area due to the unavailability of necessary specialty services at the hospital.
- Hospital is rural and located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each of 2 out of 3 years.
- Hospital is rural and the travel time between the hospital and the nearest like hospital is at least 45 minutes.

If an IPPS hospital qualifies to be a SCH, the hospital can be paid the higher of the federal payment rate paid to IPPS hospitals or a cost-based hospital-specific rate as described in § 412.78. Under OPPS, a rural SCH can receive a 7.1 percent add on payment for most services with certain exceptions, in accordance with § 419.43(g). These criteria to qualify for SCH status demonstrate that SCHs are likely to be the sole hospital in an area. Furthermore, additional payments provided under Medicare FFS for SCHs, demonstrates Medicare's interest in ensuring these hospitals are able to provide services to the Medicare beneficiaries who may have limited access to providers in their area. As a result, we believe that we should provide SCHs additional protections from hospital responsibility for repayment in this model. We note that we propose to exclude these add-on payments for SCHs, as described in section III.C.3.a of this proposed rule.

MDHs are defined as a hospital that meets the following criteria:

- Located in a rural area.
- Has 100 beds or less.
- Is not a SCH.
- Sixty percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during specified time periods as provided in § 412.108.

MDHs also qualify for special additional payments under the IPPS where an MDH can receive the higher of a payment under the federal standard rate for IPPS hospitals or the payment under federal standard rate for IPPS hospitals plus 75 percent of the difference in payments between a cost based hospital-specific rate and the federal standard rate as described in § 412.108(c). These criteria demonstrate that MDHs are small, rural hospitals that have a high Medicare case mix percentage and receive additional payments under the IPPS to ensure financial stability and preserve beneficiary access to care to these hospitals. Thus, we believe these factors demonstrate that we should provide additional safeguards from hospital responsibility for repayment in order to preserve access to care. We note that we propose to exclude these payment enhancements for MDHs, as described in section III.C.3.a. of this proposed rule.

RRCs are defined as IPPS hospitals with at least 275 beds that meet the following criteria:

- Fifty percent of the hospital's Medicare patients are referred from other hospitals or from physicians who are not on the staff of the hospital.
- At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital.
- At least 60 percent of all services the hospital furnishes to Medicare patients are furnished to patients who live more than 25 miles from the hospital.

If a hospital does not meet the criteria described previously, a hospital can also qualify for RRC status if a hospital meets the following criteria:

- For specified period of time, the hospital has a case-mix that equals the lower of the median case mix index (CMI) value for all urban hospitals nationally; or the median CMI value for urban hospitals located in its region, excluding those hospitals receiving indirect medical education payments.
- Its number of discharges is at least—

++ 5,000 (or 3,000 for an osteopathic hospital); or

++ The median number of discharges for urban hospitals in the census region in which it is located, set by the CMS through IPPS rulemaking.

- Additionally, a hospital must meet one of the following criteria:

++ More than 50 percent of its active medical staff are specialists who meet the conditions specified at § 412.96(c)(3).

++ At least 60 percent of all discharges are for inpatients who reside more than 25 miles from the hospital.

++ At least 40 percent of all inpatients treated are referred from other hospitals or from physicians who are not on the hospital's staff.

As an RRC, a hospital can qualify for several additional payments under the IPPS. For example, an RRC is not subject to the 12 percent cap on Medicare Disproportionate Share Hospital payments that a rural hospital would otherwise be subject to, in accordance with § 412.106(d). Although RRCs are larger and have a higher Medicare patient mix, they often serve as the sole provider to treat higher acuity cases, as demonstrated by the RRC qualification criteria. As a result of these unique characteristics of these hospitals, RRCs can receive additional payments under Medicare FFS. Thus, it is also important to provide additional protections for RRCs such that participation in this model does not

result in significant financial loss that may reduce access for Medicare beneficiaries.

For these reasons, we propose a stop-loss limit of 3 percent of episode payments for these categories of hospitals in performance year 2 and a stop-loss limit of 5 percent of episode payments for performance years 3 through 5. More specifically, in performance year 2, a rural hospital, SCH, RRC or MDH that is a participant hospital would owe Medicare due to the raw NPRA no more than 3 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CCJR episodes with that anchor MS–DRG in the performance year. Additionally, in performance years 3 through 5, a rural hospital, SCH, RRC or MDH that is a participant hospital would owe Medicare due to the raw NPRA no more than 5 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CCJR episodes with that anchor MS–DRG in the performance year. We believe a different stop-loss limit policy is warranted given the different spending patterns and the unique hospital characteristics for these groups of hospitals as described earlier. We believe this proposal strikes an appropriate balance between protecting hospitals that often serve as the only access of care for Medicare beneficiaries and having these hospitals meaningfully participate in the model. We note that this proposal does not impact the proposed stop-gain policy for these categories of hospitals. Rural hospitals, SCHs, MDHs and RRCs still have the opportunity to participate in full gains at 20 percent similar to other hospitals.

Hospitals can apply for SCH, MDH and RRC status through their MACs and Regional Office at any time. MACs maintain the list of SCHs, MDHs, and RRCs in the CMS Provider Specific File, which they update on a quarterly basis. The special hospital designations recorded in the Provider Specific File are used in Medicare claims pricing to ensure that these hospitals are paid according to their special hospital designation. Additionally, CMS can identify which hospitals are considered rural for the purpose of this policy, using the Provider Specific File to identify physical geographic location of a hospital and the MACs to identify whether an urban hospital has reclassified to rural under 42 CFR 412.103 or located in a rural census tract of an MSA defined under 42 CFR 412.103(a)(1). Thus, we propose to identify rural hospitals, MDHs, SCHs and RRCs at the time of reconciliation using the Provider Specific File updated in December of the end of the performance year and information from the MACs, and those hospitals would be subject to the 3 percent stop-loss limit policy for that performance year 2, and 5 percent stop-loss limit policy in performance years 3 through 5. For example, to identify the hospitals that would receive a 3 percent stop-loss limit for performance year 2, we would use the Provider Specific File updated in December 2017. We note that the special Medicare payment designation of MDH status has been extended through FY 2017 by legislation under the Medicare Access and CHIP Reauthorization Act of 2015. As a result, the proposed additional protections for hospital responsibility for repayment for MDHs would only apply to the extent that MDH status exists under Medicare. In other words, should MDH expire on or after September 30, 2017, we would not identify hospitals as MDHs to receive the 5-percent stop-loss limit policy for performance year 3. Though MDH status is set to expire after the third quarter of 2017, we would still identify MDHs to receive the 3-percent stop loss limit policy for all of performance year 2.

We note that we also considered excluding rural hospitals, SCHs, MDHs and RRCs from the CCJR model altogether due to our concerns of placing significant responsibility for actual episode payment above the target price on these hospitals. Additionally, we were also concerned that from an evaluation perspective, we would not have sufficient sample size of CCJR episodes from these categories of hospitals to have significant results of how these groups of hospitals perform under this model. We weighed our reasons for excluding these hospitals with the potential qualitative information we would gain from payment innovation tests on rural hospitals in this model. We concluded that because the CCJR model strives to test episode payment for a broad variety of hospitals, it would be preferable to include these hospitals in the CCJR model and provide additional protections from a large repayment responsibility. We welcome public comment on our proposed stop-loss limit for rural hospitals, SCHs, MDHs and RRCs and on our alternative consideration to exclude these hospitals entirely from the CCJR model.

d. Proposed Hospital Responsibility for Increased Post-Episode Payments

We noted that while the proposed CCJR episode would extend 90-days post-discharge from the anchor hospitalization, some hospitals may have an incentive to withhold or delay medically necessary care until after an episode ends to reduce their actual episode payments. We do not believe this would be likely, especially given the relatively long episode duration. However, in order to identify and address such inappropriate shifting of care, we propose to calculate for each performance year the total Medicare Parts A and B expenditures in the 30-day period following completion of each episode for all services covered under Medicare Parts A and B, regardless of whether or not the services are included in the proposed episode definition (section III.B of this proposed rule), as is consistent with BPCI Model 2. Because we base the proposed episode definition on exclusions, identified by MS–DRGs for readmissions and ICD–9–CM diagnosis codes for Part B services as discussed in section III.B. of this proposed rule, and Medicare beneficiaries may typically receive a wide variety of related (and unrelated) services during the CCJR episode that extends 90 days following discharge from the anchor hospitalization, there is some potential for hospitals to inappropriately withhold or delay a variety of types of services until the episode concludes, without attending carefully to the episode definition, especially for Part B services where diagnosis coding on claims may be less reliable. This inappropriate shifting could include both those services that are related to the episode (for which the hospital would bear financial responsibility as they would be included in the actual episode spending calculation) and those that are unrelated (which would not be included in the actual episode spending calculation), because a hospital engaged in shifting of medically necessary services outside the episode for potential financial reward may be unlikely to clearly distinguish whether the services were related to the episode or not in the hospital's decisions.

This calculation would include prorated payments for services that extend beyond the episode as discussed in section III.C.3.b. of this proposed rule. Specifically, we would identify whether the average 30-day post-episode spending for a participant hospital in any given performance year is greater than three standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all CCJR eligible hospitals in the same region as the participant hospital. We propose that beginning in performance year 2, if the hospital's average post-episode spending exceeds

this threshold, the participant hospital would repay Medicare for the amount that exceeds such threshold, subject to the stop-loss limits proposed elsewhere in this proposed rule. We seek comment on this proposal to make participant hospitals responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode and for our proposed methodology to calculate the threshold for high post-episode spend.

9. Proposed Appeal Procedures

Under the CCJR model, we propose that we would determine target prices for episodes of care using the methodology described in section III.C. of this proposed rule. We propose to institute a reconciliation payment process as described in section III.C.6, of this proposed rule, and we propose to retrospectively calculate a participant hospital's actual episode performance relative to its target price after the completion of each performance year. The difference between the actual episode spending of each CCJR episode and the target price of that episode (calculated as target price subtracted by CCJR actual episode payment) would be aggregated for all episodes initiated at a participant hospital during each performance year. This calculation for a participant hospital would be adjusted for post-episode payment increases and stop gain and stop loss limits, as described in section III.C.6.a. of this proposed rule. We propose to use quality measure percentiles to determine hospital eligibility to receive the reconciliation payment and use the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment, as described in section III.C.5. of this proposed rule. The NPRA would be reflected in a report sent to the participant hospital called the CCJR Reconciliation Report.

We also propose to institute appeals processes for the CCJR model that would allow participant hospitals to appeal matters related to reconciliation and payment (that are previously discussed in this section), as well as non-payment related issues, such as enforcement matters detailed in section III.C.12.

a. Payment Processes

The proposed processes with regard to reconciliation, payment, use of quality measures to determine payment, and stop-loss and stop-gain policies are set forth in detail in sections III.C.5–8. In this section, we propose an appeals processes that will apply to the matters addressed in sections III.C.5–8, as well as matters not related to payment or reconciliation. These appeals processes will apply to the following payment and reconciliation processes:

- Starting with the CCJR Reconciliation Report for performance year 1, if the CCJR Reconciliation Report indicates the reconciliation amount is positive, CMS would issue a payment, in a form and manner specified by CMS, for that amount to the awardee within 30 calendar days from the issue date of the CCJR Reconciliation Report, unless the participant hospital selects to pursue the calculation error and reconsideration review processes, in which case payment will be delayed as detailed later in this section.
- For performance year 1, if the CCJR reconciliation report indicates a repayment amount, the participant hospital would not be required to make payment for that amount to CMS, as we have proposed not to hold hospitals financially responsible for negative NPRAs for the first performance year. In addition, if it is determined that a CCJR hospital has a positive NPRA for performance year 1, and the subsequent calculation for performance year 1 the following year, as described in section III.C.6. of this proposed rule, determines that in aggregate the performance year 1 NPRA and the subsequent calculation amount for performance year 1 is a negative value (adding together the NPRA amount from the reconciliation for performance year 1 as well as the amount determined in the subsequent calculation, which would be detailed on the CCJR reconciliation report for performance year 2), the hospital would only be financially responsible for a repayment amount that would net the performance year 1 NPRA and subsequent calculation for year 1 to zero. This would be true for performance year 1 only, given our proposal to begin phasing in financial responsibility in year 2 of the model as discussed in section III.C.2.c. of this proposed rule. For performance years 2 through 5 of the model, for example, if the NPRA for performance year 1 for a given hospital were $3,000, and the subsequent calculation performed in Q2 2018 to account for claims run-out and overlaps determined a repayment amount of $3,500 for claims incurred and overlap during performance year 1, $3,000 would be applied to the CCJR reconciliation report for performance year 2. If the NPRA for performance year 2 were $5,000, the repayment amount of $3,000 would be netted against the $5,000, and the reconciliation payment for performance year 2 would be $2,000. Given that downside risk has been waived for performance year 1, the remaining $500 would not be added to the CCJR reconciliation report for performance year 2. However, beginning with the reconciliation process for performance year 3, any repayment amounts generated through the subsequent calculation process detailed in section III.C.6.b. would be netted against any repayment or reconciliation amount on the respective CCJR reconciliation reports for performance years 2, 3, 4, and 5. Starting with the reconciliation for performance year 2, if the CCJR Reconciliation Report indicates the NPRA is negative, the participant hospital would make payment for the absolute value of that amount to CMS within 30-calendar days from the issue date of the CCJR Reconciliation Report, in a form and manner specified by CMS. Where the participant hospital does not issue payment within 30-calendar days, we will issue a demand letter requiring payment be made immediately.
- The reconciliation or repayment amount may include adjustments, arising from matters from the previous performance year, as necessary to account for subsequent calculations performed for performance years that were specified in earlier CCJR Reconciliation Reports, as discussed in section III.C.6. of this proposed rule. For example, we would potentially make determinations of additional monies owed by Medicare to participant hospitals or vice versa in subsequent periods based on the availability of updated Medicare administrative data. These subsequent calculations would be contained in the succeeding reconciliation report. For example, the subsequent calculations applicable to performance year 1 would be contained in the reconciliation report for performance year 2.
- If the participant hospital fails to pay CMS the amount owed by the date indicated in the demand letter, CMS will recoup owed monies from participant hospital's present and future Medicare payments to collect all monies due to CMS. While we propose that a participant hospital may enter into financial arrangements with CCJR collaborators that allow for some risk-sharing, as discussed in section III.C. of this proposed rule, the participant hospital would be solely liable for the repayment of the negative repayment amount to CMS. Where the participant hospital fails to repay CMS in full for all monies owed, CMS would invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of the Treasury, pursuant to 31 U.S.C. 3711(g).

b. Calculation Error

We propose the following calculation error process for participant hospitals to contest matters related to payment or reconciliation, of which the following is a non-exhaustive list: The calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CCJR reconciliation report; the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment. Participant hospitals would review their CCJR reconciliation report and be required to provide written notice of any error, in a calculation error form that must be submitted in a form and manner specified by CMS. Unless the participant provides such notice, the reconciliation report would be deemed final within 30 calendar days after it is issued, and CMS would proceed with payment or repayment. If CMS receives a timely notice of an error in the calculation, CMS would respond in writing within 30 calendar days to either confirm or refute the calculation error, although CMS would reserve the right to an extension upon written notice to the participant hospital. We propose that if a participant hospital does not submit timely notice of calculation error in accordance with the timelines and processes specified by CMS, the participant hospital would be precluded from later contesting any of the following matters contained in the CCJR reconciliation report for that performance year: any matter involving the calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CCJR reconciliation report; any matter involving the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.

c. Dispute Resolution

(1) Limitations on Review

In accordance with section 1115A(d) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites or participants to test those models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under subsection 1115A(b)(3).
- The termination or modification of the design and implementation of a model under subsection 1115A(b)(3)(B).
- Decisions about expansion of the duration and scope of a model under subsection 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

(2) Matters Subject to Dispute Resolution

We propose that a participant hospital may appeal an initial determination that is not precluded from administrative or judicial review by requesting reconsideration review by a CMS official. The request for review must be submitted for receipt by CMS within 10 days of the notice of the initial determination. Initial determinations that are not precluded from administrative or judicial review would include the involuntary termination of a participant hospital's participation in the CCJR model.

(3) Dispute Resolution Process

We propose the following dispute resolution process. First, we propose that only a participant hospital may utilize the dispute resolution process. Second, in order to access the dispute resolution process a participant hospital must have timely submitted a calculation error form, as previously discussed, for any matters related to payment. We propose these matters would include any amount or calculation indicated on a CCJR reconciliation report, including calculations not specifically reflected on a CCJR reconciliation report but which generated figures or amounts reflected on a CCJR reconciliation report. The following is a non-exhaustive list of the matters we propose would need to be first adjudicated by the calculation error process as previously detailed: calculations of reconciliation or repayment amounts; calculations of NPRA; and any calculations or percentile distribution involving quality measures that we propose could affect reconciliation or repayment amounts. If a participant hospital wants to engage in the dispute resolution process with regard to one of these matters, we propose it would first need to submit a calculation error form. Where the participant hospital does not timely submit a calculation error form, we propose the dispute resolution process would not be available to the participant hospital with regard to those matters for the reconciliation report for that performance year.

If the participant hospital did timely submit a calculation error form and the participant hospital is dissatisfied with CMS's response to the participant hospital's notice of calculation error, the hospital would be permitted to request reconsideration review by a CMS reconsideration official. The reconsideration review request would be submitted in a form and manner and to an individual or office specified by CMS. The reconsideration review request would provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA or post-episode spending amount in accordance with CCJR rules. The following is a non-exhaustive list of representative payment matters:

- Calculations of NPRA, post-episode spending amount, target prices or any items listed on a reconciliation report.
- The application of quality measures to a reconciliation payment, including the calculation of the percentiles thresholds of quality measure performance to determine eligibility to receive reconciliation payments, or the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.
- Any contestation based on the grounds that CMS or its representative made an error in calculating or recording such amounts.

Where the matter is unrelated to payment, such as termination from the model, the participant hospital need not submit a calculation error form. We propose to require the participant hospital to timely submit a request for reconsideration review, in a form and manner to be determined by CMS. Where such request is timely received, we propose CMS would process the request as discussed later in this section.

We propose that the reconsideration review would be an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official would make reasonable efforts to notify the hospital in writing within 15 calendar days of receiving the participant hospital's reconsideration review request of the date and time of the review, the issues in dispute, the review procedures, and the procedures (including format and deadlines) for submission of evidence (the ''Scheduling Notice''). The CMS reconsideration official would make reasonable efforts to schedule the

review to occur no later than 30 days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) (as in effect on the publication date of this proposed rule) would apply to reviews conducted pursuant to the reconsideration review process for CCJR. The CMS reconsideration official would make reasonable efforts to issue a written determination within 30 days of the review. The determination would be final and binding.

We solicit comment on our proposals related to appeals rights under this model. The two-step appeal process for payment matters—(1) calculation error form, and (2) reconsideration review—is used broadly in other CMS models. We seek comment on whether we should develop an alternative appeal process. We are also interested in whether there should be appeal rights for reductions or eliminations of NPRA as a result of enforcement actions, as discussed in section III.C.12 of this proposed rule, and if so, whether the process for such appeals should differ from the processes proposed here.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the new proposed part 510 of the CFR.

10. Proposed Financial Arrangements and Beneficiary Incentives

a. Financial Arrangements and Beneficiary Incentives

As discussed earlier in this proposed rule, we propose that CCJR would be a retrospective episode payment model, under which Medicare payments for services included in an episode of care would continue to be made to all providers and suppliers under the existing payment systems, and episode payment would be based on later reconciliation of episode actual spending under those Medicare payment systems to the episode target price. If the episode actual spending is less than the target price, the participant hospital would receive a reconciliation payment, assuming quality performance thresholds are met and the stop-gain threshold is not exceeded. If the episode actual spending exceeds the target price, beginning in performance year 2 hospitals would repay the difference to Medicare up to the stop-loss threshold.

We believe that participant hospitals may wish to enter into financial arrangements with providers and suppliers caring for beneficiaries in CCJR episodes in order to align the financial incentives of those providers and suppliers with the model goals of improving quality and efficiency for LEJR episodes. For example, given that the proposed episode duration is 90 days following discharge from the anchor hospital stay and the episodes are broadly defined (see section III.B of this proposed rule), many providers and suppliers other than the participant hospital will furnish related services to beneficiaries during episodes. Those providers and suppliers may include physicians, physician group practices, skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), long term care hospitals (LTCHs), outpatient therapy providers, and others. We expect that participant hospitals will identify key providers and suppliers for CCJR beneficiaries in their communities and then establish close partnerships with them to assist the hospital in redesigning care for LEJR episodes to improve quality and efficiency, coordinating and managing care for beneficiaries, monitoring episode performance, and refining care pathways. These providers and suppliers may invest substantial time and other resources in these activities, yet they would neither be the direct recipients of any reconciliation payments from Medicare, nor directly responsible for repaying Medicare for excess episode spending. Therefore, we believe it is possible that a participant hospital that may receive a reconciliation payment from Medicare or may need to repay Medicare may want to enter into financial arrangements with other providers and suppliers to share risks and rewards under CCJR.

In addition to providers and suppliers with which the participant hospital may want to enter into financial arrangements to share risks and reward, we expect that participant hospitals may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as: episode data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; CCJR beneficiary care coordination and management; monitoring participant hospital compliance with the terms and conditions of the CCJR model; or other model-related activities. These organizations may play important roles in a hospital's plans to implement the CCJR model based on the experience these organizations may bring to the hospital's successful participation in the model, such as prior experience with bundled payment initiatives, care coordination expertise, familiarity with the local community, and knowledge of Medicare claims data. We expect that all relationships established between participant hospitals and these organizations for purposes of the CCJR model would only be those permitted under existing law and regulation, including any relationships that would include the participant hospital's sharing of CCJR model risks and rewards with these organizations. We would expect that all of these relationships would solely be based on the level of engagement of the organization's resources to directly support the participant hospitals' CCJR model implementation.

Additionally, because the proposed broadly defined LEJR episodes extend 90-days post-discharge from the anchor hospital stay, we believe that participant hospitals caring for CCJR beneficiaries may want to offer beneficiary incentives to encourage beneficiary adherence to recommended treatment and active patient engagement in recovery. Such incentives should be closely related to the provision of high quality care during the episode and advance a clinical goal for a CCJR beneficiary, and should not serve as inducements to beneficiaries to seek care from the participant hospital or other specific suppliers and providers. Such incentives may help participant hospitals reach their quality and efficiency goals for CCJR episodes, while benefitting beneficiaries' health and the Medicare Trust Fund if hospital readmissions and complications are reduced while recovery continues uninterrupted or accelerates.

(1) Financial Arrangements Under the CCJR Model

As previously noted, we believe that given the financial incentives of episode payment in CCJR, participant hospitals in the model may want to engage in financial arrangements to share reconciliation payments or hospital internal cost savings or both, as well as responsibility for repaying Medicare, with providers and suppliers making contributions to the hospital's episode performance on spending and quality. Such arrangements would allow the participant hospitals to share all or some of the reconciliation payments they may be eligible to receive from CMS, or the participant hospital's internal cost savings that result from care for beneficiaries during a CCJR episode. Likewise, such arrangements could allow the participant hospitals to share the responsibility for the funds needed to repay Medicare with providers and suppliers engaged in caring for CCJR beneficiaries, if those providers and suppliers have a role in the hospital's episode spending or quality performance. We propose to use the term ''CCJR collaborator'' to refer to

such providers and suppliers, who may include the following:

- SNFs.
- HHAs.
- LTCHs.
- IRFs.
- Physician Group Practices (PGPs).
- Physicians, nonphysician practitioners, and outpatient therapy providers.

We believe that CCJR collaborators should have a role in the participant hospital's episode spending or quality performance. Accordingly, we propose that the CCJR collaborator would directly furnish related items or services to a CCJR beneficiary during the episode and/or specifically participate in CCJR model LEJR episode care redesign activities, such as attending CCJR meetings and learning activities; drafting LEJR episode care pathways; reviewing CCJR beneficiaries' clinical courses; developing episode analytics; or preparing reports of episode performance, under the direction of the participant hospital or another CCJR collaborator that directly furnishes related items and services to CCJR beneficiaries. Note that we propose later in this section a limit on Gainsharing Payments (as that term is defined later in this section) to physician or nonphysician CCJR collaborators, as well as to physician group practices, related to PFS payments for services furnished to CCJR beneficiaries. Therefore, in addition to playing a role in the participant hospital's episode spending or quality performance, physician, nonphysician, and physician group practice CCJR collaborators must additionally directly furnish services to CCJR beneficiaries in order to receive a Gainsharing Payment as result of their financial arrangement with the participant hospital. We seek comment on our proposed definition of CCJR collaborators, as well as our proposed definition of a provider's or supplier's role in the participant hospital's episode spending or quality performance.

We propose that certain financial arrangements between a participant hospital and a CCJR collaborator be termed a ''CCJR Sharing Arrangement,'' and that the terms of each CCJR Sharing Arrangement be set forth in a written agreement between the participant hospital and the CCJR collaborator. We propose to use the term ''Participation Agreement'' to refer to such agreements. We propose that a ''CCJR Sharing Arrangement'' would be a financial arrangement contained in a Participation Agreement to share only the following: (1) CCJR reconciliation payments (as that term is defined in section III.C of this proposed rule); (2) the participant hospital's internal cost savings (as that term is defined later in this section); and (3) the participant hospital's responsibility for repayment to Medicare, as discussed later in this section. Where a payment from a participant hospital to a CCJR collaborator is made pursuant to a CCJR Sharing Arrangement, we propose to define that payment as a ''Gainsharing Payment.'' A Gainsharing Payment may only be only composed of the following: (1) Reconciliation payments; (2) internal cost savings; or (3) both. Where a payment from a CCJR collaborator to a participant hospital is made pursuant to a CCJR Sharing Arrangement, we propose to define that payment as an ''Alignment Payment.'' We propose that CCJR Sharing Arrangements that provide for Alignment Payments would not relieve the participant hospital of its ultimate responsibility for repayment to CMS. Many of the programmatic requirements discussed later in this proposed rule for Gainsharing Payments and Alignment Payments are similar to those in Model 2 of the BPCI initiative.

The CCJR Sharing Arrangements between participant hospitals and CCJR collaborators must be solely related to the contributions of the CCJR collaborators to care redesign that achieve quality and efficiency improvements under this model for CCJR beneficiaries. All Gainsharing Payments or Alignment Payments between participant hospitals and CCJR collaborators resulting from these arrangements must be auditable by HHS, as discussed later in this section, to ensure their financial and programmatic integrity. We emphasize that any CCJR collaborator that receives a Gainsharing Payment or makes an Alignment Payment must have furnished services included in the episode to CCJR beneficiaries. Furthermore, the payment arrangements for Gainsharing Payments or Alignment Payments contained in a CCJR Sharing Arrangement must be actually and proportionally related to the care of beneficiaries in a CCJR episode, and the CCJR collaborator must be contributing to the care redesign strategies of the participant hospital.

We considered whether CCJR collaborators should be termed ''participants'' in this model, or whether the term ''participant'' should refer only to the participant hospitals located in MSAs selected for participation. If CCJR collaborators are participants in the model, we propose that their activities with regard to CCJR beneficiaries would be regulated directly by CMS. However, if CCJR collaborators are not participants, but rather are participating entities and individuals in the CCJR model through signed agreements with participant hospitals, their activities with regard to CCJR beneficiaries would be governed by the Participation Agreement between a CCJR collaborator and a participant hospital. Given the large number of potential CCJR collaborators, the expected varied nature of their respective arrangements with participant hospitals, and the potential administrative burden in reporting information to CMS, we believe the activities of CCJR collaborators with regard to CCJR beneficiaries would be best managed by participant hospitals. As we discussed earlier in this proposed rule, one justification for proposing that acute care hospitals be the provider type financially responsible under the CCJR model is the position of the hospital with respect to other providers and suppliers, in terms of coordinating care for CCJR beneficiaries. Given that position, we propose that where participant hospitals enter into Participation Agreements that contain CCJR Sharing Arrangements with CCJR collaborators, the participant hospital must also be responsible for ensuring that those providers and suppliers comply with the terms and requirements of this proposed rule. We seek comments on this proposal; specifically, whether CCJR collaborators should be termed participants in this model and subject to the applicable requirements, or whether the responsibility for compliance with the model's requirements is better managed by participant hospitals. We are particularly interested in comments that address the advantages and disadvantages of making CCJR collaborators participants in the model, and whether there are certain provider or supplier types that CMS should consider including as ''participants'' in the model.

The following discussion outlines our proposed requirements and responsibilities of participant hospitals that engage in such CCJR Sharing Arrangements. We believe these proposed requirements and responsibilities are essential to ensuring that all CCJR Sharing Arrangements are for the sole purpose of aligning the financial incentives of collaborating providers and suppliers with those of the participant hospital toward the CCJR model goals of improved LEJR episode care quality and efficiency. We believe that the rationale for and details of these arrangements must be documented and auditable by HHS, with a direct tie between the arrangements and the

participant hospital's episode performance. Finally, we believe that the proposed limitations to the arrangements, as described later in this section, are necessary to ensure the integrity of the CCJR model by minimizing incentives for problematic behaviors, such as patient steering. We seek comments on all proposed requirements regarding CCJR Sharing Arrangements.

With respect to whether certain entities or individuals should be prevented from participating in the CCJR model, either as participant hospitals or CCJR collaborators, we considered whether CMS should conduct screening for program integrity purposes. Many CMS models conduct screening during the application process and periodically thereafter. These screenings examine provider and supplier program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. Where a screening reveals that a provider or supplier has a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues, we may remove that provider or supplier from the model. We utilize these screening processes for many CMS models, including the BPCI initiative.

For several reasons, we believe that this type of screening for participant hospitals is inapplicable to the CCJR model. Most importantly, this model seeks to evaluate the performance in the model of hospitals located in a particular MSA. We believe it is important that all hospitals that meet the criteria for participation in the model be included, even if those hospitals have a history of program integrity issues. Further, we propose that CMS would evaluate the quality of care and institute beneficiary protections in ways that would go beyond some of the efforts of previous or existing CMS models. We solicit comments on this proposal, including whether screening of participant hospitals or CCJR collaborators might be appropriate or useful in aiding HHS' program integrity efforts and identifying untrustworthy parties or parties with program integrity history problems.

(a) CCJR Sharing Arrangement Requirements

We propose that each CCJR Sharing Arrangement must include and set forth in writing at a minimum—

- A specific methodology and accounting formula for calculating and verifying internal cost savings, if the participant hospital elects to share internal cost savings through Gainsharing Payments with CCJR collaborators. We propose to define internal cost savings as the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CCJR episodes of care. Internal cost savings would not include savings realized by any individual or entity that is not the participant hospital. Each CCJR Sharing Arrangement must include specific methodologies for accruing and calculating internal cost savings of the participant hospital, where the hospital intends to share internal cost savings through a CCJR Sharing Arrangement with a CCJR collaborator. The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with Generally Accepted Accounting Principles (GAAP) and Government Auditing Standards (The Yellow Book). The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CCJR collaborator or both;
- A description of the methodology and accounting formula for calculating the percentage or dollar amount of a reconciliation payment received from CMS that will be paid as a Gainsharing Payment from the participant hospital to the CCJR collaborator;
- A description of the methodology, frequency or dates of distribution, and accounting formula for distributing and verifying any and all Gainsharing Payments;
- A description of the arrangement between the participant hospital and the CCJR collaborator regarding Alignment Payments, where the hospital and CCJR collaborator agree through a CCJR Sharing Arrangement to share risk for repayment amounts due to CMS, as reflected on a CCJR reconciliation report. The description of this arrangement must include safeguards to ensure that such Alignment Payments are made solely for purposes related to sharing responsibility for funds needed to repay Medicare in the CCJR model. This description should also include a methodology, frequency of payment, and accounting formula for payment and receipt of any and all Alignment Payments;
- A provision requiring the participant hospital to recoup Gainsharing Payments paid to CCJR collaborators if Gainsharing Payments were based on the submission of false or fraudulent data;
- Plans regarding care redesign, changes in care coordination or delivery that are applied to the participant hospital or CCJR collaborators or both, and any description of how success will be measured;
- Management and staffing information, including type of personnel or contactors that will be primarily responsible for carrying out changes to care under the model;
- The participant hospital must maintain records identifying all CCJR collaborators, and the participant hospital's process for determining and verifying the eligibility of CCJR collaborators to participate in Medicare; and
- All CCJR Sharing Arrangements must require compliance, from both the participant hospital and the CCJR collaborator, with the proposed polices regarding beneficiary notification set forth in section III.F of this proposed rule.

With respect to these requirements for Participation Agreements and CCJR Sharing Arrangements, we considered whether we should require participant hospitals and CCJR collaborators to periodically report this information to CMS for purposes of enforcement of these proposed regulations. However, we are mindful of the administrative burden in reporting this information as well as the challenges associated with creating a universal collection tool that would account for all the various iterations of financial arrangements into which participant hospitals and CCJR collaborators may enter. Therefore, we are proposing to require participant hospitals to retain this documentation as previously described, as well as in section III.C.10(d) of this proposed rule. We seek comment on this proposal as well as whether CMS should require participant hospitals and CCJR collaborators to periodically report data such as: Gainsharing Payments and/or Alignment Payments distributed and received; name and identifier (NPI, CCN, TIN) of all CCJR collaborators; and any other relevant information related to Participation Agreements and CCJR Sharing Arrangements that would assist HHS with enforcement of these regulations.

We solicit comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(b) Participation Agreement Requirements

We propose that the Participation Agreement must obligate the parties to comply, and must obligate the CCJR collaborator to require any of its employees, contractors or designees to comply, without limitation, to with the following requirements:

• Each individual's or entity's participation in the CCJR Sharing Arrangement is voluntary and without penalty for nonparticipation.

• Any Gainsharing Payments made pursuant to a CCJR Sharing Arrangement must be made only from the participant hospital to the CCJR collaborator with whom the participant hospital has signed a Participation Agreement containing a CCJR Sharing Arrangement. Additionally, we propose to require the following for all CCJR Sharing Arrangements between a participant hospital and a CCJR collaborator that is a physician group practice:

++ Where a Gainsharing Payment is made to a CCJR collaborator that is a physician group practice, all monies contained in such a Gainsharing Payment must be shared only with physician or nonphysician practitioners that furnished a service to a CCJR beneficiary during an episode of care in the calendar year from which the Net Payment Reconciliation Amount (NPRA), as that term is defined in section III.C.6. of this proposed rule, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a Gainsharing Payment. We further propose that each CCJR Sharing Arrangement between a participant hospital and a CCJR collaborator that is physician group practice must stipulate that the physician group practice may not retain any portion of a Gainsharing Payment or distribute, by any method, any portion of a Gainsharing Payment to physician or nonphysician practitioners who did not furnish a service to a CCJR beneficiary during an episode of care in the calendar year from which the NPRA or internal cost savings was generated.

• Any Alignment Payments made pursuant to a CCJR Sharing Arrangement may be made only to the participant hospital from the entity or individual with whom the participant hospital has signed a Participation Agreement containing a CCJR Sharing Arrangement.

• Each CCJR Sharing Arrangement must require that the CCJR collaborator be in compliance with all Medicare provider enrollment requirements at § 424.500 *et seq.,* including having a valid and active TIN or NPI.

• Any internal cost savings or reconciliation payments that the participant hospital seeks to share through CCJR Sharing Arrangements must meet the requirements set forth in the final CCJR rule (as finalized) and be administered by the participant hospital in accordance with GAAP. In no event may the participant hospital distribute any amounts pursuant to a CCJR Sharing Arrangement that are not comprised of either internal cost savings or a reconciliation payment, as those terms are defined in this proposed rule. All amounts determined to be internal cost savings by the participant hospital must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. In no case may internal cost savings reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

• Any Alignment Payments that the participant hospital receives through a CCJR Sharing Arrangement must meet the requirements set forth in the final CCJR rule (as finalized) and be administered by the participant hospital in accordance with GAAP.

• CCJR Sharing Arrangements must not include any amounts that are not Alignment Payments or Gainsharing Payments.

• Further, we propose that each Participation Agreement—

++ Between the participant hospital and a CCJR collaborator must obligate the CCJR collaborator to provide the participant hospital and HHS access to the CCJR collaborator's records, information, and data for purposes of monitoring and reporting and any other lawful purpose. Records, information, and data regarding the CCJR Sharing Arrangement must have sufficient detail to verify compliance with all material terms of the CCJR Sharing Arrangement and the terms of the CCJR model;

++ Must require the participant hospital and the CCJR collaborator to include in their compliance programs specific oversight of their CCJR participation agreements and compliance with the requirements of the CCJR mode;

++ Must require compliance, from both the participant hospital and the CCJR collaborator, with the proposed polices regarding beneficiary notification set forth in section III.F; and

++ Must require the board or other governing body of the participant hospital to have responsibility for overseeing the participant hospital's participation in the model, its arrangements with CCJR collaborators, its payment of Gainsharing Payments and receipt of Alignment Payments, and its use of beneficiary incentives in the CCJR model.

• Participation Agreements must require all CCJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by HHS or its designees for the purposes of operating the CCJR model.

• Each Participation Agreement must require the CCJR collaborator to permit site visits from CMS, or one of its designees, for purposes of evaluating the model.

We solicit comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(c) Gainsharing Payment and Alignment Payment Conditions and Restrictions

We propose the following conditions and restrictions concerning Gainsharing Payments and Alignment Payments made pursuant to a CCJR Sharing Arrangement:

• No entity or individual, whether or not a party to a Participation Agreement, may condition the opportunity to receive Gainsharing Payments in CCJR on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, any CCJR collaborators, and any individual or entity affiliated with a participant hospital or CCJR collaborator.

• Participant hospitals would not be required to share reconciliation payments, internal cost savings, or responsibility for repayment to CMS with other providers and suppliers. However, where a participant hospital elects to engage in those activities, we propose that such activities be limited to the provisions prescribed in this proposed rule.

• We propose that Gainsharing Payments must be distributed on an annual basis, and are required to meet the following criteria:

++ Must be clearly identified and comply with all provisions in this proposed rule, as well as all applicable laws, statutes, and rules;

++ Must not be a loan, advance payments, or payments for referrals or other business; and

++ Must be made by electronic funds transfer (EFT).

• We propose that Alignment Payments from a CCJR collaborator to a

participant hospital may be made at any interval, and are required to meet the following criteria:

++ Must be clearly identified and comply with all provisions in this proposed rule, as well as all applicable laws, statutes, and rules;

++ Must not be issued, distributed, or paid prior to the calculation by CMS of a reconciliation report reflecting a negative Net Payment Reconciliation Amount (NPRA);

++ Must not be a loan, advance payments, or payments for referrals or other business; and

++ Must be made by electronic funds transfer (EFT).

• We propose that each CCJR Sharing Arrangement stipulate that any CCJR collaborator that is subject to any action involving noncompliance with the provisions of this propose rule, engaged in fraud or abuse, providing substandard care, or have other integrity problems not be eligible to receive any Gainsharing Payments related to NPRA generated during the time that coincides with the action involving any of the issues previously listed until the action has been resolved.

• No entity or individual, as whether or not a party to a Participation Agreement, may condition the opportunity to make or receive Alignment Payments in CCJR on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, any CCJR collaborators, and any individual or entity affiliated with a participant hospital or CCJR collaborator.

• In a calendar year, the aggregate amount of the total Gainsharing Payments distributed by the participant hospital that are derived from a CCJR reconciliation payment may not exceed the amount of the reconciliation payment that the participant hospital received from CMS.

• In a calendar year, the aggregate amount of the total Alignment Payments received by the participant hospital may not exceed 50 percent of the participant hospital's repayment amount due to CMS. If no repayment amount is due, then no Alignment Payments may be received by the participant hospital.

• We propose that the participant hospital must retain at least 50 percent of its responsibility for repayment to CMS, pursuant to the repayment amount reflected in each annual reconciliation report, under the CCJR model. Given that the participant hospital will be responsible for developing and coordinating care redesign strategies in response to its participation in the CCJR model, we believe it is important that the participant hospital retain a significant portion of its responsibility for repayment to CMS. For example, upon receipt of a reconciliation report indicating that the participant hospital owes $100 to CMS, the participant hospital would be permitted to receive no greater than $50 in Alignment Payments, in the aggregate, from its CCJR collaborators.

• Further, we propose that a CCJR Sharing Arrangement must limit the amount a single CCJR collaborator may make in Alignment Payments to a single participant hospital. We propose that a single CCJR collaborator not make an Alignment Payment to a participant hospital that represents an amount greater than 25 percent of the repayment amount reflected on the participant hospital's annual reconciliation report. For example, upon receipt of a reconciliation report indicating that the participant hospital owes $100 to CMS, the participant hospital would be permitted to receive no more than $25 in an Alignment Payment from a single entity or individual who is a CCJR collaborator of the participant hospital.

• Gainsharing Payments and Alignment Payments must not induce the participant hospital, CCJR collaborators, or the employees, contractors, or designees of the participant hospital or CCJR collaborators to reduce or limit medically necessary services to any Medicare beneficiary.

• Individual physician and nonphysician practitioners, whether or not a party to a CCJR Sharing Arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

• Entities furnishing services to beneficiaries during a CCJR episode, whether or not a party to a CCJR Sharing Arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

• Gainsharing methodologies for calculating Gainsharing Payments and Alignment Payments must not directly account for volume or value of referrals, or business otherwise generated, between or among a participant hospital, any CCJR collaborators, and any individual or entity affiliated with a participant hospital or CCJR collaborator.

• Gainsharing Payments must be derived solely from reconciliation payments or internal cost savings or both.

• The total amount of Gainsharing Payments for a calendar year paid to an individual physician or nonphysician practitioner who is a CCJR collaborator must not exceed a cap. The cap is 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital's CCJR beneficiaries during a CCJR episode by that physician or nonphysician practitioner. This cap of 50 percent on Gainsharing Payments to individual physician or nonphysician practitioner is consistent with the same policy for the BPCI initiative. The purpose of this cap is to limit the amount of Gainsharing Payments an individual practitioner may receive due to his/her provision of services included in the CCJR model.

• The total amount of Gainsharing Payments for a calendar year paid to an physician group practice that is a CCJR collaborator must not exceed a cap. The cap is 50 percent of the sum of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished by physician or nonphysician practitioner members of the physician group practice to the participant hospital's CCJR beneficiaries during a CCJR episode by those physicians or nonphysician practitioners.

We solicit comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(d) Documentation and Maintenance of Records

We propose to require participant hospitals and CCJR collaborators to comply with audit and document retention requirements similar to those required by the Medicare Shared Savings Program, BPCI Model 2, and other Innovation Center models. Specifically, with respect to all Participation Agreements and CCJR Sharing Arrangements, the participant hospital and CCJR collaborator must:

• Comply with the retention requirements regarding Participation Agreements and CCJR Sharing Arrangements set forth in subsection III.C.10(a)–(d).

• Maintain and give CMS, the Office of Inspector General of the Department of Health and Human Services (OIG), and the Comptroller General or their designee(s) access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality performance measures, billings, and CCJR Sharing Arrangements related to

CCJR) sufficient to enable the audit, evaluation, inspection, or investigation of the participant hospital's compliance, as well as the compliance of any CCJR collaborator that has a CCJR Sharing Arrangement with the participant hospital, with CCJR requirements, the Participation Agreement, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, the calculation, distribution, receipt, or recoupment of Gainsharing Payments or Alignment Payments.

• Maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CCJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital or CCJR collaborator at least 30 calendar days before the normal disposition date; or

++ There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CCJR collaborator in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

• Notwithstanding any CCJR Sharing Arrangements between the participant hospital and CCJR collaborators, the participant hospital must have ultimate responsibility for adhering to and otherwise fully complying with all provisions of the CCJR model.

• OIG Authority is not limited or restricted by the provisions of the CCJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CCJR collaborators, or any other person or entity or their records, data, or information, without limitation.

• None of the provisions of the CCJR model limits or restricts any other government authority permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CCJR collaborators, or any other person or entity or their records, data, or information, without limitation.

We solicit comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(2) Beneficiary Incentives Under the CCJR Model

We believe that the CCJR model will incent participant hospitals to furnish directly and otherwise coordinate services throughout the episode that lead to higher quality care for the beneficiary and lower episode spending. We believe that one mechanism that may be useful to the participant hospital in achieving these goals is the provision of certain items and services to the beneficiary during the episode of care. We also considered whether this policy on beneficiary incentives should extend to providers and suppliers, other than the participant hospital, that furnish services during the CCJR episode of care. However, as discussed in section III.A, given our belief that the participant hospital is best positioned to coordinate the care of beneficiaries, we believe they are also better suited than other providers and suppliers to provide beneficiary incentives. Thus, we propose to include in the CCJR model certain in-kind patient engagement incentives to the beneficiary, subject to the following conditions:

• The incentive must be provided by the participant hospital to the beneficiary during CCJR episode of care.

• There must be a reasonable connection between the item or service and the beneficiary's medical care.

• The item or service must be a preventive care item or service or an item or service that advances a clinical goal for a CCJR beneficiary, including the following: Increasing the beneficiary's engagement in the management of his or her own health care; adherence to a treatment or drug regimen; adherence to a follow-up care plan; reduction of readmissions and complications resulting from LEJR procedures; and management of chronic diseases and conditions that may be affected by the LEJR procedure.

• Items of technology comply with certain safeguards regarding value, as discussed later in this section.

• The participant hospital must maintain contemporaneous documentation of the incentives provided to beneficiaries for a period of 10 years.

• The cost of the incentives is not shifted to another federal health care program.

For example, under this proposal, participant hospitals could provide incentives such as post-surgical monitoring equipment to track patient weight and vital signs for post-surgical patients discharged directly to home, but they could not provide theater tickets, which would bear no reasonable connection to the patient's medical care. Similarly, we are proposing that participant hospitals might provide post-surgical monitoring equipment, but not broadly used technology that is more valuable to the beneficiary than equipment that is reasonably necessary for the patient's post-surgical care. In such circumstances, a reasonable inference arises that the technology would not be reasonably connected to the medical care of the patient. Among other things, this safeguard precludes incentives that might serve to induce beneficiaries inappropriately to receive other medical care that is not included in the episode.

We propose that participant hospitals would be required to maintain contemporaneous documentation of such items and services furnished that exceed $10, including the date and identity of the beneficiary to whom the item or service was provided. We further propose that the required documentation be maintained for a period of 10 years.

We propose that items and services involving technology provided to beneficiaries may not exceed $1,000 in retail value at the time of donation for any one beneficiary in any one CCJR episode. Items of technology exceeding $50 in retail value at the time of donation must remain the property of the participant hospital and must be retrieved from the beneficiary at the end of the episode, with the documentation of the date of retrieval. In addition, the amount and nature of the technology must be the minimum necessary to achieve the goals previously noted earlier in this section. Finally, we propose that beneficiary incentives may not be tied to the receipt of services outside the episode of care and that the cost of the incentives cannot be shifted to a federal health care program. The aforementioned proposals regarding beneficiary incentives are consistent with the policies on beneficiary incentives in other CMS models, such as the BPCI initiative.

We seek comment on our proposal for beneficiary incentives under CCJR. In addition to general comments on the proposal, we are interested in comments on whether the $1,000 limit on technology items and services is necessary, reasonable, and appropriate. We also solicit comment on whether retrieving technology valued at more than $50 is too burdensome and whether elimination of that requirement will prevent abuse. We also solicit comment on the documentation requirement for items and services furnished that exceed $10, or whether a different amount would be more

appropriate and less burdensome. We welcome comments on additional program integrity safeguards for these arrangements.

(3) Compliance With Fraud and Abuse Laws

Certain arrangements between and among participant hospitals and third parties or beneficiaries may implicate the civil monetary penalty (CMP) law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act), or the physician self-referral prohibition (section 1877 of the Act). In many cases, arrangements that implicate these laws can be structured to comply with them by using existing safe harbors and exceptions. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain specified fraud and abuse laws as may be necessary solely for purposes of testing of payment models under section 1115A(b) of the Act. A waiver is not needed for an arrangement that does not implicate the fraud and abuse laws or that implicates the fraud and abuse laws but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. Accordingly, pursuant to section 1115A(d)(1) of the Act, the Secretary will consider whether waivers of certain fraud and abuse laws are necessary to test the CCJR model as the model develops. The vehicle for promulgating waivers, if any, is under consideration. Such waivers, if any, would be promulgated separately from this proposed regulation by OIG (as to sections 1128A and 1128B of the Act) and CMS (as to section 1877 of the Act), to which the respective authorities have been delegated.

The requirements of the CCJR final rule will bear on the need for and scope of any fraud and abuse waivers that might be granted for the CCJR model. Because of the close nexus between the final regulations governing the structure and operations of the CCJR model and the development of any fraud and abuse waivers necessary to carry out the provisions of the model, CMS and OIG may, when considering the need for or scope of any waivers, consider comments submitted in response to this proposed rule and the provisions of the CCJR final rule.

11. Proposed Waivers of Medicare Program Rules

a. Overview

We believe it may be necessary and appropriate to provide additional flexibilities to hospitals participating in CCJR, as well as other providers that furnish services to beneficiaries in CCJR episodes. The purpose of such flexibilities would be to increase LEJR episode quality and decrease episode spending or internal costs or both of providers and suppliers that results in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, and beneficiaries. These possible additional flexibilities could include use of our waiver authority under section 1115A of the Act, which provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act.

As we have stated elsewhere in sections I.B and III.A of this proposed rule, our previous and current efforts in testing episode payment models have led us to believe that models where entities bear financial responsibility for total Medicare spending for episodes of care hold the potential to incentivize the most substantial improvements in episode quality and efficiency. As discussed in section III.C of this proposed rule, we are proposing that hospitals participating in this model be eligible for reconciliation payments based on improved performance starting in performance year 1, and we would phase-in repayment responsibility for excess episode spending starting in performance year 2. We believe that where participant hospitals bear repayment responsibility for excess episode spending beyond the target price while high quality care is valued, they will have an increased incentive to coordinate care furnished by the hospital and other providers and suppliers throughout the episode to improve the quality and efficiency of care. With these incentives present, there may be a reduced likelihood of over-utilization of services that could otherwise result from waivers of Medicare program rules. Given these circumstances, waivers of certain program rules for providers and suppliers furnishing services to CCJR beneficiaries may be appropriate to offer more flexibility than under existing Medicare rules for such providers and suppliers, so that they may provide appropriate, efficient care for beneficiaries. An example of such a program rule that could be waived to potentially allow more efficient LEJR episode care would be the 3-day inpatient hospital stay requirement prior to a covered SNF stay for beneficiaries who could appropriately be discharged to a SNF after less than a 3-day inpatient hospital stay.

In addition, we believe that waivers of certain Medicare program rules are necessary to make reconciliation payments to or recoup payments from participant hospitals as a result of the Net Payment Reconciliation Amount (NPRA) for each performance year as discussed in section III.C.6.a. of this proposed rule, as well as to exclude beneficiary cost-sharing from these reconciliation payments or recoupments.

We welcome comments on possible waivers under section 1115A of the Act of certain Medicare program rules beyond those specifically discussed in this proposed rule that might be necessary to test this model. We will consider the comments that are received during the public comment period and our early model implementation experience and may make future proposals regarding program rule waivers during the course of the model test. We are especially interested in comments explaining how such waivers could provide providers and suppliers with additional ways that are not permitted under existing Medicare rules to increase quality of care and reduce unnecessary episode spending, but that could be appropriately used in the context of CCJR where participant hospitals bear full responsibility for total episode spending by performance year 3. We are also interested in receiving comments regarding the timing and manner in which such waivers, were they to be offered, would be implemented. For example, would it be necessary and appropriate to offer program waivers early in the model test to allow providers and suppliers adequate time to adjust their care coordination strategies to implement changes permitted by the waivers, despite there being no full repayment responsibility for excess episode spending until performance year 3? What program integrity and beneficiary protection risks could be introduced by waivers of the program rules described later in this section of this proposed rule and how could we mitigate those risks? What other issues should be considered when making use of waiver authority with respect to program rules? What operational issues do CMS and providers and suppliers furnishing services to beneficiaries in the model need to consider and what processes would need to be in place to implement these alternative program policies?

What implications would there be for provider and supplier infrastructure, including IT and other systems and processes? What provider education would be needed? We note that any waivers included in a final rule would be offered to participant hospitals, but depending on the specifics of each waiver, might be applied to services furnished by providers and suppliers other than the hospital. Where that is the case, we seek input on how we may best educate and disseminate information using methods effective in reaching providers and suppliers. Additionally, we seek comment on how we would appropriately and accurately track the use of waivers by providers and suppliers other than participant hospitals.

Specific program rules for which we propose waivers under the CCJR model to support provider and supplier efforts to increase quality and decrease episode spending and for which we invite comments are included in the sections that follow. We propose that these waivers of program rules would apply to the care of beneficiaries who are in CCJR episodes at the time when the waiver is used to bill for a service that is furnished to the beneficiary, even if the episode is later cancelled as described in section III.B.3.b of this proposed rule. If a service is found to have been billed and paid by Medicare under circumstances only allowed by a program rule waiver for a beneficiary not in the CCJR model at the time the service was furnished, CMS would recoup payment for that service from the provider or supplier who was paid, and require that provider and supplier to repay the beneficiary for any coinsurance previously collected.

We also generally seek comment on any additional Medicare program rules that it may be necessary to waive using our authority under section 1115A of the Act in order to effectively test the CCJR model that we could consider in the context of our early model implementation experience to inform any future proposals we may make.

b. Post-Discharge Home Visits

We expect that the broadly defined LEJR episodes with a duration of 90 days following hospital discharge as we propose in section III.B. of this proposed rule will result in participant hospitals redesigning care by increasing care coordination and management of beneficiaries following surgery. This will require participant hospitals to pay close attention to any underlying medical conditions that could be affected by the anchor hospitalization and improving coordination of care across care settings and providers. Beneficiaries may have substantial mobility limitations during LEJR episodes following discharge to their home or place of residence that may interfere with their ability to travel easily to physicians' offices or other health care settings. Adopting new strategies to increase beneficiary adherence to and engagement with recommended treatment and follow-up care following discharge from the hospital or PAC setting will also be important to high quality episode care. Scientific evidence exists [42] to support the use of home nursing visits among Medicare beneficiaries in improving care coordination following hospital discharge. In addition, we believe the financial incentives in this episode payment model will encourage hospitals to closely examine the most appropriate PAC settings for beneficiaries so that the clinically appropriate setting of the lowest acuity is recommended following discharge from the anchor hospitalization. We expect that all these considerations will lead to greater interest on the part of hospitals and other providers and suppliers caring for CCJR beneficiaries in furnishing services to beneficiaries in their home or place of residence. Such services could include visits by licensed clinicians other than physicians and nonphysician practitioners

In order for Medicare to pay for home health services, a beneficiary must be determined to be ''home-bound''. Specifically, sections 1835(a) and 1814(a) of the Act require that a physician certify (and recertify) that in the case of home health services under the Medicare home health benefit, such services are or were required because the individual is or was ''confined to the home'' and needs or needed skilled nursing care on an intermittent basis, or physical or speech therapy or has or had a continuing need for occupational therapy. A beneficiary is considered to be confined to the home if the beneficiary has a condition, due to an illness or injury, that restricts his or her ability to leave home except with the assistance of another individual or the aid of a supportive device (that is, crutches, a cane, a wheelchair or a walker) or if the beneficiary has a condition such that leaving his or her home is medically contraindicated. While a beneficiary does not have to be bedridden to be considered confined to the home, the condition of the beneficiary must be such that there exists a normal inability to leave home and leaving home requires a considerable and taxing effort by the beneficiary. Absent this condition, it would be expected that the beneficiary could typically get the same services in an outpatient or other setting. Thus, the homebound requirement provides a way to help differentiate between patients that require medical care at home versus patients who could more appropriately receive care in a less costly outpatient setting. Additional information regarding the homebound requirement is available in the Medicare Benefit Manual (Pub 100–02); Chapter 7, ''Home Health Services,'' Section 30.1.1, ''Patient Confined to the Home.''

We considered whether a waiver of the homebound requirement would be appropriate under the CCJR model, particularly beginning in performance year 2, where hospitals begin to bear repayment responsibility for excess episode spending. Waiving the homebound requirement would allow additional beneficiaries to receive home health care services in their home or place of residence. As previously discussed, physician certification that a beneficiary meets the homebound requirement is a prerequisite for Medicare coverage of home health services, and waiving the homebound requirement could result in lower episode spending in some instances. For example, if a beneficiary is allowed to have home health care visits, even if the beneficiary is not considered homebound, the beneficiary may avoid a hospital readmission. All other requirements for the Medicare home health benefit would remain unchanged. Thus, under such a waiver, only beneficiaries who otherwise meet all program requirements to receive home health services would be eligible for coverage of home health services without being homebound.

However, we are not proposing to waive the homebound requirement under CCJR for several reasons. Based on the typical clinical course of beneficiaries after LEJR procedures, we believe that many beneficiaries would meet the homebound requirement for home health services immediately following discharge from the anchor hospitalization or following discharge to their home or place of residence from a SNF that furnished PAC services immediately following the hospital discharge, so they could receive medically necessary home health services under existing program rules. Home health episodes are 60 days in duration, and payment adjustments are made for beneficiaries who require only a few visits during the episode or who

[42] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS. JAMA. 1999:281(7):613–620. doi:10/1001/jama.281.7.613

are discharged during the episode. For those CCJR beneficiaries who could benefit from home visits by a licensed clinician for purposes of assessment and monitoring of their clinical condition, care coordination, and improving adherence with treatment but who are not homebound, we do not believe that paying for these visits as home health services under Medicare is necessary or appropriate, especially given that Medicare payments for home health services are set based on the clinical care furnished to beneficiaries who are truly homebound. Finally, in other CMS episode payment models, such as BPCI, we have not waived the homebound requirement for home health services.

In BPCI, we have provided a waiver of the ''incident to'' rule to allow a physician or nonphysician practitioner participating in care redesign under a participating BPCI provider to bill for services furnished to a beneficiary who does not qualify for Medicare coverage of home health services as set forth under § 409.42 where the services are furnished in the beneficiary's home during the episode after the beneficiary's discharge from an acute care hospital. The ''incident to'' rules are set forth in § 410.26(b)(5), which requires services and supplies furnished incident to the service of a physician or other practitioner must be provided under the direct supervision (as defined at § 410.32(b)(3)(ii)) of a physician or other practitioner.

In BPCI, the waiver is available only for services that are furnished by licensed clinical staff under the general supervision (as defined at § 410.32(b)(3)(i)) of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner), or of the same entity that employs or contracts with the physician (or other practitioner), and while the services may be furnished by licensed clinical staff they must be billed by the physician (or other practitioner) in accordance with CMS instructions using a Healthcare Common Procedures Coding System (HCPCS) G-code created by CMS specifically for the BPCI initiative. As discussed in section III.B of this proposed rule, participants in the BPCI initiative are permitted to select the duration of an episode as either 30 days, 60 days or 90 days. In the case of the incident to waiver under BPCI, the waiver allows physician and nonphysician practitioners to furnish the services not more than once in a 30-day episode, not more than twice in a 60-day episode, and not more than three times in a 90-day episode. All other Medicare coverage and payment criteria must be met.

For the CCJR model, we propose to waive the ''incident to'' rule set forth in § 410.26(b)(5), to allow a CCJR beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of residence any time during the episode. The waiver would not apply for beneficiaries who would qualify for home health services under the Medicare program, as set forth under § 409.42. Therefore these visits could not be billed for such beneficiaries. We propose to allow licensed clinicians, such as nurses, either employed by a hospital or not, to furnish the service under the general supervision of a physician, who may be either an employee or a contractor of the hospital. We propose to allow services furnished under such a waiver to be billed under the PFS by the physician or nonphysician practitioner or by the hospital to which the supervising physician has reassigned his or her benefits. In the latter scenario, we note that the post-discharge home visit services would not be ''hospital services,'' even when furnished by clinical staff of the hospital.

We propose that up to 9 post-discharge home visits could be billed and paid during each 90-day post-anchor hospitalization CCJR episode. Given the average PAC length of stay of approximately 45 days for these episodes and the incentives under CCJR to improve efficiency, which may shorten PAC stays, 9 visits would represent a home visit on average of once per week for two-thirds of the 90-day episode duration, the period of time when the typical beneficiary may have concluded PAC in an efficient episode. We believe that a home visit of once a week to a non-homebound beneficiary who has concluded PAC and who could also receive services in the physician's office or hospital outpatient department as needed, along with telehealth visits in the home from a physician or NPP as proposed in the next section, should be sufficient to allow comprehensive assessment and management of the beneficiary throughout the LEJR episode. We propose that the service be billed with HCPCS code GXXXX (Coordinated quality care—joint replacement model home visit for patient assessment performed by a qualified health care professional for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and making beneficiary connections to community and other services; (for use only in the Medicare-approved coordinated quality care—joint replacement model); may not be billed for a 30-day period covered by a transitional care management code) and paid at approximately $50 under the PFS. The standard PFS ratesetting methodologies establish relative value units (RVUs) based on the resources required to furnish the typical service. Final RVUs under the CY 2016 PFS for the proposed new HCPCS code for CCJR home visits will be included in the CCJR final rule. In addition, we propose to update the values each year to correspond to final values established under the PFS.

The waiver would not apply with respect to a CCJR beneficiary who has qualified, or would qualify, for home health services when the visit was furnished. We expect that the visits by licensed clinicians could include patient assessment, monitoring, assessment of functional status and fall risk, review of medications, assessment of adherence with treatment recommendations, patient education, communication and coordination with other treating clinicians, care management to improve beneficiary connections to community and other services, etc. These post-discharge home visits would remove barriers to follow-up care outside of the home with providers and suppliers and allow the beneficiary to be treated in his or her home environment or place of residence, where potential safety concerns, such as tripping hazards, could quickly be identified and remediated. Given these occasions for further patient assessment and intervention, we believe that where such post-discharge home visits are furnished, there are opportunities to increase patient-centered care coordination and decrease episode spending, potentially resulting in higher quality care for beneficiaries and increased episode efficiency which may benefit the beneficiaries, the Medicare Trust Fund, and participant hospitals.

We also propose to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. The PFS payment for the surgical procedure includes 90 days of post-operative care furnished by the surgeon. Post-operative follow-up care is not separately billable by the surgeon or, unless there is a transfer of care, by another practitioner. The current construction of the global packages included in PFS payments reflects a

narrow view of surgical follow-up care that does not encompass broader, more comprehensive models of post-operative care, such as an episode model like CCJR. As we have noted in the past, it is also difficult to determine the appropriate valuation of the various components of the current global packages (2015 Physician Fee Schedule 79 FR 67584). We do not believe that the CCJR post-discharge home visits, which can include nursing assessments for chronic conditions for which care may be affected by the surgery, would replace or substantially duplicate the kind of post-operative visits involved in furnishing post-operative follow-up care for the global surgery procedure under the PFS. Instead, we anticipate that the work of these post-discharge visits will be similar to the work furnished by the physician coordinating the patient's overall episode care. Therefore, we propose to waive the global surgery billing rules to allow the surgeon or other practitioners to furnish and bill for the post-discharge home visits during surgical global periods.

We plan to monitor utilization patterns of post-discharge home visits under CCJR to monitor for overutilization and significant reductions in medical home health services. We seek comments on the proposed waiver of the ''incident to'' rule to pay for a maximum number of post-discharge home visits to beneficiaries who do not qualify for home health services by licensed clinicians under the general supervision of a physician.

c. Billing and Payment for Telehealth Services

As discussed in the previous section, we expect that the CCJR model design features will lead to greater interest on the part of hospitals and other providers and suppliers caring for CCJR beneficiaries in furnishing services to beneficiaries in their home or place of residence, including physicians' professional services. While physicians may furnish and be paid by Medicare for home visits under the PFS, few visits are actually furnished to Medicare beneficiaries because of the significant physician resources required for such visits and the general structure of most physician office-based practices. For example, in 2014 only 2.6 million physician or nonphysician practitioner home visits were furnished to Medicare beneficiaries in contrast to almost 250 million office or other outpatient evaluation and management visits furnished by physicians or nonphysician practitioners. CCJR would create new incentives for comprehensive episode care management for beneficiaries, including early identification and intervention regarding changes in health status following discharge from the anchor hospitalization. We understand that participant hospitals may want to engage physicians in furnishing timely visits to homebound or non-homebound CCJR beneficiaries in their homes or places of residence to address concerning symptoms or observations raised by beneficiaries themselves, clinicians furnishing home health services, or licensed clinicians furnishing post-discharge home visits, while physicians committed to LEJR care redesign may not be able to revise their practice patterns to meet this home visit need for CCJR beneficiaries.

Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. The telehealth services must be furnished to a beneficiary located in one of the eight types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the site must satisfy at least one of the requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. Generally, for Medicare payment to be made for telehealth services under the Physician Fee Schedule several conditions must be met, as set forth under § 410.78(b). Specifically, the service must be on the Medicare list of telehealth services and meet all of the following other requirements for payment:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. For the list of approved Medicare telehealth services, see the CMS Web site at *www.cms.gov/Medicare/Medicare-General-information/telehealth/*. Under section 1834(m)(4)(F)(ii) of the Act, CMS has an annual process to consider additions to and deletions from the list of telehealth services. We do not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

Some literature suggests that technologies that enable health care providers to deliver care to patients in locations remote from providers are being increasingly used to complement face-to-face patient-provider encounters in both urban and rural areas.[43] In these cases, the use of remote access technologies may improve the accessibility and timeliness of needed care, increase communication between providers and patients, enhance care coordination, and improve the efficiency of care. We note that certain professional services that are commonly furnished remotely using telecommunications technology are paid under the same conditions as in-person physicians' services, and thus do not require a waiver to be considered as telehealth services. Such services that do not require the patient to be present in person with the practitioner when they are furnished are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in person at the medical facility furnishing care to the patient.

In other CMS episode payment models, such as BPCI Models 2 and 3, we determined it was necessary to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. This waiver allows telehealth services to be furnished to eligible telehealth individuals when they are located at one of the eight originating sites at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements. For CCJR, we propose a waiver of this same provision as well as waiver of the requirement that the eligible telehealth individual be in an originating site when the otherwise eligible individual is receiving telehealth services in his or her home or place of residence. This waiver would allow providers and suppliers furnishing services to CCJR beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and to allow the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of residence. We believe that these waivers are essential to maximize the opportunity to improve the quality of care and efficiency for LEJR episodes under CCJR.

Specifically, like the telehealth waiver for BPCI, we propose to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Waiver of this requirement would allow beneficiaries located in any region to receive services related to the episode to be furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–9 principal diagnosis code that is not excluded from the proposed CCJR episode definition (see section III.B.2 of this proposed rule) could be furnished to a CCJR beneficiary, regardless of the beneficiary's geographic location. Under CCJR, this waiver would support care coordination and increasing timely access to high quality care for all CCJR beneficiaries, regardless of geography. Additionally, we propose, only for the purpose of testing the CCJR model, waiving the originating site requirements of section 1834(m)(4)(C)(ii)(I)–(VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we propose to waive the requirement only when telehealth services are being furnished in the CCJR' beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–9 principal diagnosis code that is not excluded from the proposed CCJR episode definition (see section III.B.2 of this proposed rule) could be furnished to a CCJR beneficiary in his or her home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. For example, subsequent hospital care services could not be furnished to beneficiaries in their home since those beneficiaries would not be inpatients of the hospital.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are located in that setting. Section 1834(m) of the Act provides for particular conditions under which Medicare can make payment for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However we do not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the location of the practitioner is unspecified. Therefore, in order to create a mechanism to report E/M services accurately under the CCJR model, we propose to create a specific set of HCPCS G-codes to describe the E/M services furnished to CCJR beneficiaries in their homes via telehealth.

Among the existing E/M visit services, we envision these services would be most similar to those described by the office and other outpatient E/M codes. Therefore, we propose to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the beneficiary's residence and the virtual presence of the practitioner. Specifically, we propose to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, (CPT codes 99201 through 99205 for new patient visits and CPT codes 99212 through 99215 for established patient visits.) For example, the proposed G-code for a level 3 E/M visit for an established patient would be a telehealth visit for the evaluation and management of an established patient in the patient's home, which requires at least 2 of the following 3 key components:

- An expanded problem focused history;
- An expanded problem focused examination;
- Medical decision making of low complexity.

Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the patient's or family's needs or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real-time, audio and video intercommunications technology.

We note that we are not proposing a G-code to parallel the level 1 office/outpatient visit for an established patient, since that service does not require the presence of the physician or other qualified health professional. We also believe this would duplicate the home visits for non-homebound beneficiaries previously proposed in this section.

We propose to develop payment rates for these new telehealth G-codes for E/M services in the patient's home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we propose to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, we believe that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and malpractice risk to marginal levels. Therefore, we propose to adopt work and malpractice (MP) RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner's time and intensity and malpractice liabilities when conducting a visit via telehealth are comparable to the office visit. Final RVUs under the CY 2016 PFS will be included in the CCJR final rule. Additionally, we propose to update these values each year to correspond to final values established under the PFS. We considered whether each level of visit typically would warrant support by auxiliary licensed clinical staff within the context of the CCJR model. The cost of such staff and any associated supplies, for example, would be incorporated in the practice expense (PE) RVUs under the PFS. For the lower level visits, levels 1 through 3 for new and 2 and 3 for established visits, we did not believe that the visit would necessarily require auxiliary medical staff to be available in the patient's home. We anticipate these lower level visits would be the most commonly furnished and would serve as a mechanism for the patient to consult quickly with a practitioner for concerns that can be easily described and explained by the patient. We do not propose to include PE RVUs for these services, since we do not believe that virtual visits envisioned for this model typically incur the kinds of costs included in the PE RVUs under the PFS. For higher level visits, we typically would anticipate some amount of support from auxiliary clinical staff. For example, wound examination and minor wound debridement would be considered included in an E/M visit and would require licensed clinical staff to be present in the beneficiary's home during the telehealth visit in order for

the complete service to be furnished. We believe it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for CCJR beneficiaries in LEJR episodes without licensed clinical staff support in the home.

However, we also note that this proposed model already includes several avenues for licensed clinical staff to be in the patient's home, either through a separately paid home visit as proposed for the model or through home health services as discussed earlier in this section of this proposed rule. Therefore, although we consider support by auxiliary clinical staff to be typical for level 4 or 5 E/M visits furnished to CCJR beneficiaries in the home via telehealth, we do not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we would expect to observe level 4 and 5 E/M visits to be reported on the same claim with the same date of service as a home visit or during a period of authorized home health care. If neither of these occurs, we propose to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit and if they were not, to document the reason that such a high-level visit would not require such personnel.

We note that because the services described by the proposed G-codes, by definition, are furnished remotely using telecommunications technology, they therefore are paid under the same conditions as in-person physicians' services and they do not require a waiver to the requirements of section 1834(m) of the Act. We also note that because these home telehealth services are E/M services, all other coverage and payment rules regarding E/M services would continue to apply.

Under CCJR, this proposal to waive the originating site requirements and create new home visit telehealth HCPCS codes would support the greatest efficiency and timely communication between providers and beneficiaries by allowing beneficiaries to receive telehealth services at their places of residence.

With respect to home health services paid under the home health prospective payment system (HH PPS), we emphasize that telehealth visits under this model cannot substitute for in-person home health visits per section 1895(e)(1)(A) of the Act. Furthermore, telehealth services by social workers cannot be furnished for CCJR beneficiaries who are in a home health episode of care because medical social services are included as home health services per section 1861(m) of the Act and paid for under the Medicare HH PPS. However, telehealth services permitted under section 1834 of the Act and furnished by physicians or other practitioners, specifically physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, nurse anesthetists, psychologists, and dieticians, can be furnished for CCJR beneficiaries who are in a home health episode of care. Finally, sections 1835(a) and 1814(a) of the Act require that the patient has a face-to-face encounter with the certifying physician or an allowed nonphysician practitioner (NPP) working in collaboration with or under the supervision of the certifying physician before the certifying physician certifies that the patient is eligible for home health services. Under § 424.22(a)(1)(v), the face-to-face encounter can be performed up to 90 days prior to the start of home health care or within 30 days after the start of home health care. Section 424.22(a)(1)(v)(A) also allows a physician, with privileges, who cared for the patient in an acute or PAC setting (from which the patient was directly admitted to home health) or an allowed NPP working in collaboration with or under the supervision of the acute or PAC physician to conduct the face-to-face encounter.

Although sections 1835(a) and 1814(a) of the Act allow the face-to-face encounter to be performed via telehealth, we are not proposing that the waiver of the telehealth geographic site requirement for telehealth services and the the originating site requirement for telehealth services furnished in the CCJR beneficiary's home or place of residence would apply to the face-to-face encounter required as part of the home health certification when that encounter is furnished via telehealth. In other words, when a face-to-face encounter furnished via telehealth is used to meet the requirement for home health certification, the usual Medicare telehealth rules apply with respect to geography and eligibility of the originating site. We expect that this policy will not limit CCJR beneficiaries' access to medically necessary home health services because beneficiaries receiving home health services during a CCJR episode will have had a face-to-face encounter with either the physician or an allowed NPP during their anchor hospitalization or a physician or allowed NPP during a post-acute facility stay prior to discharge directly to home health services.

Under the proposed waiver of the geographic site requirement and originating site requirement, all telehealth services would be required to be furnished in accordance with all Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service would be waived if there is no facility as an originating site (that is, the service was originated in the beneficiary's home). Finally, providers and suppliers furnishing a telehealth service to a CCJR beneficiary in his or her home or place of residence during the episode would not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service. Beneficiaries would be able to receive services furnished pursuant to the telehealth waivers only during the CCJR LEJR episode.

We plan to monitor patterns of utilization of telehealth services under CCJR to monitor for overutilization or reductions in medically necessary care, and significant reductions in face-to-face visits with physicians and NPPs. We plan to specifically monitor the distribution of new telehealth home visits that we are proposing, as we anticipate greater use of lower level visits. Given our concern that auxiliary licensed clinical staff be present for level 4 and 5 visits, we will monitor our proposed requirement that these visits be billed on the same claim with the same date of service as a home nursing visit, during a period authorized home health care, or that the physician document the presence of auxiliary licensed clinical staff in the home or an explanation as to the specific circumstances precluding the need for auxiliary staff for the specific visit. We seek comments on the proposed waivers with respect to telehealth services, and the proposed creation of the home visit telehealth codes.

d. SNF 3-Day Rule

We expect that the CCJR model will encourage participant hospitals and their provider and supplier partners to redesign care for LEJR episodes across the continuum of care extending to 90 days post-discharge from the anchor hospital stay. We believe that hospitals will seek to develop and refine the most efficient care pathways so beneficiaries

receive the lowest intensity, clinically appropriate care at each point in time throughout the episode. We understand that in some cases, particularly younger beneficiaries undergoing total knee replacement, certain beneficiaries receiving LEJR procedures may be appropriately discharged from the acute care hospital to a SNF in less than the 3 days required under the Medicare program for coverage of the SNF stay. While total knee arthroplasty (TKA) remains payable by Medicare to the hospital only when furnished to hospital inpatients, we have heard from some stakeholders that these procedures may be safely furnished to hospital outpatients with a hospital outpatient department stay of only 24 hours. Finally, we note that the current geometric mean hospital length of stay for LEJR procedures for beneficiaries without major complications or comorbidities (MS–DRG 470) is only 3 days and that for MS–DRG 469 for beneficiaries with such complications or comorbidities is 6 days. Thus, we believe it is possible that hospitals working to increase episode efficiency may identify some CCJR beneficiaries who could be appropriately discharged from the hospital to a SNF in less than 3 days, but that early discharge would eliminate Medicare coverage for the SNF stay unless a waiver of Medicare requirements were provided under CCJR.

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing or skilled rehabilitation care or both. Pursuant to section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3-consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. We refer to this as the SNF 3-day rule. We note that the SNF 3-day rule has been waived or is not a requirement for Medicare SNF coverage under other CMS models or programs, including BPCI Model 2. BPCI Model 2 awardees that request and are approved for the waiver can discharge Model 2 beneficiaries in less than 3 days from an anchor hospital stay to a SNF, where services are covered under Medicare Part A as long as all other coverage requirements for such services are satisfied.

Currently, FFS Medicare beneficiary discharge patterns to a SNF immediately following hospitalization for an LEJR procedure vary regionally across the country, from a low of approximately 10 percent of Medicare beneficiaries to a high of approximately 85 percent.[44] Additionally, a study of Medicare beneficiaries has shown that over the period of time between 1991 and 2008, as the inpatient hospital length-of-stay for total hip arthroplasty (THA) decreased from an average of 9.1 days to an average of 3.7 days, the average percentage of primary THA patients discharged directly to home declined from 68 percent to 48 percent while the proportion discharged directly to skilled care (primarily SNFs) increased from 17.8 percent to 34.3 percent.[45] During this same period of time, 30-day all-cause readmission increased from 5.8 percent to 8.5 percent. Similar to the CCJR payment policies we propose in section III.C of this proposed rule, which would require participating CCJR hospitals to repay Medicare for excess episode spending beginning in performance year 2, participants in BPCI Model 2 assume financial responsibility for episode spending for beneficiaries included in a Model 2 episode. Episode payment models like BPCI and CCJR have the potential to mitigate the existing incentives under the Medicare program to overuse SNF benefits for beneficiaries, as well as to furnish many fragmented services that do not reflect significant coordinated attention to and management of complications following hospital discharge. The removal of these incentives in an episode payment model lays the groundwork for offering participant hospitals greater flexibility around the parameters that determine SNF stay coverage. BPCI participants considering the early discharge of a beneficiary pursuant to the waiver during a Model 2 episode must evaluate whether early discharge to a SNF is clinically appropriate and SNF services are medically necessary. Next, they must balance that determination and the potential benefits to the hospital in the form of internal cost savings due to greater financial efficiency with the understanding that a subsequent hospital readmission, attributable to premature discharge or low quality SNF care, could substantially increase episode spending while also resulting in poorer quality of care for the beneficiary. Furthermore, early hospital discharge for a beneficiary who would otherwise not require a SNF stay (that is, the beneficiary has no identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis) following a hospital stay of typical length does not improve episode efficiency under an episode payment model such as BPCI or CCJR.

Because of the potential benefits we see for participating CCJR hospitals, their provider partners, and beneficiaries, we propose to waive in certain instances the SNF 3-day rule for coverage of a SNF stay following the anchor hospitalization under CCJR beginning in performance year 2 of the model when repayment responsibility for actual episode spending that exceeds the target price begins. We propose to use our authority under section 1115A of the Act with respect to certain SNFs that furnish Medicare Part A post-hospital extended care services to beneficiaries included in an episode in the CCJR model. We believe this waiver is necessary to the model test so that participant hospitals can redesign care throughout the episode continuum of care extending to 90 days post-discharge from the anchor hospital stay in order to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. However, we are not proposing to waive this requirement in performance year 1, when participating hospitals are not responsible for excess actual episode spending. We believe that there is some potential for early hospital discharge followed by a SNF stay to increase actual episode spending over historical patterns unless participant hospitals are particularly mindful of this potential unintended consequence. Without participant hospital repayment responsibility in performance year 1, we are concerned that Medicare would be at full risk under the model for increased episode spending because, without a financial incentive to closely manage care, hospitals might be more likely to discharge beneficiaries to SNFs early leading to increased episode spending for which the hospital would bear no responsibility. Beginning in performance year 2 and continuing through performance year 5, we propose to waive the SNF 3-day rule because participant hospitals will bear partial or full responsibility (capped at the proposed stop-loss limit described in section III.C. of this proposed rule) for excess episode actual spending, thereby providing a strong incentive in those years for participant hospitals to redesign care with both quality and efficiency outcomes as priorities. All other Medicare rules for coverage and payment of Part A-covered SNF services would continue to apply to CCJR

[44] ''Analysis of Medicare claims with admission dates from July 1, 2013 through June 30, 2014 accessed through the Chronic Conditions Warehouse.''

[45] Cram P, Lu X, Kaboli PJ, et al. Clinical Characteristics and Outcomes of Medicare Patients Undergoing Total Hip Arthroplasty, 1991–2008. JAMA. 2011;305(15):1560–1567.

beneficiaries in all performance years of the model.

In addition, because the average length of stay for Medicare beneficiaries hospitalized for LEJR procedures without major complications or comorbidities is already relatively short at 3 days and in view of our concerns over protecting immediate CCJR beneficiary safety and optimizing health outcomes, we propose to require that participant hospitals may only discharge a CCJR beneficiary under this proposed waiver of the SNF 3-day rule to a SNF rated an overall of three stars or better by CMS based on information publicly available at the time of hospital discharge. Problem areas due to early hospital discharge may not be discovered through model monitoring and evaluation activities until well after the episode has concluded, and the potential for later negative findings alone may not afford sufficient beneficiary protections. CMS created a Five-Star Quality Rating System for SNFs to allow SNFs to be compared more easily and to help identify areas of concerning SNF performance. The Nursing Home Compare Web site (*www.medicare.gov/NursingHomeCompare/*) gives each SNF an overall rating of between 1 and 5 stars. Skilled nursing facilities with 5 stars are considered to have much above average quality, and SNFs with one star are considered to have quality much below average. Published SNF ratings include distinct ratings of health inspection, staffing, and quality measures, with ratings for each of the three sources combined to calculate an overall rating. These areas of assessment are all relevant to the quality of SNF care following discharge from the anchor hospitalization initiating a CCJR episode, especially if that discharge occurs after less than three days in the hospital. A study of the clinical factors that kept patients in a Danish hospital unit dedicated to discharge in three days or fewer following total hip and knee arthroscopy procedures found that that pain, dizziness, and general weakness were the main clinical reasons for longer hospitalization, as well as problems with personal care and walking 70 meters with crutches.[46] Medicare beneficiaries discharged from the hospital to a SNF in less than three days may be at higher risk of these uncomfortable symptoms and disabling functional problems not being fully resolved at hospital discharge, although we expect that under the CCJR episode payment model participant hospitals will have a strong interest in ensuring appropriate discharge timing so that hospital readmissions and complications are minimized. Nevertheless, because of the potential greater risks following early inpatient hospital discharge, we believe it is appropriate that all CCJR beneficiaries discharged from the participant hospital to a SNF in less than 3 days be admitted to a SNF that has demonstrated that it is capable of providing quality care to patients with significant unresolved post-surgical symptoms and problems. We believe such a SNF would need to provide care of at least average overall quality, which would be represented by an overall SNF 3-star or better rating.

We propose that the waiver be available for the CCJR beneficiary's care. The SNF would insert a Treatment Authorization Code on the claim for a beneficiary in the model where the SNF seeks to the use the waiver. This process would promote coordination between the SNF and the participant hospital, as the SNF would need to be in close communication with the participant hospital to ensure that the beneficiary is in the model at the time the waiver is used. We propose that where the beneficiary would be eligible for inclusion in a CCJR episode of care at the time of hospital discharge, use of the waiver would be permitted where it is medically necessary and appropriate to discharge the beneficiary to a SNF prior to a 3-day inpatient stay.

Beneficiaries would be eligible to receive services furnished under the 3-Day Rule waiver only during the CCJR episode. We plan to monitor patterns of SNF utilization under CCJR, particularly with respect to hospital discharge in less than 3 days to a SNF, to ensure that beneficiaries are not being discharged prematurely to SNFs and that they are able to exercise their freedom of choice without patient steering. We seek comment on our proposal to waive the SNF 3-day stay rule for stays in SNFs rated overall as three stars or better following discharge from the anchor hospitalization in CCJR episodes.

e. Waivers of Medicare Program Rules To Allow Reconciliation Payment or Repayment Actions Resulting From the Net Payment Reconciliation Amount

In order to make reconciliation payment to or carry out recoupment from a participant hospital that results from the NPRA calculation for each performance year as discussed in section III.C.6.a. of this proposed rule, we believe we would need to waive certain Medicare program rules. Therefore, in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we would waive requirements of the Act for all Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under this proposed payment model for CCJR participant hospitals selected in accordance with CMS's proposed selection methodology. In addition, we do not propose that reconciliation payments or repayments change beneficiary cost-sharing from the regular Medicare program cost-sharing for the related Part A and Part B services that were paid for CCJR beneficiaries and aggregated to determine actual episode spending in the calculation of the NPRA. We therefore would waive the requirements of sections 1813 and 1833(a) of the Act to the extent that they would otherwise apply to reconciliation payments or repayments from a participant hospital under the CCJR model. We seek comment on our proposed waivers related to repayment and recoupment actions as a result of the NRPA calculated.

12. Proposed Enforcement Mechanisms

CMS must have certain mechanisms to enforce compliance with the requirements of the model, either by the participant hospital, or by an entity or individual participating in the CCJR model by furnishing a service to a beneficiary during a CCJR episode. The following discussion details the enforcement mechanisms we propose to make available to CMS for the CCJR model.

We propose an enforcement structure that would be consistent with other CMMI models. We believe that Model 2 of the BPCI initiative is an appropriate model for comparison, given that Model 2 and CCJR share many of the same policy characteristics, particularly with respect to episode definition. For example, the participation agreement between CMS and a participant (called an Awardee) in BPCI Model 2 provides that CMS may immediately or with advance notice terminate the awardee's participation in the model or require the Awardee to terminate its agreement (''participant agreement'') with a participating provider or supplier that is not in compliance with BPCI requirements. In such circumstances, CMS may direct the Awardee to terminate its participant agreement with a participating provider or supplier because the Awardee has a participation agreement with CMS, whereas the participating provider or supplier does

[46] Husted H, Lunn TH, Troelsen A, Gaarm-Larsen L, Kristensen BB, Kehlet H. Why still in hospital after fast-track hip and knee arthroplasty? Acta Orthopaedica. 2011; 82(6)679–684.

not. CMS may require termination of the Awardee or a participating provider or supplier if—

• CMS determines that it no longer has the funds to support the BPCI model;

• CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act; or

• The BPCI awardee or an individual or entity participating in BPCI under the awardee does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payer status.

++ Is subject to sanctions or final actions of an accrediting organization or federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of the BPCI agreement.

++ Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the BPCI initiative.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

Under the terms of the BPCI agreement, upon CMS's termination of the agreement for any of the reasons previously listed in this section, CMS may immediately cease the distribution of positive reconciliation payments to the awardee and the awardee must immediately cease the distribution of any gainsharing payments.

Many CMMI models also allow for CMS to impose remedial actions to address noncompliance by either a participant that has a direct relationship (participation agreement) with CMS, or by any individual or entity participating in the CMMI model pursuant to an agreement with the participant hospital. For example, with respect to the BPCI Model 2, where CMS determines that there may be noncompliance, CMS may take any or all of the following actions:

• Notify the BPCI awardee of the specific performance problem.

• Require the awardee to provide additional data to CMS or its designees.

• Require the awardee to stop distributing funds to a particular individual or entity.

• Require the awardee to forego the receipt of any positive reconciliation payments from CMS.

• Request a corrective action plan from the awardee.

++ If CMS requests a corrective action plan, then the following requirements apply to awardees in the BPCI initiative:

— The awardee must submit a corrective action plan for CMS approval by the deadline established by CMS.

— The corrective action plan must address what actions the awardee will take within a specified time period to ensure that all deficiencies are corrected and that it remains in compliance with the BPCI agreement.

Under the CCJR model, we propose that CMS would have the enforcement mechanisms detailed in this section available for use against participant hospitals and any entity or individual furnishing a service to a beneficiary during a CCJR episode, where the participant hospital or such entity or individual: (1) Does not comply with the CCJR model requirements; or (2) are identified as noncompliant via CMS' monitoring of the model or engage in behavior related to any of the reasons previously described that apply to the BPCI initiative. These mechanisms will support the goals of CCJR to maintain or improve quality of care. Given that participant hospitals may receive reconciliation payments, and choose to distribute or share those payments with other providers or suppliers (''CCJR collaborators'') we believe that enhanced scrutiny and monitoring of participant hospitals and CCJR collaborators under the model is necessary and appropriate. Participant hospitals and CCJR collaborators will also be subject to all existing requirements and conditions for Medicare participation not otherwise waived under section 1115A(d)(1) of the Act.

We propose that CMS would have the option to use any one or more of the following enforcement mechanisms for participant hospitals in CCJR. We further propose that these enforcement mechanisms could be instituted and applied in any order, as is consistent with other CMMI models:

• Warning letter—We propose to give CMS the authority to issue a warning letter to participant hospitals to put them on notice of behavior that may warrant additional action by CMS. This letter would inform participant hospitals of the issue or issues identified by CMS leading to the issuance of the warning letter.

• Corrective Action Plan—We propose to give CMS the authority to request a corrective action plan from participant hospitals. We propose the following requirements for corrective action plans:

++ The participant hospital would be required to submit a corrective action plan for CMS approval by the deadline established by CMS.

++ The corrective action plan would be required to address what actions the participant hospital will take within a specified time period to correct the issues identified by CMS.

++ The corrective action plan could include provisions requiring that the participant hospital terminate Participation Agreements with CCJR collaborators that are determined by HHS to be engaging in activities involving noncompliance with the provisions of this proposed rule, engaged in fraud or abuse, providing substandard care, or experiencing other integrity problems.

++ The participant hospital's failure to comply with the corrective action plan within the specified time period could result in additional enforcement action, including: (1) Termination; (2) automatic forfeiture of all or a portion of any reconciliation payments as that term is defined in section III.C. of this proposed rule; (3) CMS's discretionary reduction or elimination of all or a portion of the hospital's reconciliation payment; or (4) a combination of such actions.

• Reduction or elimination of reconciliation amount—We propose to give CMS the authority to reduce or eliminate a participant hospital's reconciliation amount based on noncompliance with the model's requirements, negative results found through CMS' monitoring activities, or the participant hospital's noncompliance associated with a corrective action plan (as noted previously). For example, where CMS requires a participant hospital to submit a corrective action plan, the result of the participant hospital's failure to timely comply with that requirement could be a 50 percent reduction in the reconciliation amount due to the participant hospital at the end a performance year, where the participant hospital's reconciliation report reflects a positive reconciliation amount. We solicit comments on whether negative monitoring results and noncompliance with program requirements or corrective action plans should result in automatic forfeiture of all or a portion of positive NPRA, the amount that could be forfeited or reduced, the number of performance periods over which NPRA may be forfeited or reduced per instance or episode of noncompliance, whether the amount should be a fixed percentage of NPRA or a variable amount depending on the nature and severity of the noncompliance, and the criteria

CMS should use in deciding the severity of noncompliance.

Where the participant hospital's reconciliation report reflects a repayment amount, forfeiture of a reconciliation amount would not be an option for that performance year. In such a case, we considered whether CMS would require the participant hospital to forfeit a certain percentage of a reconciliation amount in the reconciliation report for a future performance year. However, in the case of a failure to comply with the model's requirements, presence of negative results found through CMS's monitoring activities, or noncompliance associated with a corrective action plan, we believe a policy that would increase the amount of repayment amount on the reconciliation report for the performance year in which the noncompliance occurred by the participant hospital is more likely to result in compliance from the hospital. Therefore, we propose to add 25 percent to a repayment amount on a reconciliation report, where the participant hospital fails to timely comply with a corrective action plan or is noncompliant with the model's requirements, We seek comments on this forfeiture policy, including the percentage to be added to a repayment amount on a reconciliation report; the number of performance periods over which a reconciliation amount may be forfeited or reduced per instance or episode of noncompliance; whether the amount should be a fixed percentage of a reconciliation amount or repayment amount, as applicable, or a variable amount depending on the nature and severity of the noncompliance; and the criteria CMS should use in deciding the severity of noncompliance.

• Termination from the model—Given the provisions we have proposed outlining the participation of hospitals in the model, we believe that, in contrast to other CMS models, termination from the CCJR model would contradict the model's design. As a result, in some circumstances termination from the model may be unlikely to be a sufficient mechanism to deter noncompliance by participant hospitals. While we believe termination is a remedy unlikely to be frequently used by CMS in this model, we nonetheless leave open the possibility that in extremely serious circumstances termination might be appropriate, and for that reason, we propose to include it as an available enforcement option. Where a participant hospital is terminated from the CCJR model, we propose that the hospital would remain liable for all negative NPRA generated from episodes of care that occurred prior to termination. We propose that CMS may terminate the participation in CCJR of a participant hospital when the participant hospital, or a CCJR collaborator that has a Participation Agreement with a participant hospital and performs functions or services related to CCJR activities, fails to comply with any of the requirements of the CCJR model. We further propose that CMS could terminate the participant hospital's participation in the model, or require a participant hospital to terminate a Participation Agreement with a CCJR collaborator for reasons including, but not limited to the following:

• CMS determines that it no longer has the funds to support the CCJR model.

• CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act.

• The CCJR participant hospital, or an individual or entity participating in CCJR under the participant hospital does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payor status.

++ Is subject to sanctions or final actions of an accrediting organization or federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of this proposed rule.

++ Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the CCJR model.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

++ Is subject to action involving violations of the physician self-referral prohibition, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CCJR model

• Other Enforcement Mechanisms—We seek to incorporate policies regarding enforcement mechanisms that are necessary and appropriate to test the CCJR model. Thus, we seek public comment on additional enforcement mechanisms that would contribute to the following goals:

++ Allow CMS to better operate or monitor the model.

++ Appropriately engage and encourage all entities and individuals furnishing a service to a beneficiary during a CCJR episode to comply with the requirements and provisions of the CCJR model.

++ Preserve the rights of Medicare beneficiaries to receive medically necessary care, to not be endangered by providers and suppliers engaging in noncompliant activities, and to be able to choose from whom they want to receive care.

We seek public comment on these proposals and invite commenters to propose additional safeguards we should consider in this proposed rule.

D. Quality Measures and Display of Quality Metrics Used in the CCJR Model

1. Background

a. Purpose of Quality Measures in the CCJR Model

The priorities of the National Quality Strategy [47] include making care safer and more affordable, promoting effective communication and coordination as well as engaging patients and families in their care. We believe quality measures that encourage providers to focus on the National Quality Strategy priorities will ultimately improve quality of care and cost efficiencies. As described earlier in section III.C.5 of this proposed rule, we are proposing that in order for a hospital in the CCJR model to receive a reconciliation payment for the applicable performance year, the participant hospital's measure results must meet or exceed certain thresholds compared to the national hospital measure results calculated for all HIQR-participant hospitals for all three measures for each performance period. More specifically, for performance years 1 through 3, a participant hospital's measure results must be at or above the 30th percentile of the national hospital measure results calculated for all hospitals under the HIQR Program for each of the three measures for each performance period (for a detailed discussion see section III.C.5.b of this proposed rule. For performance years 4 and 5, a participant hospital's measure results must be at or above the 40th percentile of the national hospital measure results (for a detailed discussion see section III.C.5.b. of this proposed rule). In this section, we fully describe the proposed quality measures that will be used for public reporting and to determine whether a participant

[47] National Quality Strategy. Working for Quality: About the National Quality Strategy. Available at: *http://www.ahrq.gov/workingforquality/about.htm#develnqs.* Accessed on April 15, 2015.

hospital is eligible for the reconciliation payment under the CCJR model. We are proposing a complication measure, readmission measure, and a patient experience survey measure for the CCJR model. We note that these measures will assess the priorities of safer care, transitions of care and effective communication, and engagement of patients in their care, respectively. Specifically, we are proposing the following three CMS outcome measures:

- The Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) (as referred to as THA/TKA Complications measure (NQF #1550)).
- The Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (as referred to as THA/TKA Readmissions measure (NQF #1551)).
- HCAHPS Survey (NQF #0166).

For the inpatient hospital settings, these fully developed measures are endorsed by the National Quality Forum (NQF), and recommended by the NQF Measure Application Partnership (MAP) with subsequent implementation in the HIQR Program, HVBP Program, and the HRRP (see FY 2015 IPPS/LTCH final rule 79 FR 50031, 50062, 50208 and 50209, and 50259). These measures are also publicly reported on Hospital Compare.

An important purpose of the proposed quality measures for the CCJR model is to provide transparent information on hospital performance for the care of patients undergoing eligible elective joint replacement surgery and to ensure that care quality is either maintained or improved. The proposed measures assess the following key outcomes for patients undergoing elective joint replacement surgery:

- Serious medical and surgical complications.
- Unplanned readmissions.
- Patient experience.

We note that complications and unplanned readmissions result in excess inpatient and post-acute spending, and reductions in these undesirable events will improve patient outcomes while simultaneously lowering healthcare spending. The THA/TKA Complications measure (NQF #550) will inform quality improvement efforts targeted towards minimizing medical and surgical complications during surgery and the postoperative period. The THA/TKA Readmission measure (NQF #1551) captures the additional priorities of care provided in the transition to outpatient settings and communication with patients and providers during and immediately following inpatient admission. Improved quality of care, specifically achieved through coordination and communication among providers and with their patients and their caregivers, can favorably influence performance on these measures. We believe improvement in measure performance will also mean improved quality of care and reduced cost.

Additionally, we continue to focus on patient experience during hospitalizations, and believe that the HCAHPS Survey measure provides not only the opportunity for patients to share their lower extremity joint replacement hospital experience, but also for hospitals to improve quality of care based on patient experience. For example, the HCAHPS Survey ''categories of patient experience'' specifically provides areas (for example, communication with doctors and nurses, responsiveness of hospital staff, pain management) in which a hospital could improve transition of care and increase patient safety (for detailed description of patient experience areas covered by HCAHPS surveys see section III.D.2.c. of this proposed). Additionally, the survey includes measures related to nurse and physician communication, pain management, timeliness of assistance, explanation of medications, discharge planning and cleanliness of the hospitals to provide specific areas for hospitals to improve on.[48] Specific questions on provider communication include the following:

- How often the patient believed providers listened carefully to his or her questions?
- Whether the purpose of medications and associated adverse events were explained?
- Whether discussions on post-discharge instructions and plans occurred so that the patient had a clear understanding of how to take medications and an understanding of his or her responsibilities in managing his or her health post-discharge?

All of these areas of patient experience would be invaluable to improving hospital quality of care. We note that Manary, *et al.*[2] suggest that by focusing on patient outcomes we can improve patient experience and that timeliness of measuring patient experience is important due to the potential for recall inaccuracies; survey administration for HCAHPS surveys must begin between 2 and 42 days after discharge from a hospital.

We are aware that there is concern whether there is a relationship between patient satisfaction and quality of surgical care. To address this question Tsai *et al.*[49] recently assessed patient satisfaction using the HCAHPS Survey results and correlated quality performance using nationally implemented structural, process and outcome surgical measures (that is, structural, process and outcome surgical measures in the Hospital Value Based Purchasing, and the Hospital Readmission Reduction Programs). The study found a positive relationship between patient experience of care and surgical quality of care, among the 2,953 hospitals that perform six high cost and high frequency surgical procedures that are also associated with morbidity and mortality in Medicare beneficiaries. The study included hip replacement procedures, and specifically noted that those hospitals with high patient satisfaction also had high performance on nationally implemented surgical quality measures (such as the Surgical Care Improvement Project measures and 30-day risk-adjusted readmission and peri-operative mortality outcome measures). Finally, we note that although the HCAHPS Survey measure is not specific to joint replacements, the survey provides all patients the opportunity to comment on their hospital experience, including patients who have received lower extremity joint replacements, which helps to inform hospitals on areas for improvement. While HCAHPS scores are aggregated at the hospital level, the surgical service line is one of three service lines encompassed by the survey.[50]

We strive to align as many measures and programs as is feasibly possible. We believe proposing fully developed measures that are used in other CMS hospital quality programs will minimize the burden on participant hospitals for having to become familiar with new measures and will allow us to appropriately capture quality data for the CCJR model.

[48] Manary MP, Boulding W, Staelin R, Glickman SW. The Patient Experience and Health Outcomes. New England Journal of Medicine. Jan 2013; 368(3):201–203.

[49] Tsai TC, Orav EJ, Jha AK. Patient Satisfaction and quality of surgical care in US hospitals. Annals of Surgery. 2015; 261:2–8.

[50] Giordano LA, Elliott MN, Goldstein E, Lehrman WG, Spencer PA. Development, Implementation, and Public Reporting of the HCAHPS Survey. Medical Care Research and Review. 2010;67(1):27–37.

b. Public Display of Quality Measures in the CCJR Model

We believe that the display of measure results is an important way to educate the public on hospital performance and increase the transparency of the model. As discussed later in this section of this proposed rule, for the CCJR model, we are proposing to display quality measure results on the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*). We believe that the public and hospitals are familiar with this Web site and how the information is displayed. The proposed measures have been displayed on Hospital Compare over the past few years. Finally, while also aligning the display of data for the CCJR model with other CMS hospital quality programs, we believe that the public and 'hospitals' familiarity with the Hospital Compare Web site will make it simpler to access data.

2. Proposed Quality Measures for Performance Year 1 (CY 2016) and Subsequent years

a. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550)

(1) Background

THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. Between 2009 and 2012, there were 337,419 total hip arthroplasty (THA) procedures and 750,569 total knee arthroplasty (TKA) procedures for Medicare FFS patients 65 years and older.[51] The post-operation complications of these procedures are high considering these are elective procedures, and usually, the complications are devastating to patients. For example, rates for periprosthetic joint infection, a rare but devastating complication, have been reported at 2.3 percent for THA/TKA patients with rheumatoid arthritis after 1 year of follow-up [52] and 1.6 percent in Medicare patients undergoing TKA after 2 years of follow up.[53] Two studies reported 90-day death rates following THA at 0.7 percent [54] and 2.7 percent, respectively.[55] Reported rates for pulmonary embolism following TKA range from 0.5 percent to 0.9 percent.[56 57 58] Reported rates for septicemia range from 0.1 percent, during the index admission[59] to 0.3 percent, 90 days following discharge for primary TKA.[60] Rates for bleeding and hematoma following TKA have been reported at 0.94 percent [61] to 1.7 percent.[62] Combined, THA and TKA procedures account for the largest payments for procedures under Medicare.[63] Both hip and knee arthroplasty procedures improve the function and quality of life of patients with disabling arthritis, and the volume and cost associated with these procedures are very high. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures.

The proposed measure developed by CMS, and currently implemented in the Hospital IQR and Hospital Value-Based Purchasing Program, assesses a hospital's risk standardized complication rate, which is the rate of complications occurring after elective primary THA and TKA surgery. The measure outcome is the rate of complications occurring after THA and TKA during a 90-day period that begins with the date of the index admission for a specific hospital; an index admission is the hospitalization to which the complications outcome is attributed. The following outcomes (either one or more) are considered complications in this measure: Acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding, pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. The data indicated that the median hospital-level risk-standardized complication rate for 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent in hospitals. The variation in complication rates suggests that there are important differences in the quality of care delivered across hospitals, and that there is room for quality improvement. In 2010, we developed the proposed measure of hospital-level risk-standardized complication rate (RSCR) following elective primary THA and TKA surgery, which was later endorsed by the NQF (NQF #1550). In its Pre-Rulemaking Report for 2012,[64] the Measure Application Partnership (MAP) also recommended the inclusion of this measure in the HIQR Program; we have not submitted this measure for use in the post-acute care settings as the measure was developed for the acute care hospital setting. This measure has been publicly reported on Hospital Compare since FY 2014 and in the HIQR Program since FY 2015 (FY 2015 IPPS/LTCH final rule 79 FR 50062). Finally, we note a comparison of the median hospital-level risk-standardized complication rates for hospitals between April 1, 2011 and March 31, 2014 illustrates a performance gap (median RSCR of 3.1 percent with a range from 1.4 percent to 6.9 percent) indicating

[51] Suter L, Grady JL, Lin Z et al.: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[52] Bongartz, T, Halligan CS, Osmon D, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. Arthritis Rheum. 2008; 59(12): 1713–1720.

[53] Kurtz S, Ong K, Lau E, Bozic K, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010;468:5.

[54] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684. Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371.

[55] Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371. Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[56] Mahomed NN, Barrett JA, Katz JN, et al. Rates and outcomes of primary and revision total hip replacement in the United States medicare population. J Bone Joint Surg Am. Jan 2003;85–A(1):27–32.

[57] Khatod M, Inacio M, Paxton EW, et al. Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812–819.

[58] Solomon DH, Chibnik LB, Losina E, et al. Development of a preliminary index that predicts adverse events after total knee replacement. Arthritis & Rheumatism. 2006;54(5):1536–1542.

[59] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[60] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[61] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[62] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1): 95–100.

[63] Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of Medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008; 23(6 Suppl 1):133–138.

[64] National Quality Forum. MAP Final Reports. Available at: *http://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report__Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx.* Accessed on April 1 6, 2015, page 78.

there is still room for quality improvement.[65]

(2) Data Sources

We propose to use Medicare Part A and Part B FFS claims submitted by the participant hospital as the data source to calculate the measure. Index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 1 to 2 months prior to the index (initial) admission. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(3) Cohort

The THA/TKA Complication measure (NQF #1550) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. THA and TKA procedures eligible for inclusion are defined using ICD–9–CM codes 81.51 and 81.54, respectively. We propose that the cohort will include all hospitals included in the CCJR model, but the CCJR model cohort may differ slightly from the hospital cohort that is currently captured in the measures through the HIQR program. That is, the CCJR model cohort is a randomly selected group of acute care hospitals and therefore may not include all of the HIQR program acute care hospitals (for a detailed discussion on selection of hospitals for the model see section III.A.4. of this proposed rule).

(4) Inclusion and Exclusion Criteria

An index admission is the hospitalization to which the complication outcome is attributed. The measure includes the following index admissions for patients:

- Enrolled in Medicare FFS.
- Aged 65 or over.
- Enrolled in Part A and Part B Medicare for the 12 months prior to the date of index admission and during the index admission.
- Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

++ Femur, hip, or pelvic fractures coded in principal or secondary discharge diagnosis fields of the index admission.

++ Partial hip arthroplasty (PHA) procedures with a concurrent THA/TKA.

++ Revision procedures with a concurrent THA/TKA.

++ Resurfacing procedures with a concurrent THA/TKA.

++ Mechanical complication coded in the principal discharge diagnosis field.

++ Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

++ Removal of implanted devices/prostheses.

++ Transfer from another acute care facility for the THA/TKA.

The following admissions would be excluded from the measure:

- Admissions for patients discharged against medical advice (AMA).
- Admissions for patients with more than two THA/TKA procedure codes during the index hospitalization.
- Consistent with the FY 2016 IPPS/LTCH proposed rule, admissions for patients without at least 90 days post-discharge enrollment in FFS Medicare; this exclusion is an update to the measure signaled in the HIQR program section of the FY2016 IPPS/LTCH proposed rule (80 FR 24572 through 24574) to ensure that disproportionate Medicare FFS disenrollment does not bias the measure results.

After applying these exclusion criteria, we randomly select one index admission for patients with multiple index admissions in a calendar year. Therefore, we exclude the other eligible index admissions in that year. Identification and use of a single index admission in a calendar year is done because this measure includes mortality as an outcome and the probability of death increases with each subsequent admission, preventing each episode of care from being mutually independent. Therefore only one index admission is selected to maintain measure integrity.

We note that THA/TKA Complication measure (NQF #1550) does not capture patients undergoing partial hip arthroplasty procedures. We excluded partial hip arthroplasty procedures primarily because partial hip arthroplasty procedures are done for hip fractures. Therefore, they are not elective procedures. Also, partial hip arthroplasty procedures are typically performed on patients who are older, frailer, and have more comorbid conditions. Although this exclusion is not fully harmonized with MS–DRG 469 and 470, which includes partial hip arthroplasty procedures, this measure will still provide strong incentive for improving and maintaining care quality across joint replacement patients as hospitals typically develop protocols for lower extremity joint arthroplasty that will address peri-operative and post-operative care for both total and partial hip arthroplasty procedures. As previously cited in the Episode Definition of the CCJR model (section III.B. of this proposed rule) the frequency of administrative claims data using ICD–9 codes for 2014 indicated that partial hip arthroplasty (ICD–9 code: 81.52) accounted for 12 percent of the administrative claims, while Total Hip replacement (ICD–9 code: 81.51) and Total Knee replacement (ICD–9 code: 81.54) accounted for 87 percent of the administrative claims for 2014. We also note that the same surgeons and care teams frequently perform both procedures. Therefore, quality improvement efforts initiated in response to the THA/TKA Complication measure (NQF #1550) are likely to benefit patients undergoing similar elective procedures, such as partial hip arthroplasty and revision THA/TKA procedures, and possibly even non-elective THA/TKA procedures, such as fracture-related THA.

(5) Risk-Adjustment

We note that CCJR-we chose to align this measure with the risk-adjustment methodologies adopted for the HIQR program and the HRRP in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act (FY 2013 IPPS/LTCH final rule 77 FR 53516 through 53518 and FY 2015 IPPS/LTCH final rule; 79 FR 50024, 50031, and 50202). We note that the risk-adjustment takes into account the patient case-mix to assess hospital performance. The patient risk factors are defined using the Hierarchical Condition Categories (CC), which are clinically relevant diagnostic groups of ICD–9–CM codes.[66] The CCs used in the risk adjustment model for this measure, are provided on the CMS QualityNet *Web site* (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=Qnet Public%2FPage%2FQnetTier4&cid=1228772783162*). We note that the measure uses all Part A and B administrative claims ICD–9 codes for the year prior to and including the index admission. The Part A and B administrative claims ICD–9 codes are

[65] Suter L, Zang W, Parzynski C, et al. 2015 Procedure-Specific Complication Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 4.0). 2015.

[66] Pope G, Ellis R, Ash A, *et al.*, Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

used to inform the risk prediction for each patient; diagnostic codes from post-acute care settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. Use of the Part A and B data does not mean the measures are applicable to post-acute care settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. The measure would meet the requirement if it applied since risk-adjustment adjusts for hospital patient mix, including age and comorbidities, to ensure that hospitals that care for a less healthy patient population are not penalized unfairly. The measure methodology defines ''complications'' as acute myocardial infarction (AMI); pneumonia; sepsis/septicemia; pulmonary embolism; surgical site bleeding; death; wound infection; periprosthetic joint infection; and mechanical complication within 0 to 90 days post the index date of admission, depending on the complication. The decision on the appropriate follow-up period of 0 to 90 days was based on our analysis of 90-day trends in complication rates using the 2008 Medicare FFS Part A Inpatient Data. We found that rates for mechanical complications are elevated until 90 days post the date of index admission. We found that the rates for four other complications—death, surgical site bleeding, wound infection, and pulmonary embolism—are elevated for 30 days, and that rates for AMI, pneumonia, and sepsis/septicemia level off 7 days after the date of index admission.

(6) Calculating the Risk-Standardized Complication Rate and Performance Period

Analogous to how we calculate hospital risk-standardized readmission rates with all readmission measures and risk-standardized mortality rates with the mortality measures used in CMS hospital quality programs, we calculate the hospital risk-standardized complication rate by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw complication rate. The 3-year rolling performance period would be consistent with that used for HIQR (FY 2015 IPPS/LTCH final rule 79 FR 50208 and 50209). For performance year-one of the CCJR model, we propose that the performance period for the THA/TKA Complication measure (NQF #1550) we propose to be April 2013 through March 2016. As noted in this proposed rule, the THA/TKA Readmissions measure (NQF #1551) uses a 30-day window of follow-up, which is different from the 90-day window of follow-up used in the THA/TKA Complications measure (NQF #1550). Section III.D.4. of this proposed rule, Form and Manner, summarizes performance periods for years 1 through 5 of the CCJR JR model.

We seek public comment on this proposal to assess quality performance through implementation of the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) measure.

b. Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551)

(1) Background

The objective of CMS's Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (as referred to as THA/TKA Readmission measure (NQF #1551)) measure is to assess readmission from any cause within 30 days of discharge from the hospital following elective primary THA and TKA. As previously stated, outcome measures such as complications and readmissions are the priority areas for the HIQR Program. Elective primary THA and TKA are commonly performed procedures that improve quality of life. THA and TKA readmissions are disruptive to patients' quality of life, costly to the Medicare program, and data support that readmission rates can be improved through better care coordination and other provider actions.[67] Furthermore, we believe that there is an opportunity for hospitals to improve quality of life for the patient. From July 1, 2011 to June 30, 2014, Medicare FFS claims data indicate that 30-day hospital-level risk-standardized readmission rates ranged from 2.6 percent to 8.5 percent among hospitals with a median rate of 4.8 percent. The mean risk-standardized readmission rate was 4.9 percent.[68] This variation suggests there are important differences in the quality of care received across hospitals, and that there is room for improvement. A measure that addresses readmission rates following THA and TKA provides an opportunity to provide targets for efforts to improve the quality of care and reduce costs for patients undergoing these elective procedures. The measure also increases transparency for consumers and provides patients with information that could guide their choices. We believe that a risk-adjusted readmission outcome measure can provide a critical perspective on the provision of care, and support improvements in care for the Medicare patient population following THA/TKA hospitalization. We note that the THA/TKA Readmission measure (NQF #1551) has wide stakeholder support, with NQF endorsement in January 2012, and support by the MAP for the HIQR Program (2012 Pre-Rulemaking report [19]), and for HRRP (2013 Pre-Rulemaking report [69]). Finally, THA/TKA Readmission Measure (NQF #1551) has been publicly reported since FY 2014 (79 FR 50062), and was implemented in both the HIQR program (77 FR 53519 through 53521) and HRRP (78 FR 50663 and 50664).

(2) Data Sources

We propose to use Medicare Part A and Part B FFS claims submitted by the participant hospital as the data source for calculation of the THA/TKA Readmission measure (NQF #1551). Index admission diagnoses and in-hospital comorbidity data are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment status is obtained from Medicare's enrollment database which contains beneficiary demographic,

[67] Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: a systematic meta-review. *BMC Health Services Research.* 2007;7:47.

[68] Suter L, Desai N, Zang W, *et al.* 2015 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Readmission Measure (Version 4.0), Isolated Coronary Artery Bypass Graft (CABG) Surgery—Version 2.0. 2015; *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[69] National Quality Forum. MAP Final Reports. Available at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.* Accessed on April 16, 2015, page 143.

benefit/coverage, and vital status information.

(3) Cohort

The THA/TKA Readmission measure (NQF #1551) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. THA and TKA procedures eligible for inclusion are defined using ICD–9–CM codes 81.51 and 81.54, respectively. We propose that the cohort will include all hospitals included in the CCJR model, but the CCJR model cohort may differ slightly from the hospital cohort that is currently captured in the measures through the HIQR program. That is, the CCJR model cohort is a randomly selected group of acute care hospitals and therefore may not include all of the HIQR program acute care hospitals (for a detailed discussion on selection of hospitals for the model see section III.A. of this proposed rule.)

(4) Inclusion and Exclusion Criteria

We propose that an index admission is the anchor hospitalization to which the readmission outcome is attributed. The measure includes index admissions for patients:

- Enrolled in Medicare FFS.
- Aged 65 or over.
- Discharged from non-federal acute care hospitals alive.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission and during the index admission.
- Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

++ Femur, hip, or pelvic fractures coded in principal or secondary discharge diagnosis fields of the index admission.

++ Partial hip arthroplasty (PHA) procedures with a concurrent THA/TKA.

++ Revision procedures with a concurrent THA/TKA.

++ Resurfacing procedures with a concurrent THA/TKA.

++ Mechanical complication coded in the principal discharge diagnosis field.

++ Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

++ Removal of implanted devices/prostheses.

++ Transfer from another acute care facility for the THA/TKA.

- This measure excludes index admissions for patients:

++ Without at least 30 days post-discharge enrollment in FFS Medicare.

++ Discharged against medical advice (AMA).

++ Admitted for the index procedure and subsequently transferred to another acute care facility.

++ With more than two THA/TKA procedure codes during the index hospitalization.

Finally, for the purpose of this measure, admissions within 30 days of discharge from an index admission are not eligible to also be index admissions. Thus, no hospitalization will be counted as both a readmission and an index admission in this measure.

This measure does not capture patients undergoing partial hip arthroplasty procedures, as partial hip arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, frailer, and have more comorbid conditions. Although this exclusion is not fully harmonized with MS–DRG 469 and 470, which includes partial hip arthroplasty procedures, this measure would still provide strong incentive for improving and maintaining care quality across joint replacement patients. We believe the THA/TKA Readmission measure (NQF #1551) provides strong incentive for quality improvement because hospitals typically develop protocols for lower extremity joint arthroplasty that will address peri-operative and post-operative care for both total and partial hip arthroplasties, and the same surgeons and care teams frequently perform both procedures. Therefore, quality improvement efforts initiated in response to the THA/TKA Readmission measure (NQF #1551) are likely to benefit patients undergoing similar elective procedures, such as partial hip arthroplasty and revision THA/TKA procedures, and possibly even non-elective THA/TKA procedures, such as fracture-related THA.

(5) Risk-Adjustment

We note that CCJR-we chose to align this measure with the risk-adjustment methodologies adopted for Readmission measure (NQF #1551) under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521). We also note that the measure risk-adjustment takes into account patient age and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for readmission using diagnosis codes collected from all patient claims 1 year prior to patient index hospitalization for THA and TKA. As previously noted in the THA/TKA Complication measure (NQF #1550), Part A and B administrative claims ICD–9 codes are used to inform the risk prediction for each patient; diagnostic codes from post-acute care settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. Use of the Part A and B data does not mean the measures are applicable to post-acute care settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. We note that the patient diagnosis codes are grouped using Hierarchical Condition Categories (CCs), which are clinically relevant diagnostic groups of ICD–9–CM codes.[70] The CCs used in the risk adjustment model for this measure, are provided on the CMS QualityNet *Web site* (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694*). In summary, age and comorbidities present at the time of admission are adjusted for differences in hospital case mix (patient risk factors). The measure uses the hierarchical logistic regression model (HLM) statistical methodology for risk adjustment.

(6) Calculating the Risk-Standardized Readmission Rate and Performance period

We propose to calculate hospital risk-standardized readmission rates consistent with the methodology used to risk standardize all readmission measures and mortality measures used in CMS hospital quality programs. Using HLM, we calculate the hospital-level elective primary THA/TKA risk-standardized readmission rate by producing a ratio of the number of ''predicted'' readmissions (that is, the adjusted number of readmissions at a specific hospital) to the number of ''expected'' readmissions (that is, the number of readmissions if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw readmission rate. The 3-year rolling performance period would be consistent with that used for the HIQR program (FY 2015 IPPS/LTCH final rule 79 FR 50208 and 50209). For performance year-one of the CCJR model, we propose that the performance period for the THA/TKA Readmission measure (NQF

[70] Pope G, Ellis R, Ash A, *et al.*, Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

#1551) would be July 2013 through June 2016. As noted in this proposed rule for the section on the THA/TKA Complications measure (NQF #1550), there is a 90-day window of follow-up which is different from the THA/TKA Readmissions measure (NQF #1551). Section III.D.4.Form and Manner, of this proposed rule summarizes performance periods for years 1 through 5 of the CCJR model years.

We invite public comments on this proposal to include Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) or both in the CCJR model to assess quality performance. We also invite public comment on inclusion of other potential quality measures in the model.

c. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey

(1) Background

The HCAHPS Survey (NQF #0166) is a CMS survey and a national, standardized, publicly reported survey of patients' experience of hospital care. The HCAHPS Survey is endorsed by the NQF (#0166); CMS is the measure steward. The HCAHPS survey, also known as CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience. The HCAHPS Survey asks recently discharged patients 32 questions about aspects of their hospital experience that they are uniquely suited to address. The core of the survey contains 21 items that ask ''how often'' or whether patients experienced a critical aspect of hospital care. The survey also includes four items to direct patients to relevant questions, five items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports (see 77 FR 53513 through 53515). Eleven HCAHPS measures (seven composite measures, two individual items and two global items) are currently publicly reported on the Hospital Compare Web site for each hospital participating in the HIQR Program (see 79 FR 50259.) Each of the seven currently reported composite measures is constructed from two or three survey questions. The seven composites summarize the following:

- How well doctors communicate with patients.
- How well nurses communicate with patients.
- How responsive hospital staff are to patients' needs.
- How well hospital staff helps patients manage pain.
- How well the staff communicates with patients about medicines.
- Whether key information is provided at discharge.
- How well the patient was prepared for the transition to post-hospital care.

Lastly, the two individual items address the cleanliness and quietness of patients' rooms, while the two global items report patients' overall rating of the hospital, and whether they would recommend the hospital to family and friends. We propose to adopt a measure in the CCJR model that uses HCAHPS survey data to assess quality performance and capture patient experience of care.

(2) Data Sources

The HCAHPS Survey is administered to a random sample of adult inpatients between 48 hours and 6 weeks after discharge. As previously discussed in section III.D.5. of this proposed rule, the HCAHPS survey data is collected on inpatient experience, is not limited to Medicare beneficiaries, and does not distinguish between types of Medicare beneficiaries. Patients admitted in the medical, surgical and maternity care service lines are eligible for the survey; the survey is not restricted to Medicare beneficiaries. Hospitals may use an approved survey vendor, or collect their own HCAHPS data (if approved by CMS to do so) (for a detailed discussion see 79 FR 50259). To accommodate hospitals, the HCAHPS Survey can be implemented using one of the following four different survey modes:

- Mail.
- Telephone.
- Mail with telephone follow-up.
- Active Interactive Voice Recognition (IVR).

Regardless of the mode used, hospitals are required to make multiple attempts to contact patients. Hospitals may use the HCAHPS Survey alone, or include additional questions after the 21 core items discussed previously. Hospitals must survey patients throughout each month of the year, and hospitals participating in the HIQR Program must target at least 300 completed surveys over 4 calendar quarters in order to attain the reliability criterion CMS has set for publicly reported HCAHPS scores (see 79 FR 50259). The survey itself and the protocols for sampling, data collection, coding, and file submission can be found in the current HCAHPS Quality Assurance Guidelines manual, available on the HCAHPS Web site located at: *http://www.hcahpsonline.org.* (The HCAHPS Survey is available in several languages, and all official translations of the HCAHPS Survey instrument are available in the current HCAHPS Quality Assurance Guidelines at *http://www.hcahpsonline.org/qaguidelines.aspx.*)

(3) Cohort

Hospitals, or their survey vendors, submit HCAHPS data in calendar quarters (3 months). Consistent with other quality reporting programs, we propose that HCAHPS scores would be publicly reported on Hospital Compare based on 4 consecutive quarters of data. For each public reporting, the oldest quarter of data is rolled off, and the newest quarter is rolled on (see 79 FR 50259).

(4) Inclusion and Exclusion Criteria

The HCAHPS Survey is broadly intended for patients of all payer types who meet the following criteria:

- Eighteen years or older at the time of admission.
- Admission includes at least one overnight stay in the hospital.
- Non-psychiatric MS–DRG/principal diagnosis at discharge.
- Alive at the time of discharge.

There are a few categories of otherwise eligible patients who are excluded from the sample frame as follows:

- ''No-Publicity'' patients—Patients who request that they not be contacted.
- Court/Law enforcement patients (that is, prisoners); patients residing in halfway houses are included.
- Patients with a foreign home address (U.S. territories—Virgin Islands, Puerto Rico, Guam, American Samoa, and Northern Mariana Islands are not considered foreign addresses and are not excluded).
- Patients discharged to hospice care (Hospice-home or Hospice-medical facility).
- Patients who are excluded because of state regulations.
- Patients discharged to nursing homes and skilled nursing facilities.

The HCAHPS Survey is intended for short-term, acute care hospitals. Both IPPS and Critical Access Hospitals participate in the survey; specialty hospitals, psychiatric hospitals and children's hospitals do not.

(5) Case-Mix-Adjustment

To ensure that HCAHPS scores allow fair and accurate comparisons among hospitals, CMS adjusts for factors that are not directly related to hospital performance but which affect how patients answer survey items. This includes the mode of survey administration and characteristics of

patients that are out of a hospital's control. Patient-mix adjustments (also known as case-mix adjustment) control for patient characteristics that affect ratings and that are differentially distributed across hospitals. Most of the patient-mix items are included in the ''About You'' section of the survey, while others are taken from hospital administrative records. Based on the HCAHPS mode experiment,[71] and consistent with previous studies of patient-mix adjustment in HCAHPS and in previous hospital patient surveys, we employ the following variables in the patient-mix adjustment model:

- Self-reported general health status (specified as a linear variable).
- Education (specified as a linear variable).
- Type of service (medical, surgical, or maternity care).
- Age (specified as a categorical variable).
- Admission through emergency room (discontinued in 2010).
- Lag time between discharge and survey.
- Age by service line interaction.
- Language other than English spoken at home.

Once the data are adjusted for patient-mix, there is a fixed adjustment for the mode of survey administration (mail, telephone, mail with telephone follow-up, and active Interactive Voice Response).

Information on patient-mix adjustment (risk adjustment) and survey mode adjustment of HCAHPS scores can be found at *http://www.hcahpsonline.org/modeadjustment.aspx.*

(6) HCAHPS Scoring

Regarding the HCAHPS survey measure, we identified the methodology used to assess hospitals in the HIQR program as reasonable for use in the CCJR model since this is a survey that many hospitals and patients are familiar with. In determining HCAHPS performance, we propose to utilize the HCAHPS Linear Mean Roll-up (HLMR) score. The HLMR summarizes performance across the 11 publicly reported HCAHPS measures for IPPS hospitals with 100 or more completed HCAHPS surveys in a 4-quarter period. The HLMR is calculated by taking the average of the linear mean scores (LMS) for each of the 11 publicly reported HCAHPS measures. The LMS, which was created for the calculation of HCAHPS Star Ratings, summarizes all survey responses for each HCAHPS measure; a detailed description of LMS can be found in HCAHPS Star Rating Technical Notes, at *http://www.hcahpsonline.org/StarRatings.aspx.*

We propose that hospitals participating in the CCJR model also have at least 100 completed HCAHPS surveys over a given 4-quarter period to be evaluated on HCAHPS for the CCJR model.

The responses to the survey items used in each of the 11 HCAHPS measures described previously are combined and converted to a 0 to 100 linear-scaled score (LMS) as follows:

- ''Never'' = 0; ''Sometimes'' = 33⅓; ''Usually'' = 66⅔; and ''Always'' = 100 (For HCAHPS Survey items 1–9, 11, 13–14, and 16–17).
- ''No'' = 0; and ''Yes'' = 100 (For items 19 and 20).
- Overall Rating ''0'' = 0; Overall Rating ''1'' = 10; Overall Rating ''2'' = 20; . . .; Overall Rating ''10'' = 100 (For item 21).
- ''Definitely No'' = 0; ''Probably No'' = 33⅓; ''Probably Yes'' = 66⅔; and ''Definitely Yes'' = 100 (For item 22).
- ''Strongly Disagree'' = 0; ''Disagree'' = 33⅓; ''Agree'' = 66⅔; and ''Strongly Agree'' = 100 (For items 23, 24, and 25).

The 0 to 100 linear-scaled HCAHPS scores are then adjusted for patient mix, survey mode, and quarterly weighting, see *http://www.hcahpsonline.org/files/HCAHPS_Stars_Tech_Notes_Apr2015.pdf.*

The HLMR summarizes performance across the 11 HCAHPS measures by taking an average of each of the LMS of the 11 HCAHPS measures, using a weight of 1.0 for each of the 7 HCAHPS composite measures, and a weight of 0.5 for each of the single item measures (Cleanliness, Quietness, Overall Hospital Rating and Recommend the Hospital). The HLMR is calculated to the second decimal place. Once the HLMR score is determined for a participant hospital, the hospital's percentile of performance can be determined based on the national distribution of hospital performance on the score.

(7) Performance Period

We propose to be consistent with the HIQR program, which uses four quarters of data (79 FR 50259). For the CCJR model, we propose to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR score for the initial year of the CCJR model. The performance period would assess data on patients discharged from July 1, 2015 through June 30, 2016. Section III.D.4 of this proposed rule, Form and Manner, summarizes performance periods for years 1 through 5 of the CCJR model years.

We invite public comments on this proposal to include HCAHPS Survey in the CCJR model to assess quality performance and capture patient experience of care.

d. Applicable Time Period

In order to align as much as is reasonably possible with other CMS hospital quality and public reporting programs in which these three measures are implemented, we propose for the THA/TKA Complication measure (NQF #1550) and the THA/TKA Readmission measure (NQF #1551) performance time periods to be consistent with the HIQR, HVBP and HRRP programs. These programs use a 3-year rolling performance (see section III.D.2.b.(6). of this proposed rule) or applicable period for the Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) and the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) measures. We similarly propose a 3-year rolling performance period for the THA/TKA Complication measure (NQF #1550) and the THA/TKA Readmission measure (NQF #1551) because a 3-year performance period yields the most consistently reliable and valid measure results. We also propose the 3-year rolling performance periods for the THA/TKA Complication measure (NQF #1550) and the THA/TKA Readmission measure (NQF #1551) because hospitals are intimately familiar with these measures. We note that reconciliation payments to hospitals as part of the CCJR are dependent upon both cost and quality outcome measures, and that making reconciliation payments solely based on cost has the potential to lead to reduced access and stinting of care. In order to address these possibilities the inclusion of performance on outcome measures is critical to ensure access and high quality care for patients undergoing these procedures. The only way to include reliable quality measures in the model upon which to base reconciliation payments for 2016 is to use measures that have a performance period that precedes the effective date of the model. Furthermore, from a measure reliability and validity perspective, it is imperative to have at least 4 quarters of data for HCAHPS survey measures and

[71] The Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores.'' M.N. Elliott, A.M. Zaslavsky, E. Goldstein, W. Lehrman, K. Hambarsoomian, M.K. Beckett and L. Giordano. *Health Services Research,* 44 (2): 501–518. 2009.

3 years of data for the THA/TKA readmission and complications measures. We intentionally chose outcome and patient experience measures for which hospitals that are already financially accountable in other IPPS programs. Consequently, the performance periods are the same periods for the THA/TKA readmission and complications measures between the CCJR model, HIQR, HVBP and HRRP programs. For the HCAHPS survey measures, there is overlap with the performance periods for the CCJR model and HIQR. Given that there is no downward payment adjustment associated with the CCJR model, that hospitals are already familiar with these measures as part of the Hospital IQR program, Hospital VBP program, and the Hospital readmission reduction program, and that hospitals are already held financially accountable for these measures, we believe it is appropriate and necessary to use performance periods that precede the effective date of the CCJR model. For the HCAHPS Survey measure, we would continue to use a 4 quarter performance period as in the HIQR program, but would not align with the Hospital IQR program performance period. We initially considered using the same Hospital IQR program performance period for the HCAHPS survey measures but realized that should we use the same Hospital IQR program performance periods for the CCJR model, other CCJR model timeframes and policy goals would not be met. Such policy goals like calculating reconciliation payment adjustments in a timely fashion during the 2nd quarter of each year. We note that HCAPHS survey results are not available until the 3rd quarter of each year. For this reason, we are not proposing that the HCAHPS survey performance period follow the HIQR program performance periods. We also propose that HCAHPS survey scores be calculated from 4 consecutive quarters of survey data; publicly reported HCAHPS results are also based on 4 quarters of data (79 FR 50259).

3. Possible New Outcomes for Future Measures

a. Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty

(1) Background

As part of our goal to move towards outcome measures that assess patient reported outcomes, we have begun development on a measure to assess improvement in patient-reported outcomes following THA/TKA procedures. The Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (hereinafter referred to as ''THA THA/TKA patient-reported outcome-based measure'') is currently under development. We specifically chose to focus on THA/TKA procedures since THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (for example, pain, mobility, and quality of life) can be measured in a scientifically sound way and are also influenced by a range of improvements in care.[72] [73] [74] We also note that THA/TKA procedures are specifically intended to improve function and reduce pain, making patient-reported outcomes the most meaningful outcome metric to assess for these common, costly procedures. Patient-reported outcomes will be assessed separately for THA and TKA procedures, though these results may be combined into a single composite measure for reporting. Therefore, we will refer to a single measure, but acknowledge the possibility of two measures, one for THA patients and one for TKA patients.

During measure development, we discovered that in order to complete measure development, we would need access to a nationally representative sample of THA and TKA inpatient surgical procedure patient-reported outcome data set that is also consistently collected at the hospital-level and contains risk variables identified by orthopedists. The rationale for requesting access to a national THA and TKA inpatient surgical procedures patient-reported data source are twofold: (1) A national data source would provide us with hospital-level data representative of the total number of THA and TKA procedures performed in hospitals, as well as representative data on hospital-level case-mix; and (2) access to a national THA and TKA inpatient surgical procedures patient-reported data source would allow us to assess and identify a set of parsimonious data elements that will minimize the data collection burden by patients, physicians and hospitals. We believe access to such data would allow for completion and testing of the current measure under development that can be appropriately used for nationwide hospital performance evaluation. We also believe the CCJR model provides a unique opportunity to resolve these measure development issues through the collection of THA and TKA patient—reported outcome data. Access to this data through the CCJR Model would address the following:

- Current data sources are not consistently collected nor collected in a uniform process and in a standardized format (that is, data elements are not consistently defined across different data sources). We note that currently available data sources tend to be limited to single hospitals or regional registries which are associated with complex data access sharing requirements.
- Current lack of uniform hospital-level data that can be used in measure development.
- Lack of incentive for physicians and hospitals to collect patient-reported outcome data such as that through the model's financial incentives associated with voluntary data submission.
- Current lack of a technically simple and feasible mechanism for hospitals to submit patient-reported data to CMS. This model would help create and optimize such a mechanism, potentially enabling future measure implementation.

In summary, the voluntary data collection initiative in the CCJR model would provide data from the patient's perspective that is necessary to finalize and test the measure specifications, including the risk model. Access to this national representative voluntarily submitted data would enable us to do the following:

- Determine a parsimonious set of risk factors that are statistically adequate for risk adjustment for patient-reported outcome.
- Examine the differences in hospital performance related to different components in the patient-reported outcome (such as functional status, pain, etc.) to finalize the statistical modeling methodology for risk adjustment.
- Evaluate the reliability of the patient-reported outcome measure.
- Examine validity of the patient-reported outcome measure upon finalization of the risk adjustment

[72] Monticone M, Ferrante S, Rocca B, et al. Home-based functional exercises aimed at managing kinesiophobia contribute to improving disability and quality of life of patients undergoing total knee arthroplasty: a randomized controlled trial. *Archives of physical medicine and rehabilitation.* Feb 2013;94(2):231–239.

[73] Galea MP, Levinger P, Lythgo N, et al. A targeted home- and center-based exercise program for people after total hip replacement: a randomized clinical trial. *Archives of physical medicine and rehabilitation.* Aug 2008;89(8):1442–1447.

[74] Moffet H, Collet JP, Shapiro SH, Paradis G, Marquis F, Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single blind randomized controlled trial. *Archives of physical medicine and rehabilitation.* Apr 2004;85(4):546–556.

model via potential testing methods such as face validity testing with national experts, comparing the measure results to similar results based on other data sources if feasible, etc.

In order to encourage participation with voluntary data submission of patient-reported outcome data, we are proposing to seek and reward voluntary participation in submission of THA/TKA patient-reported outcome-based measure data as outlined in section III.D.5.b. of this proposed rule. We note that we would not publicly report the THA/TKA voluntary data.

Finally, we intend to use a fully tested and completed THA/TKA patient-reported outcome-based measure in CMS models or programs when appropriate. If there is a decision to implement the fully developed THA/TKA patient-reported outcome-based measure, such as in the CCJR model, we would propose to adopt the measure through notice and comment rulemaking. We refer reviewers to draft measure specifications in the downloads section of the Measure Methodology Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(2) Data Sources

As previously discussed, this measure is under development, and we are proposing to reward participant hospitals that volunteer to submit provider- and patient- level data elements. We note that there is currently little uniformity across hospitals regarding collection of specific provider- and patient-level data elements that are used to assess patient outcomes after THA and TKA inpatient procedures. In the voluntary data submission for the THA/TKA patient-reported outcome-based measure, we are trying to identify a uniform set of provider- and patient-level data elements that are accurate, valid, and reliable pieces of information that can be used in the determination of improvement in various patient characteristics like those previously listed (that is, pain, mobility, and quality of life). Furthermore, in order to minimize provider and hospital burden associated with data collection and submission of provider- and hospital-level data elements, we propose using a variety of data sources for measure development. We anticipate using the following data sources are:

- Patient-reported data;
- Administrative claims-based data; and
- One or both physician-reported and electronic health record data.

Through this voluntary data submission proposal, we hope to identify a uniform set of provider- and patient-level data elements while also identifying data sources that are the least burdensome for the patients, providers, and hospitals. We propose to request that participant hospitals provide administrative claims-based data whenever possible, in order to minimize burden on patients, providers, and hospitals. Additionally, we propose to request that participant hospitals submit either hospital documentation, chart abstraction, or abstraction from the electronic health records. We propose to request submission of the following data elements:

- Pre-operative Assessments (to be collected between 90 and 0 days prior to THA/TKA procedure):

++ Age.
++ Date of Birth.
++ Gender.
++ Ethnicity.
++ THA or TKA procedure.
++ Date of admission to anchor hospitalization.
++ Date of discharge from anchor hospitalization.
++ Date of eligible THA/TKA procedure.
++ Medicare Health Insurance Claim Number.

—PROMIS Global (all items).
++ VR–12 (all items.)
++ For TKA patients Knee injury and Osteoarthritis Outcome Score (*KOOS*[75]) (all items).
++ For THA patients Hip disability and Osteoarthritis Outcome Score (*HOOS*[76]) (all items).
++ Body Mass Index.
++ Presence of live-in home support, including spouse.
++ Use of chronic (≥ 90 day) narcotics.

—American Society of Anesthesiologists (ASA) physical status classification.
++ Charnley Classification.
++ Presence of retained hardware.

—Total painful joint count.
—Quantified spinal pain.
++ Joint range of motion in degrees (specify hip or knee).
++ Use of gait aides.
++ For THA patients abductor muscles strength.
++ For THA patients presence of Trendelenberg gait.
++ For THA patients history of congenital hip dysplasia or other congenital hip disease.
++ For THA patients presence of angular, translational, or rotational deformities of the proximal femur (in degrees).
++ For TKA patients anatomic angle (femoro-tibial angle) in degrees with varus/valgus.
++ For TKA patients knee extensor strength.
++ Single Item Health Literacy Screening (SILS2) questionnaire.[77]

- Post-operative Assessments (To be collected between 270 and 365 days following THA/TKA procedure):

++ Age.
++ Date of Birth.
++ Gender.
++ Date of admission to anchor hospitalization.
++ Date of discharge from anchor hospitalization.
++ Date of eligible THA/TKA procedure
++ Medicare Health Insurance Claim Number

—PROMIS Global (all items).
++ VR–12 (all items).

—For TKA patients, Knee injury and Osteoarthritis Outcome Score (*KOOS*[78]) (all items).

—For THA patients, Hip disability and Osteoarthritis Outcome Score (*HOOS*[79]) (all items).

Finally, we note that as the measure continues to undergo development that the list of data elements may be simplified. As stated earlier in this section entitled Data Sources, we intend identify a uniform set of provider- and patient-level data elements that are accurate, valid and reliable pieces of information that can be used in the determination of improvement in various patient-reported outcomes like those previously listed (that is, pain, mobility, and quality of life). We anticipate, via public comment and experience with the voluntary data submission, that the set of data elements listed previously will be simplified.

In accordance with, and to the extent permitted by, the HIPAA Privacy Rule and other applicable law, we propose to request that participant hospitals submit

[75] What is the KOOS? Available at: *http://www.koos.nu/koospresentation.html.* Accessed on April 15, 2015.

[76] What is the HOOS? Available at: *http://www.koos.nu/hoospres.html.* Accessed on April 15, 2015.

[77] Wallace LS, Rogers ES, Roskos SE., Holiday DB, Weiss BD. Screening items to identify patients with limited health literacy skills. J Gen Intern Med. 2006;21:874–7.

[78] Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS)—development of a self-administered outcome measure. J Orthop Sports Phis There. 1998 Aug;28(2):88–96.

[79] What is the HOOS? Available at: *http://www.koos.nu/hoospres.html.* Accessed on April 15, 2015.

the data specified in the request, which we would limit to the minimum data necessary for us to conduct quality assessment and improvement activities. Regarding the process for data collection, we propose the THA/TKA voluntary data will be submitted to and collected by a CMS contractor in a manner and format similar to existing CMS data submission processes. For example, CMS would supply applicable hospitals with a file template and instructions for populating the file template with data and submitting the data; the hospitals will populate the template, log in to a secure portal, and transmit the file to the appropriate CMS contractor; the CMS contractor would also match the submitted data to Medicare administrative claims-based data and calculate completeness for determination of the reconciliation payment as noted in section III.C.5 of this proposed rule (or validated subscales or abbreviated versions of these instruments). We believe that participation in the submission of THA/TKA—voluntary data will provide the minimum information we would need that would inform us on how to continuously improve the currently specified measure in development.

We note that some of these data elements are closely aligned with data elements in e-clinical measures submitted by eligible professionals for the Medicare EHR Incentives Program for Eligible Professionals. Specifically these EHR Incentives Program measures for eligible professionals are: (1) Functional Status Assessment for Knee replacement (CMS 66); and (2) Functional Status Assessment for Hip replacement (CMS 56). We refer reviewers to CMS.gov EHR Incentives Program 2014 Eligible Professional June 2015 zip file update at *http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/eCQM_2014_EP_June2015.zip* for full measure specifications. We believe it is possible that many health IT vendors are already certified to capture, calculate and report these provider-level measures of functional status on total knee and total hip arthroplasty, and therefore we anticipate that the provider-level data elements that are identical to the THA/TKA patient-reported outcome voluntary data elements previously listed may not be as burdensome for the CCJR model participant hospitals to voluntarily submit.

(3) Cohort

The measure cohort(s) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. We would exclude from the cohort patients with fractures and mechanical complications or those undergoing revision procedures. THA and TKA patient-reported outcomes will be assessed separately but may be combined into a single composite measure for reporting.

(4) Inclusion and Exclusion Criteria

The measure cohort inclusion criteria are all patients undergoing elective primary THA/TKA procedures. Exclusion criteria will consist of patients undergoing non-elective procedures (that is, patients with fractures resulting in THA/TKA), as it is unfeasible to routinely capture pre-operative patient-reported assessments in these patients; patients with mechanical complications of prior hip and knee joint procedures and those undergoing revision THA/TKA will also be excluded, as their patient-reported outcomes may be influenced by prior care experiences and therefore may not adequately represent care quality of the hospital performing the revision procedure.

(5) Outcome

The measure will assess change between pre- and post-operative patient-reported outcomes for THA and TKA separately or as a composite measure for both procedures. The measure will use one or more of the following patient-reported outcome instruments (or validated subscales or abbreviated versions of these instruments) to calculate the measure score: the Patient Reported Outcomes Measurement Information Systems (PROMIS)-Global or the Veterans Rand 12 Item Health Survey (VR–12), and the Hip dysfunction and Osteoarthritis Outcome Score/Knee injury and Osteoarthritis Outcome Score (HOOS/KOOS) instruments to measure pre- and postoperative improvement or both. These candidate instruments were selected by a Technical Expert Panel based upon their meaningfulness to patients and clinicians, performance characteristics such as reliability, responsiveness and validity, and their perceived burden to both patients and providers. The pre-operative data collection timeframe will be 90 to 0 days before surgery, and the post-operative data collection timeframe will be 270 to 365 days following surgery. The approach to calculating the improvement or worsening of patient outcomes represented by the pre- and postoperative patient-reported survey results has not yet been determined, but will use one or more surveys to define the improvement or worsening of patient-reported outcomes to reliably identify differences between hospitals of varying performance.

(6) Risk-Adjustment (If Applicable)

We note that the measure's risk model has yet to be developed. In order to develop the risk model, final risk variable selection for the risk model will involve empirical testing of candidate risk variables as well as consideration of the feasibility and reliability of each variable. The risk model will account for the hospital level response rate as well as measureable patient-level factors relevant to patient-reported outcomes following elective THA/TKA procedures. To the extent feasible, the risk model methodology will adhere to established statistical recommendations.[80]

(7) Calculating the Risk-Standardized Rate

We note that the approach to reporting this measure(s) has yet to be developed. The measure will assess change in patient-reported outcomes between the pre-operative (90 to 0 days prior to the elective primary THA/TKA procedure) and post-operative (270–365 days following the elective primary THA/TKA procedure) periods.

We invite public comments on this proposal to seek voluntary participation in submitting data for a Hospital-Level Performance Measure of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty. We also welcome comments on the appropriateness of this voluntary data collection for this model and the specific data collection requirements (see section III.D.3.a.(9) of this proposed rule) and data elements proposed.

(8) Performance Period

We propose defining performance periods for each year of the model as outlined in Table 16. A performance period for the voluntary THA/TKA data submission, are those timeframes in which an anchor hospital admission occurs for eligible THA/TKA voluntary data submission procedure. For the first year of the CCJR model, hospitals voluntarily submitting data will only be

[80] Ash AS, Fiengerg SE., Louis TA, Normand ST, Stukel TA, Utts J. STATISTICAL ISSUES IN ASSESSING HOSPITAL PERFORMANCE, Commissioned by the Committee of Presidents of Statistical Societies. Original report submitted to CMS on November 28, 2011, Revised on January 27, 2012. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf.* Accessed on April 15, 2015.

asked to submit data for a 3-month period. The 3-month period for THA/TKA voluntary data reporting was identified due to data processing and coordination of other proposed timelines in this model. Data submitted for the first year would be for cases that fulfill the measure specifications described in section III.D.3.a. of this proposed rule, and would be restricted to the pre-operative data elements on cases performed between April 1, 2016 and June 30, 2016. The proposed timing allows matching of the patient-reported data with relevant administrative claims-based data in order to accurately calculate the percent of eligible elective primary THA/TKA patients for which THA/TKA voluntary data was successfully submitted. The April 1st date acknowledges the measure requirement of the 90-day window prior to surgery during which hospitals can collect pre-operative data. The June 30th end date was selected because it correlates with the THA/TKA readmission measure performance period end date currently implemented for the HIQR program and the HRRP. Both of these dates provide the greatest feasibility for data collection.

For year 2, THA/TKA voluntary data reporting would be 3 months of post-operative data for cases performed between April 1, 2016 and June 30, 2016, and 12 months of pre-operative data for cases performed between July 1, 2016 and June 30, 2017.

For year 3 and subsequent years of the model, the performance periods for submission of voluntary data will consist of 12-month time periods.

TABLE 16—EXAMPLE OF POTENTIAL PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION

CCJR model year	Performance period	Patient population eligible for THA/TKA voluntary data submission	Requirements for successful THA/TKA voluntary data submission *
2016	April 1, 2016 through June 30, 2016.	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016.
2017	April 1, 2016 through June 30, 2016.	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016.
2017	July 1, 2016 through June 30, 2017.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2017.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.
2018	July 1, 2016 through June 30, 2017.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2017.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.
2018	July 1, 2017 through June 30, 2018.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018.
2019	July 1, 2017 through June 30, 2018.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018.
2019	July 1, 2018 through June 30, 2019.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019.
2020	July 1, 2018 through June 30, 2019.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019.
2020	July 1, 2019 through June 30, 2020.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2020.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2019 and June 30, 2020.
2016	3 months	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016.
2017	15 months	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2017.	1. Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016. 2. Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.
2018	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2018.	1. Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.

TABLE 16—EXAMPLE OF POTENTIAL PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION—Continued

CCJR model year	Performance period	Patient population eligible for THA/TKA voluntary data submission	Requirements for successful THA/TKA voluntary data submission *
			2. Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018.
2019	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2019.	1. Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018. 2. Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019.
2020	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2020.	1. Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019. 2. Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2019 and June 30, 2020.

* Requirements for determining successful submission of THA/TKA voluntary data are located in section III.D.3.a.(9) of this proposed rule.

The proposed performance period enables hospitals to receive incentives for data collection starting in performance year-one, even though complete pre-operative and post-operative data collection requires a minimum 9 through 12 month time period. This 9 through 12 month time period, between the procedure and post-operative data collection, was defined through clinician and stakeholder input and provides for both sufficient elapsed time for maximum clinical benefit of THA/TKA procedures on patient-reported outcomes and accommodates common clinical care patterns in which THA/TKA patients return to their surgeon one year after surgery. We invite public comments on our proposal of defining performance year-one episodes for a participating hospital as an anchor hospital admission for an eligible THA/TKA procedure between April 1, 2016 and June 30, 2016, with subsequent year performance time periods each being 12-month periods and starting every July 1st.

(9) Requirements for ''Successful'' Submission of THA/TKA Voluntary Data

In order for CMS to assess if participant hospitals are eligible for reconciliation payment after receiving the THA/TKA voluntary data, requirements to determine if the submitted data will inform measure development have been identified. We believe that the following criteria should be used to determine if a participant hospital has successfully submitted THA/TKA voluntary data. We note that successful THA/TKA voluntary data submission, as stated briefly in section III.C.5. of this proposed rule, requires completion of all of the following:

- Submission of the data elements listed in section III.D.3.a.(2).of this proposed rule.
- Data elements listed in section III.D.3.a.(2) of this proposed rule must be submitted on at least 80 percent of their eligible elective primary THA/TKA patients (as described in section III.D.3.a.(3) of this proposed rule).
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent data collection period.

To fulfill THA/TKA voluntary data collection criteria for performance year-one, only pre-operative data collection and submission on at least 80 percent of eligible elective primary THA/TKA patients is required. To successfully submit THA/TKA voluntary data for performance years 2 through 5, hospitals must submit both pre-operative and post-operative patient reported outcome data on at least 80 percent of eligible elective primary THA/TKA patients. A potential example of the performance periods for which we would like to have THA/TKA voluntary data is summarized in section III.D.3.a.of this proposed rule.

Table 16 also summarizes the performance periods for pre-operative and post-operative THA/TKA voluntary data. Finally, hospitals volunteering to submit THA/TKA data will be required to submit pre-operative data on all eligible patients and post-operative data elements only on those patients at least 366 days out from surgery. Therefore, hospitals are not expected to collect and submit post-operative THA/TKA voluntary data on patients who are fewer than 366 days from the date of surgery.

We previously described a THA/TKA eligible patient in section III.D.3.a.(2) of this proposed rule. This description is important as these patients are those in which we seek submission of voluntary data. We also selected the requirement of submitting 80 percent of eligible elective primary THA/TKA patients' data because this volume of cases will result in a high probability that we will have a have a national sample of THA/TKA patient data representative of each hospital's patient case mix. Having 80 percent of the eligible elective primary THA/TKA patients will enable an accurate and reliable assessment of patient-reported outcomes for use in measure development. We note that data used for outcome measure development must adequately represent the population that is anticipated to be measured and in this case that population would be those experiencing elective primary THA/TKA inpatient surgical procedures. Data that more accurately reflects the patient outcomes and case mix of the population to be measured will allow, during measure development, a more scientifically accurate and reliable measure. Having 80 percent of eligible elective primary THA/TKA recipient data will result in a more reliable measure that is better

able to assess hospital performance than a measure created from a less representative patient sample. Furthermore, we considered setting the requirement at 100 percent of the eligible elective primary THA/TKA patients, but concluded that a requirement of 100 percent data collection may not be feasible for all hospitals or may be excessively burdensome to achieve. Therefore we set the requirement at 80 percent of the eligible elective primary THA/TKA patients. We believe acquisition of 80 percent of the eligible elective primary THA/TKA patients will provide representative data for measure development while decreasing patient, provider and hospital burden. We seek public comment of these requirements to determine successful voluntary submission of THA/TKA data. We also seek public comment specifically on the requirement for data on 80 percent of the eligible elective primary THA/TKA patients.

b. Measure That Captures Shared Decision-Making Related to Elective Primary Total Hip and/or Total Knee Arthroplasty

In addition to the patient-reported functional status outcomes, we note that shared-decision making is an important aspect of care around elective procedures such as primary total hip and total knee arthroplasty. We also note that lower episode expenditures achieved through improved efficiency may yield the unintended consequence of a compensatory increase in the number of episodes initiated. Use of shared decision-making prior to episode initiation can serve as an important tool to ensure appropriate care. Though there are no developed measures, we seek feedback on the opportunity to capture quality data related to shared decision-making between patients and providers. Examples of such a measure could include concepts such as a trial of conservative medical therapy prior to elective procedures or broader shared decision-making measures. We invite public comment on whether such a measure concept would be appropriate for the CCJR model. If we develop a measure that captures shared decision-making related to elective primary total hip and total knee arthroplasty or both, we would propose through rulemaking or other means to add that measure to the CCJR model.

c. Future Measures Around Care Planning

The person-centered shared care plan is an important tool that can help providers across settings collaborate around a customized plan that reflects a patient's goals and offers providers critical information about all of the treatment a beneficiary has received. Health IT solutions are increasingly supporting the exchange of care plan information across settings so that providers and individuals have access to necessary information whenever and wherever it is needed. In the 2015 Edition of certification criteria for health information technology (80 FR 16842) the Office of the National Coordinator for Health Information Technology (ONC) has proposed the adoption of a new criterion to ensure health IT can capture, display, and exchange a robust care plan document in accordance with new standards released in the Consolidated Clinical Document Architecture Release 2. While further measure development is needed, we are seeking comment on the appropriateness of a future quality measure which would assess the use of shared care plans in the care of beneficiaries participating in the CCJR model.

d. Future Measures for Use of Health IT and Health Information Exchange

We believe the use of health IT tools is a critical component of effective coordination across settings of care. Under bundled payment models, in which providers across the continuum of care share accountability for the clinical management and total cost of an episode of care, the capacity to share information electronically across disparate provider systems is essential for delivering efficient, safe, high quality care. As discussed in the August 2013 Statement ''Principles and Strategies for Accelerating Health Information Exchange'' (available at *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*), we believe that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. ONC has released a draft document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at *http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf*), which describes barriers to interoperability across the current health IT landscape, the desired future state that will be necessary according to the industry to enable a learning health system, and a suggested path for moving forward. ONC will focus on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. Under section 1833(z)(3)(D)(i)(I) of the Act, as amended by section 101(e) of the Medicare Access and CHIP Reauthorization Act, providers participating in qualifying alternative payment models under Medicare will be required to use certified EHR technology beginning in 2019. As this date approaches, we believe it will be important for providers working in these models to demonstrate adoption of health information technology.

We believe that use of certified health IT tools and the interoperable exchange of health information is a critical capability for CCJR model participants to be able to deliver the high-quality care and effective coordination across settings that will be required to demonstrate success under the model. Moreover, we believe that it will be important to incentivize adoption and use of these enabling technologies among model participants including post-acute care providers, by linking these activities to participant eligibility to receive reconciliation payments.

While we are not proposing to add a measure for certified health IT use for the program's initial performance year, we are seeking comment on how we might incorporate such a measure beginning in the 2017 performance year. We invite stakeholder comment on the following questions:

- Is successful attestation as part of the EHR Incentive Program for Medicare hospitals tin he applicable reporting year the most appropriate quality measure for assessing hospital performance on the use of health IT and interoperable health information in the CCJR model?
- Should the model include a performance measure that would be specific to the ability of hospitals to conduct electronic care coordination using certified health IT, for instance, the measure of transitions of care which hospitals currently report on as part of the EHR Incentives Program for Medicare Hospitals?
- What other measures could be used to assess hospital performance on the use of health IT and interoperable health information while minimizing program and provider collection and reporting burden?

We seek public comments on how we might incorporate an electronic measure beginning in the 2017 performance year,

and public comments on the questions posed previously in this rule.

We also seek public comment on the appropriateness of quality measures for post-acute care patients, physicians and facilities that care for THA/TKA surgical procedure patients.

4. Form, Manner and Timing of Quality Measure Data Submission

We believe it is important to be transparent and to outline the form, manner and timing of quality measure data submission so that accurate measure results are provided to hospitals, and that timely and accurate calculation of measure results are consistently produced to determine annual reconciliation payment.

We propose that data submission for Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) and Hospital-Level Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) (or both) be accomplished through the existing HIQR program processes. Since these measures are administrative claims based measures, hospitals will not need to submit data. We propose that the same mechanisms used in the HIQR program to collect HCAHPS survey measure data also be used in the CCJR model (79 FR 50259). For the hospitals that voluntarily submit data for the THA/TKA patient-reported outcome-based performance measure we anticipate, if it is technically feasible, for data submission processes to be broadly similar to those summarized for the HIQR program for chart abstracted and administrative claims based measures. We would create a template for hospitals to complete with the THA/TKA voluntary data, provide a secure portal for data submission, and provide education and outreach on how to use these mechanisms for data collection and where to submit the THA/TKA voluntary data. We describe potential processes for voluntary data collection in section III.D.3.a.(2) of this proposed rule, Data Sources. These processes are broadly similar to those used by the HIQR program.

We invite public comment on the proposal to collect quality measure data through mechanisms similar to those used in the Hospital IQR program.

5. Proposed Display of Quality Measures and Availability of Information for the Public From the CCJR Model

We believe display of quality data is an important way to educate the public on hospital performance. We have used several methods to report quality data to the public, including posting data on the Hospital Compare Web site and *data.medicare.gov.* Data has been available for viewing on these Web sites and in downloadable databases since 2005, and are well-known mechanisms for providing information to the public. We are proposing to post data for measures included in the CCJR model for each participant hospital on the Hospital Compare Web site in an easily understood format. The applicable time periods for the measures during the CCJR model initiative are summarized in Table 17.

TABLE 17—SUMMARY OF QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CCJR MODEL

Measure title	CCJR model year				
	1st	2nd	3rd	4th	5th
THA/TKA Complication *	April 1, 2013–March 31, 2016.	April 1, 2014–March 31, 2017.	April 1, 2015–March 31, 2018.	April 1, 2016–March 31, 2019.	April 1, 2017–March 31, 2020.
THA/TKA ** Readmission	July 1, 2013–June 30, 2016.	July 1, 2014–June 30, 2017.	July 1, 2015–June 30, 2018.	July 1, 2016–June 30, 2020.	July 1, 2017–June 30, 2016.
HCAHPS ***	July 1, 2015–June 30, 2016.	July 1, 2016–June 30, 2017.	July 1, 2017–June 30, 2018.	July 1, 2018–June 30, 2019.	July 1, 2019–June 30, 2020.

* Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).
** Hospital-Level Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).
*** HCAHPS (NQF #0166) Survey.

The proposed time periods for the THA/TKA Complications measure (NQF #1550), and the THA/TKA Readmission measure (NQF #1551) are consistent with HIQR program performance periods for July 2017 public reporting. The HCAHPS quality information will be the measure results. We believe the public is familiar with the proposed measures, which have been publicly reported in past releases of Hospital Compare as part of the Hospital IQR Program. In order to minimize confusion and facilitate access to the data on the measures included in the CCJR model, we propose to post the data on each participant hospital's performance on each of the 3 proposed quality measures in a downloadable format in a section of the Web site specific to the CCJR model, similar to what is done for HRRP and the Hospital-Acquired Conditions Reduction Program. We also propose to post data on whether or not each participant hospital met the proposed threshold (section III.C.5.b. of this proposed rule) for receiving a reconciliation payment in the same downloadable database.

In addition, we believe information about functional status both pre- and post-operatively is important for hip and knee replacements. We are developing a functional status measure that we believe will provide this needed information. The measure, Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (see section III.D.3 of this proposed rule for a detailed description), requires comprehensive testing before it can be used in a CMS program. As part of the effort to collect data on functional status voluntarily from hospitals, we are proposing that hospitals that voluntarily submit data for this measure be acknowledged through the use of a symbol on Hospital Compare. The data submitted voluntarily for the functional status measure would not be publicly reported along with the other measures in the program.

We invite public comments on these proposals to post data for mandatorily required measures on the Hospital Compare Web site and to acknowledge hospitals that voluntarily submit data for the functional status measure with an icon on the Hospital Compare Web site.

Finally, in accordance with section 1115A of the Act, we are proposing section III.D. in the new proposed part 510 of the Code of Federal Regulations.

E. Data Sharing

1. Overview

In this section, we propose to provide data to the hospital participants of the CCJR model. CMS has experience with a range of efforts designed to improve care coordination for Medicare beneficiaries, including the Medicare Shared Savings Program (MSSP), Pioneer Accountable Care Organization (ACO) Model, and BPCI, all of which make certain data available to participants. The CCJR model proposes in section III.C.2. of this proposed rule to financially incentivize hospitals, through retrospective bundled payments, to engage in care redesign efforts to improve quality of care and reduce spending for the aggregate Part A and B FFS (FFS) spending for beneficiaries included in the model during the inpatient hospitalization and 90 days post-discharge. Given this, we believe it is necessary to provide historical and ongoing claims data representing care furnished during episodes of care for LEJRs to hospitals so that they can, among other things, adequately structure their care pathways, coordinate care for beneficiaries, and estimate acute inpatient and post-acute spending within LEJR episodes.

As noted previously, this would not be the first instance in which we have provided claims data to entities participating in a CMS model or program. For example, participants in MSSP initially receive historical aggregate information on their financial performance as well as updated financial data throughout their tenure in the program. In addition, MSSP participants receive certain beneficiary-identifiable claims information in accordance with our regulations (see Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 FR 67844 through 67849, November 2, 2011). The MSSP regulation noted that while an ACO may have complete information for the services it provides or coordinates on behalf of its FFS beneficiary population, it may not have complete information on a FFS beneficiary who chose to receive services, medications or supplies from non-ACO providers and suppliers. Thus, we decided to provide ACOs participating in the MSSP with an opportunity to request CMS claims data on the premise that more complete beneficiary-identifiable information would enable practitioners in an ACO to better coordinate and target care strategies. Recently, we noted that the ACOs participating in the MSSP have reported how important access to real time data is for providers to improve care coordination across all sites of care, including outpatient, acute, and post-acute sites of care. Furthermore, we noted our view that providers across the continuum of care are essential partners to physicians in the management of care. (See Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations: Proposed Rule, 79 FR 72779).

Similarly, participants in the Pioneer ACO model can request historical claims data of beneficiaries aligned with the particular Pioneer ACO entity, and the entities continue to receive certain ongoing data regarding the services furnished to those beneficiaries. (See *http://innovation.cms.gov/Files/fact-sheet/Pioneer-ACO-Model-Beneficiaries-Rights-Fact-Sheet.pdf*). In addition, we provide BPCI participants with the opportunity to request beneficiary-level claims data regarding their own patients, both for the historical period of 2009–2012 that was used to set baseline prices for entities participating in BPCI, as well as ongoing monthly claims feeds containing Medicare FFS claims for beneficiaries that could have initiated an episode of care for that particular BPCI participant. These monthly claims feeds provide BPCI participants with data for both acute and post-acute care spending for beneficiaries that could have initiated an episode of care at that BPCI participant.

Based on our experience with these efforts, we believe that providing a similar opportunity for hospitals participating in the CCJR model to request data is necessary for participant hospitals to have the relevant information to allow for practice changes supported by CCJR and to identify services furnished to beneficiaries receiving LEJRs under the model. Specifically, providing participant hospitals with certain claims and summary information on beneficiaries in accordance with established privacy and security protections would improve their understanding of the totality of care provided during an episode of care. With this greater understanding, we anticipate that hospitals would be better equipped to evaluate their practice patterns and actively manage care delivery so that care for beneficiaries is better coordinated, quality and efficiency are improved, and payments aligned more appropriately to the medically necessary services beneficiaries have a right to receive. We also expect that providing this data to CCJR participants will benefit beneficiaries by allowing providers to use the data to improve care coordination activities in areas that may be currently lacking. However, we also expect that CCJR hospitals are able to, or will work toward, independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

Accordingly, we believe that making certain data available to CCJR hospitals, as we do with ACOs participating in the MSSP and Pioneer model, would help them to monitor trends and make needed adjustments in their practice patterns. In order for CCJR participants to understand and track their care patterns, we propose to provide the participants with beneficiary-level claims data for the historical period used to calculate a CCJR hospital's target price as well as ongoing quarterly beneficiary-identifiable claims data in response to their request for such data in accordance with our regulations. Given that the CCJR model also proposes to incorporate regional pricing in the calculation of target prices, we also propose to provide participants with aggregate regional data.

2. Beneficiary Claims Data

Based on our experience with BPCI participants, we recognize that hospitals vary with respect to the kinds of beneficiary claims information that would be most helpful. While many hospitals located in MSAs that are selected for participation in CCJR model may have the ability to analyze raw claims data, other hospitals may find it more useful to have a summary of these data. Given this, we are proposing to make beneficiary claims information available through two formats.

First, for participant hospitals that lack the capacity to analyze raw claims data, we propose to provide summary beneficiary claims data reports on beneficiaries' use of health care services during the baseline and performance periods. These reports would allow participant hospitals to assess summary data on their relevant beneficiary population without requiring sophisticated analysis of raw claims data. Such summary reports will provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if the data provided by CMS to a particular hospital participant reflects that a certain post-acute care (PAC) provider admits beneficiaries who then

have significantly higher rates of inpatient readmissions than the rates experienced by other beneficiaries with similar care needs at similarly situated PAC providers, that may be evidence that the hospital could consider, among other things, the appropriateness of discharges to that provider, whether other alternatives might be more appropriate, and whether there exist certain care interventions that could be incorporated post-discharge to lower readmission rates.

Therefore, for both the baseline period and on a quarterly basis during a participant hospital's performance period, we are proposing to provide participant hospitals with an opportunity to request summary claims data that would encompass the total expenditures and claims for an LEJR episode, including the procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services for the hospital's beneficiaries whose anchor diagnosis at discharge was either MS DRG 469 or 470. We propose that these summary claims aggregate data reports would also contain payment information, utilizing the categories listed for each episode triggered by a beneficiary as follows:

- Inpatient Hospital.
- Outpatient Hospital.
- Physician.
- Long-Term Care Hospitals (LTCH).
- Inpatient Rehabilitation Facilities (IRF).
- Skilled Nursing Facilities (SNF).
- Home Health Agencies (HHA).
- Hospice.
- Ambulatory Surgical Center.
- Part-B Drugs.
- Durable Medical Equipment (DME).
- Clinical Laboratories.
- Ambulance.

These reports would likely include the following:

- Information such as admission and discharge date from the anchor hospitalization.
- The physician for the primary procedure, Medicare payments during the anchor hospitalization.
- Medicare payments during the post-acute care phase.
- Medicare payments for physician services would likely be included in these reports.

These summary claims data would reflect all Medicare Part A and Part B expenditures during the 90-day episodes, except for those claim types noted later in this section, as well as excluding expenditures related to those MS–DRGs that we are proposing to be specifically excluded from the episode of care, as set forth in section III.B.2. of this proposed rule.

Alternatively, for hospitals with a capacity to analyze raw claims data, we would make- more detailed beneficiary-level information available in accordance with established privacy and security protections. These data would enable hospitals to better coordinate and target care strategies for beneficiaries included in CCJR episodes. For example, in the BPCI initiative, we provide participants with beneficiary-level claims data for all Part A and Part B services furnished to a beneficiary treated by that BPCI participant for all MS–DRGs included in an episode that the participant has selected for participation (See ''Bundled Payments for Care Improvement Initiative (BPCI): Background on Model 2 for Prospective Participants, page 3 at *http://innovation.cms.gov/Files/x/BPCI_Model2Background.pdf.*)

These data include services furnished by the participant, as well as services furnished by other entities during the 30, 60, or 90-day episode. For example, where the entity participating in BPCI is an acute care hospital, we provide beneficiary-level claims data for all Medicare Part A and B services and supplies furnished by the hospital during the inpatient admission, as well as all post-acute services furnished to the beneficiary by the hospital or any other providers or suppliers.

The response from entities participating in BPCI has indicated that the availability of these data is necessary to monitor trends and pinpoint areas where care practice changes are appropriate, as well as assess the cost drivers during the acute and post-acute periods of the episode. Thus, for the baseline period and on a quarterly basis during a hospital's performance period, we propose to provide participant hospitals with an opportunity to request line-level claims data for each episode that is included in the relevant performance year, as described in section III.C. of this proposed rule.

For both the proposed summary claims data and the more detailed claims data formats, we propose that the sets of these files would be packaged and sent to a portal in a ''flat'' or binary format for the individual participant hospitals to retrieve. Furthermore, the files would contain information on all claims triggered by a beneficiary in a participating CCJR hospital. Finally, we note that beneficiary information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) would not be included in any beneficiary identifiable claims data shared with a hospital under our proposal.

We request comments on these proposals as well as the kinds of data and frequency of reports that would be most helpful to the hospitals' efforts in coordinating care, improving health, and producing efficiencies.

3. Aggregate Regional Data

Additionally, because we are proposing to incorporate regional pricing data in the creation of prices for CCJR, as set forth in section III.C.4 of this proposed rule, we believe it will also be necessary to provide comparable aggregate expenditure data available for all claims associated with MS–DRGs 469 and 470 for the census region in which the participant hospital is located. As noted in section III.C, we are proposing that a hospital's target price will be determined based on a blend of its own historical expenditures as well regional pricing data of all other hospitals in its region. Thus, we are also proposing to provide CCJR hospitals with aggregate data on the total expenditures during an acute inpatient stay and 90-day post-discharge period for all Medicare FFS beneficiaries whose anchor diagnosis at discharge was either MS–DRG 469 or 470 (and would have initiated a CCJR episode if discharged from a CCJR hospital) in their census region. These data would not include beneficiary-identifiable claims data, but would provide high-level information on the average episode spending for MS–DRGs 469 and 470 in the region in which the participant hospital is located. We request comments on these proposals as well as the kinds of aggregate data and frequency of data reports that would be most helpful to the hospitals' efforts in coordinating care, improving health, and producing efficiencies.

4. Timing and Period of Baseline Data

We considered various options for the timing of providing baseline data, as described previously, to CCJR participant hospitals. We considered provision of data prior to the effective date of the model, January 1, 2016, as well as providing data to participants at the point of the first payment reconciliation (described in section III.C.6. of this proposed rule). We propose to make baseline data available to hospitals participating in CCJR no sooner than 60 days after January 1, 2016, the effective date of the model. We recognize that these data are important to the abilities of CCJR participant hospitals to estimate costs,

coordinate care, and identify areas for practice transformation, and that early release of this data can facilitate their efforts to do so. We also anticipate that hospitals will view the CCJR effort as one involving continuous improvement. As a result, changes initially contemplated by a hospital could be subsequently revised based on updated information and experiences. While we would like to be able to make data available as soon as possible once the program begins, we do not believe that these baseline data must be immediately available upon its effective date as hospitals can begin considering improvements that would enhance their ability to better coordinate care and increase efficiencies in the absence of these data. Therefore, we propose to begin making baseline data available to CCJR hospitals within 60 days of CMS' receipt of the request by the participant hospital for such data, in a form, time, and manner of such requests to be determined by CMS and announced at a later date. Requests would not be accepted until the model has begun. We seek comments on this proposal.

We have also considered which period of baseline data should be shared with hospitals, for example, whether the data should represent a single year, or some longer period such as a 3-year period or more. To be most useful, we believe the baseline information should be recent enough to reflect current practices yet of a sufficient duration to reflect trends in those recent practices. For example, 1 year of data would likely reflect a hospital's most current practices, but would not be helpful for purposes of identifying trends. In contrast, 3 years of data could both reflect a hospital's most recent performance and recent performance trends. Moreover, making data available for a 3-year period aligns with our proposal to set a target price based on a 3-year period of baseline data, which is a factor in assessing CCJR hospitals' performance (see section III.C). If a hospital has access to baseline data for the 3-year period used to set its target price, then it would be able to assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality.

We alternatively considered making data available for an even longer historical period—for example, 4 or 5 years. However, we question the usefulness of information that is older than 3 years for purposes of changes contemplated for current operations. Accordingly, we are proposing to make available baseline data for up to a 3-year period. We will limit the content of this data set to the minimum data necessary for the participant hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. This period would encompass up to the 3 most recent years for which claims data are available for the hospital and would align with the baseline period we propose to utilize to establish target prices, as noted previously. We seek comments on our proposal and invite comments on alternative time periods that could better help hospitals evaluate their practice patterns and actively manage care delivery so that care is better coordinated, quality and efficiency are improved, and costs are better controlled.

5. Frequency and Period of Claims Data Updates for Sharing Beneficiary-Identifiable Claims Data During the Performance Period

The availability of periodically updated beneficiary-identifiable claims data would assist hospitals participating in CCJR to identify areas where they might wish to change their care practice patterns, as well as monitor the effects of any such changes. With respect to these purposes, we have considered what would be the most appropriate period for making updated claims information available to hospitals, while complying with the HIPAA Privacy Rule's ''minimum necessary'' provisions standard. We believe that quarterly claims data updates align with a 90-day episode window. Moreover, as a larger episode window would be included, the claims data would be more representative of total costs and hence more useful to hospitals as they consider long-term practice changes. Accordingly, we are proposing to make updated claims data available to hospitals upon receipt of a request for such information that meets CMS's requirements to ensure the applicable HIPAA conditions for disclosure have been met, as frequently as on a quarterly basis. We seek comments on this proposal.

Related to this is the period of claims that would be represented in each update. For example, we considered limiting this period to 3 months of data, which aligns with the frequency with which we would make updated claims data available. However, other than this alignment, we do not see additional reasons for artificially limiting the period to this extent. Alternatively, we considered providing an updated dataset as frequently as each quarter that would include data from up to the previous 6 quarters. We believe that this level of cumulative data would offer more complete information and allow better trend comparisons.

Accordingly, we propose to make beneficiary-identifiable and aggregate claims data available that would represent up to 6 quarters of information upon receipt of a request for such information that meets the requirements of the HIPAA Privacy Rule. We would note that we intend for the data for this model to be consistent with the performance year (January 1 through December 31). To accomplish this for the first year of CCJR (2016), we would provide, upon request and in accordance with the HIPAA Privacy Rule, claims data from January 1, 2016 to June 30, 2017 on as frequently as a running quarterly basis, as claims are available. For each quarter and extending through June 30, 2017, participants would receive data for up to the current quarter and all of the previous quarters going back to January 1, 2016. These datasets would contain all claims for all potential episodes that were initiated in 2016 and capture a sufficient amount of time for relevant claims to have been processed. We will limit the content of this data set to the minimum data necessary for the participating hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. We seek comment on our proposal.

6. Legal Permission To Share Beneficiary-Identifiable Data

We recognize that there are a number of issues and sensitivities surrounding the disclosure of beneficiary-identifiable health information, and note that a number of laws place constraints on sharing individually identifiable health information. For example, section 1106 of the Act bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits for the disclosure. In this instance, the HIPAA Privacy Rule permits this proposed disclosure of individually identifiable health information by us.

In this proposed rule, we are proposing to make participant hospitals financially responsible for services that may have occurred outside of the hospital during the 90-day post-discharge period. Although we expect hospitals to be actively engaged in post-discharge planning and other care during the 90-day post-discharge period for beneficiaries receiving LEJRs, as discussed in section III.A. of this proposed rule, we believe it is necessary for the purposes of the CCJR—JR model to provide participant hospitals with beneficiary-level claims data, either in

summary or line-level claim formats for a 3-year historical period as well as on a quarterly basis during the performance period. We believe that these data constitute the minimum information necessary to enable the participant hospital to understand spending patterns during the episode, appropriately coordinate care, and target care strategies toward individual beneficiaries furnished care by the participant hospital and other providers and suppliers.

Under the HIPAA Privacy Rule, covered entities (defined as health care plans, providers that conduct covered transactions, including hospitals, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called ''protected health information'' or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule.

The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI. The hospitals and other Medicare providers and suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they conduct (or someone on their behalf conducts) one or more HIPAA standard transactions electronically, such as for claims transactions. In light of these relationships, we believe that the proposed disclosure of the beneficiary claims data for an acute inpatient stay plus 90-day post-discharge episode where the anchor diagnosis at discharge was MS–DRG 469 or 470 would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a ''health care operations'' function that falls within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines,'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination'' (45 CFR 164.501). Under our proposal, hospitals would be using the data on their patients to evaluate the performance of the hospital and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as previously discussed, we believe that this provision is extensive enough to cover the uses we would expect a participant hospital to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.''

When using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make ''reasonable efforts to limit'' the information that is used, disclosed or requested the ''minimum necessary'' to accomplish the intended purpose of the use, disclosure or request (45 CFR 164.502(b)). We believe that the provision of the proposed data elements listed previously would constitute the minimum data necessary to accomplish the CCJR model goals of the participant hospital.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when the federal government maintains a system of records by which information about individuals is retrieved by use of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

''Routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We believe that the proposed data disclosures are consistent with the purpose for which the data discussed in this proposed rule was collected and may be disclosed in accordance with the routine uses applicable to those records.

Notwithstanding these exceptions, we believe it would be appropriate to provide some form of notice to Medicare beneficiaries about sharing these data. Based on our experiences with data sharing in other CMS programs and models, we propose a strategy for notifying beneficiaries of claims data sharing in this proposed rule, and in order to provide meaningful beneficiary choice over claims data sharing with the participant hospitals in CCJR. We considered both ''opt-in'' and ''opt-out'' options for beneficiaries with respect to data sharing in CCJR. An opt-in method has some advantages, particularly with regard to the fact that consumers have consistently expressed a desire that their consent should be sought before their health information may be shared (Schneider, S. et al. ''Consumer Engagement in Developing Electronic Health Information System.'' Prepared for: Agency for Healthcare Research and Quality, July 2009, at 16. Available at: *http://healthit.ahrq.gov/ahrq-funded-projects/consumer-engagement-developing-electronic-health-information-systems)*.

An opt-out method is used successfully in most systems of electronic exchange of information because it is significantly less burdensome on patients and providers while still providing an opportunity for patients to exercise control over their data. Thus, we propose to use an ''opt-out'' approach to provide beneficiaries with the opportunity to decline claims data sharing directly through 1–800–Medicare, rather than through the participant hospital. We also propose to provide advance notification to all Medicare beneficiaries about the opportunity to decline claims data sharing with entities participating in CMS programs and models through CMS materials such as the Medicare & You Handbook. The Handbook would include information about the purpose of the model, describe the opportunity for participants to request beneficiary identifiable claims data for health care operations purposes, and provide instructions on how beneficiaries may decline claims data sharing by contacting CMS directly through 1–800–Medicare. The Handbook would also contain instructions on how a beneficiary may reverse his or her preference to decline claims data sharing by contacting 1–800–Medicare.

There are several advantages to these strategies. First, we note that 1–800–Medicare is a communication method to which beneficiaries have familiarity and broad exposure. It also has the capability for beneficiaries to use accessible alternative or appropriate assistive technology, if needed. While many procedures in MS–DRGs 469 and 470 are planned in advance, some are emergent or unplanned procedures. Thus, asking the participant hospital to provide advance notification to the beneficiary, prior to the provision of services, may be inappropriate or impossible in certain circumstances. We would continue to maintain a list of beneficiaries who have declined data sharing and ensure that their claims information is not included in the claims files shared with participants. Hospitals with patient portals or Blue Button® may have capability to garner patient input prior to discharge through a hospital intervention specific to patient and care-giver education, while also aiding the hospital to meet reporting requirements for other CMS programs, such as Meaningful Use under the EHR Incentive Program for Medicare Hospitals.

Finally, participant hospitals in CCJR will only be allowed to request beneficiary-identifiable claims data for beneficiaries who: (1) Have been furnished a billable service by the participant hospital corresponding to the episode definitions for CCJR; and (2) have not chosen to opt-out of claims data sharing. A beneficiary that chooses to opt-out of claims data sharing is only opting out of the data sharing portion of the model. The decision to opt-out does not otherwise limit CMS' use of the beneficiaries' data, whether the beneficiary can initiate an episode, inclusion in quality measures, or inclusion in reconciliation calculations. Where a beneficiary chooses to opt-out of claims data sharing, our data contractor would maintain a list of all HICNs that choose to opt-out of data sharing. We would monitor whether participant hospitals continue to request data on beneficiaries who have opted out of having their data shared and do not intend to make such data available in response to a CCJR such hospitals' requests.

We request comments on our proposals related to the provision of both aggregate and beneficiary-identifiable data to participant hospitals in CCJR. We are particularly interested in comments on the kinds and frequency of data that would be useful to hospitals, potential privacy and security issues, the implications for sharing protected health information with hospitals, and the use of a beneficiary opt-out, as opposed to an opt-in, to obtain beneficiary consent to the sharing of their information. We also request comment on whether it would be helpful to provide any such system of notices, since Medicare claims information and other electronic information is already routinely shared for many other purposes among health care providers and insurers, and generally is subject to HIPAA protections. We also propose where available, the exchange of CMS beneficiary data with the local electronic health information exchange, a system that allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically in order to facilitate the hospitals ability to share timely patient data supporting improved patient referral, access, and care coordination across varied service settings.

F. Monitoring and Beneficiary Protection

1. Introduction and Summary

We are proposing the CCJR model as we believe it is an opportunity to improve the quality of care and that the policies of the model support making care more easily accessible to consumers when and where they need it, increasing consumer engagement and thereby informing consumer choices. For example, under this model we are proposing certain waivers which would offer participant hospitals additional flexibilities with respect to furnishing telehealth services, post-discharge home visits, and care in skilled nursing facilities, as discussed in section III.C.11 of this proposed rule. We believe that this model will improve beneficiary access and outcomes. Conversely, we do note that these same opportunities could be used to try to steer beneficiaries into lower cost services without an appropriate emphasis on maintaining or increasing quality. We direct readers to sections III.C.5 and III.D. of this proposed rule for discussion of the methodology for incorporating quality into the payment structure and the measures utilized for this model.

We believe that existing Medicare provisions can be effective in protecting beneficiary freedom of choice and access to appropriate care under the CCJR model. However, because the CCJR model is designed to promote efficiencies in the delivery of all care associated with lower extremity joint replacement procedures, providers may seek greater control over the continuum of care and, in some cases, could attempt to direct beneficiaries into care pathways that save money at the expense of beneficiary choice or even beneficiary outcomes. As such, we acknowledge that some additional safeguards may be necessary under the CCJR model as providers are simultaneously seeking opportunities to decrease costs and utilization. We believe that it is important to consider any possibility of adverse consequences to patients and to ensure that sufficient controls are in place to protect Medicare beneficiaries receiving lower extremity joint replacement related services under the CCJR model.

2. Beneficiary Choice and Beneficiary Notification

Because we have proposed that hospitals in selected geographic areas will be required to participate in the model, individual beneficiaries will not be able to opt out of the CCJR model when they receive care from a participant hospital in the model. We do not believe that it is appropriate or consistent with other Medicare programs to allow patients to opt out of a payment system that is unique to a particular geographic area. For example, the state of Maryland has a unique payment system under Medicare, but that payment system does not create an alternative care delivery system, nor does it in any way impact beneficiary decisions. Moreover, we do not believe that an ability to opt out of a payment system is a factor in upholding beneficiary choice or is otherwise advantageous to beneficiaries or even germane to beneficiary decisions given that this model does not increase beneficiary cost-sharing. We also believe that full notification and disclosure of the payment model and its possible implications is critical for beneficiary understanding and protection. However, it is important to create safeguards for beneficiaries to ensure that care recommendations are based on clinical needs and not inappropriate cost savings. It is also important for beneficiaries to know that they can raise any concerns with their physicians, with 1–800–Medicare, or with their local Quality Improvement Organizations.

This proposed payment model does not limit the ability to choose among Medicare providers or the range of services available to the beneficiary. Beneficiaries may continue to choose any Medicare participating provider, or any provider who has opted out of Medicare, with the same costs, copayments and responsibilities as they

have with other Medicare services. Although the proposed model would allow participant hospitals to enter into CCJR Sharing Arrangements with certain providers and these preferred providers may be recommended to beneficiaries as long as those recommendations are made within the constraints of current law, hospitals may not restrict beneficiaries to any list of preferred or recommended providers that surpass any restrictions that already exist under current statutes and regulations. Moreover, hospitals may not charge any CCJR collaborator a fee to be included on any list of preferred providers or suppliers, nor may the hospital accept such payments, which would be considered to be outside the realm of risk-sharing agreements. Thus, this proposed payment model does not create any restriction of beneficiary freedom to choose providers, including surgeons, hospitals, post-acute care or any other providers or suppliers.

Moreover, as participant hospitals redesign care pathways, it may be difficult for providers to sort individuals based on health care insurance and to treat them differently. We anticipate that care pathway redesign occurring in response to the model will increase coordination of care, improve the quality of care, and decrease cost for all patients, not just for Medicare beneficiaries. This anticipated change in the delivery of care to all patients may further promote consistent treatment of all beneficiaries.

We believe that beneficiary notification and engagement is essential because there will be a change in the way participating hospitals are paid. We believe that appropriate beneficiary notification should explain the model, advise patients of both their clinical needs and their care delivery choices, and should clearly specify that any non-hospital provider holding a risk-sharing agreement with the hospital should be identified to the beneficiary as a ''financial partner of the hospital for the purposes of LEJR services.'' These policies seek to enhance beneficiaries' understanding of their care, improve their ability to share in the decision-making, and ensure that they have the opportunity to consider competing benefits even as they are presented with cost-saving recommendations. We believe that appropriate beneficiary notification should do all of the following:

- Explain the model and how it will or will not impact their care.
- Inform patients that they retain freedom of choice to choose providers and services.
- Explain how patients can access care records and claims data through an available patient portal and through sharing access to care-givers to their Blue Button® electronic health information.
- Advise patients that all standard Medicare beneficiary protections remain in place.

These include the ability to report concerns of substandard care to Quality Improvement Organizations (QIO) and 1–800–MEDICARE.

After carefully considering the appropriate timing and circumstances for the necessary beneficiary notification, we are proposing that participating hospitals must require all providers and suppliers who execute a CCJR Sharing Arrangement with a participant hospital to share certain notification materials, to be developed or approved by CMS, that detail this proposed payment model before they order an admission for joint replacement for a Medicare FFS patient who would be included under the model. Participant hospitals must require this notification as a condition of any CCJR Sharing Arrangement. Where a participant hospital does not have CCJR Sharing Arrangements with providers or suppliers that furnish services to beneficiaries during a CCJR episode of care, or where the admission for joint replacement for a Medicare FFS patient who would be included under the model was ordered by a physician who does not have a CCJR Sharing Arrangement, the beneficiary notification materials must be provided to the beneficiary by the participant hospital. The purpose of this proposed policy is to ensure that all beneficiaries that initiate a CCJR episode receive the beneficiary notification materials, and that they receive such materials as early as possible. We believe that this proposal targets beneficiaries for whom information is relevant, and increases the likelihood that patients will become engaged and seek to understand the model and its potential impact on their care.

We note that beneficiaries are accustomed to receiving similar notices of rights and obligations from healthcare providers prior to the start of inpatient care. However, we also considered that this information might be best provided by hospitals at the point of admission for all beneficiaries, as hospitals provide other information concerning patient rights and responsibilities at that time. We invite comment on ways in which the timing and source of beneficiary notification could best serve the needs of beneficiaries without creating unnecessary administrative work for providers. We believe that this notification is an important safeguard to help ensure that beneficiaries in the model receive all medically necessary services, but it is also an important clinical opportunity to better engage beneficiaries in defining their goals and preferences as they share in the planning of their care.

3. Monitoring for Access to Care

Given that participant hospitals would receive a reconciliation payment when they are able to reduce average costs per case and meet quality thresholds, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. We will publish these data as part of the model evaluation to promote transparency and an understanding of the model's effects. We also propose to continue to review and audit hospitals if we have reason to believe that they are compromising beneficiary access to care. For example, where claims analysis indicates an unusual pattern of referral to regional hospitals located outside of the model catchment area or a clinically unexplained increase or decrease in joint replacement surgery rates.

4. Monitoring for Quality of Care

As we noted previously, in any payment system that promotes efficiencies of care delivery, there may be opportunities to direct patients away from more expensive services at the expense of outcomes and quality. We believe that professionalism, the quality measures in the model, and clinical standards can be effective in preventing beneficiaries from being denied medically necessary care in the inpatient setting and in post-acute care settings during the 90 days post-discharge. Accordingly, the potential for the denial of medically necessary care within the CCJR model will not be greater than that which currently exists under IPPS. However, we also believe that we have the authority and responsibility to audit the medical records and claims of participating hospitals and their CCJR collaborators in order to ensure that beneficiaries receive medically necessary services. We may also monitor arrangements between participant hospitals and their CCJR collaborators to ensure that such arrangements do not result in the denial

of medically necessary care or other program or patient abuse. We invite public comment on whether there are elements of the CCJR model that would require additional beneficiary protection for the appropriate delivery of inpatient care, and if so, what types of monitoring or safeguards would be most appropriate.

With respect to post-acute care, we believe that requiring participating hospitals to engage patients in shared decision making is the most important safeguard to prevent inappropriate recommendations of lower cost care, and that such a requirement can be best effected by requiring hospitals to make this a condition of any CCJR Sharing Arrangements with practitioners who perform these procedures. Additional deterrents are created by the financial accountability of the 90-day bundle, which is sufficiently long that it encourages the provision of high-quality care to avoid the risk of complications and readmissions, which would typically occur within that time period. Physician patterns of practice are also constrained by clinical standards of care, and we believe that the risk associated with deviations from those standards provides further deterrence to compromising care.

We believe that these safeguards are all enhanced by beneficiary knowledge and engagement. Therefore, we are proposing to require that participant hospitals must, as part of discharge planning, account for potential financial bias by providing patients with a complete list of all available post-acute care options in the service area consistent with medical need, including beneficiary cost-sharing and quality information (where available and when applicable). We expect that the treating surgeons or other treating practitioners, such as physiatrists, will continue to identify and discuss all medically appropriate options with the beneficiary, and that hospitals will discuss the various facilities and providers who are available to meet the clinically identified needs. These proposed requirements for CCJR participant hospitals would supplement the existing discharge planning requirements under the hospital Conditions of Participation. We also specifically note that neither the Conditions of Participation nor this proposed transparency requirement preclude hospitals from recommending preferred providers within the constraints created by current law, as coordination of care and optimization of care are important factors for successful participation in this model. We invite comment on this proposal, including additional opportunities to ensure high quality care.

5. Monitoring for Delayed Care

This model is based in part on an incentive for hospitals to create efficiencies in the delivery of care within a 90-day episode following the joint replacement surgery. Theoretically this basis could create incentives for hospitals and other CCJR collaborators involved in any CCJR Sharing Arrangements to delay services until after that window has closed.

We believe that existing Medicare safeguards are sufficient to protect beneficiaries. First, our experience with other bundled payments such as the BPCI initiative has shown that providers focus on appropriate care first and efficiencies only when those efficiencies can be obtained in the setting of appropriate care. We believe that a 90-day post-discharge episode will sufficiently minimize the risk that services furnished in relation to the beneficiary's lower extremity joint replacement procedure will be necessary beyond the end of the episode duration. To ensure that the length of the episode duration sufficiently minimizes the risk that any lower extremity joint replacement related care will not exceed the time established for the episode, we proposed to establish a 90-day post-discharge duration. We believe that participant hospitals would be unlikely to postpone services beyond a 90-day period because the consequences of delaying care beyond this long episode duration would be contrary to usual standards of care.

However, we also note that additional monitoring would occur as a function of the payment model. We have proposed as part of the payment definition (see section III.C of this proposed rule) that certain post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode would be counted as an adjustment against savings. We believe that the inclusion of this payment adjustment would create an additional deterrent to delaying care beyond the episode duration. In addition, the data collection and calculations used to determine this adjustment provide a mechanism to check if providers are inappropriately delaying care. Finally, we note that the proposed quality measures create additional safeguards as they are used to monitor and influence hospital clinical care at the institutional level.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the new proposed Part 510. We invite public comment on our proposed requirements for notification of beneficiaries and our proposed methods for monitoring participants' actions and ensuring compliance as well as on other methods to ensure that beneficiaries receive high quality, clinically appropriate care.

G. Coordination With Other Agencies

Impacts created by payment changes under this model are entirely internal to HHS operations; coordination with other agencies is not required outside of the usual coordination involved in the publication of all HHS regulatory changes.

IV. Evaluation Approach

A. Background

The proposed CCJR model is intended to enable CMS to better understand the effects of bundled payments models on a broader range of Medicare providers than what is currently being tested under BPCI. Obtaining information that is representative of a wide and diverse group of hospitals will best inform us on how such a payment model might function were it to be more fully integrated within the Medicare program. All CMS models, which would include the proposed CCJR model, are rigorously evaluated on their ability to improve quality and reduce costs. In addition, we routinely monitor CMS models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. Outlined in this proposed rule are the proposed design and evaluation methods, the data collection methods, key evaluation research questions, and the evaluation period and anticipated reports for the proposed CCJR model.

B. Design and Evaluation Methods

Our evaluation approach for the CCJR model will have elements in common with the standard Innovation Center evaluation approaches we have taken in other projects such as the BPCI initiative, Acute Care Episode (ACE) Demonstration, Pioneer ACO model, and other Innovation Center models. Specifically, the evaluation design and methodology for the proposed CCJR model would be designed to allow for a comparison of historic patterns of care among the CCJR providers to any changes made in these patterns in response to the CCJR model.

Our evaluation methodology for this model builds upon the fact that MSAs will be selected for participation in the model by stratified random assignment. Due to the random assignment, we can evaluate the effects of the model on outcomes of interest by directly

comparing MSAs that are randomly selected to participate in the model to a comparison group of MSAs that were not randomly selected for the model (but could have been). Randomized evaluation designs of this kind are widely considered the ''gold standard'' for social science and medical research because they ensure that the systematic differences are reduced between units that do and do not experience an intervention, which ensures that (on average) differences in outcomes between participating and non-participating units reflect the effect of the intervention. In constructing the comparison group, we are considering whether to use a simple comparison group that consists of all non-selected MSAs or to instead select a comparison group from among the non-selected providers based on how well they match the providers along a variety of measurable dimensions, such as hospital size, LEJR expenditures, provider characteristics and market characteristics. The latter approach is sometimes referred to as ''post-stratification'' in the literature on the analysis of randomized experiments.

We plan to use a range of analytic methods, including regression and other multivariate methods appropriate to the analysis of stratified randomized experiments to examine each of our measures of interest. Measures of interest could include, for example, quality of and access to care, utilization patterns, expenditures, and beneficiary experience. The evaluation would also include rigorous qualitative analyses in order to capture the evolving nature of the care model interventions.

In our design, we plan to take into account the impact of the CCJR model at the geographic unit level, the hospital level, and at the patient level. We are also considering various statistical methods to address factors that could confound or bias our results. For example, we would use statistical techniques to account for clustering of patients within hospitals and markets. Clustering allows our evaluation to compensate for commonalities in beneficiary outcomes by hospitals and by markets. Thus, in our analysis, if a large hospital consistently has poor performance, clustering would allow us to still be able to detect improved performance in the other, smaller hospitals in a market rather than place too much weight on the results of one hospital and potentially lead to biased estimates and mistaken inferences. Finally, we plan to use various statistical techniques to examine the effects of the CCJR model while also taking into account the effects of other ongoing interventions such as BPCI, Pioneer ACOs, and Medicare Shared Savings Program. For example, we are considering additional regression techniques to help identify and evaluate the incremental effects of adding the CCJR model in areas where patients and market areas are already subject to these other interventions as well as potential interactions among these efforts.

C. Data Collection Methods

We are considering multiple sources of data to evaluate the effects of the CCJR model. We expect to base much of our analysis on secondary data sources such as Medicare FFS claims and required patient assessment instruments such as the Minimum Data Set (MDS) collected for skilled nursing facility stays, the Patient Assessment Instrument for Inpatient Rehabilitation Facility (IRF–PAI) collected for IRF stays and the Outcome and Assessment Information Set (OASIS) collected for home health episodes of care. The beneficiary claims data would provide information such as expenditures in total and by type of provider and service as well as whether or not there was an inpatient hospital readmission. The assessment tools would provide information on a beneficiary's functioning (for example, physical, psychological and psychosocial functioning).

In conjunction with the previously stated secondary data sources, we are considering a CMS-administered survey of beneficiaries who received an LEJR during the performance period. This survey would be administered to beneficiaries who either had received an LEJR under the CCJR model or were selected as part of a control group. The primary focus of this survey would be to obtain information on the beneficiary's perception of their functional status before and after the LEJR as well as information on their pain and LE joint symptoms, and perceptions on access to care. The administration of this beneficiary survey would be coordinated with administration of the HCAHPS survey so as to not conflict with or compromise the HCAHPS efforts. Likewise, we are considering a survey administered by CMS and guided interviews conducted by CMS with providers including, but not limited to, the orthopedic surgeons, initiating hospitals, and PAC providers participating furnishing services to beneficiaries included in the CCJR model. These surveys would provide insight on beneficiaries' experience under the model and additional information on the care redesign strategies undertaken by health care providers.

In addition, we are considering CMS evaluation contractor administered site visits with selected hospitals and PAC providers as well as focus groups with a range of populations such as PAC providers and orthopedic surgeons. We believe that these qualitative methods would provide contextual information that would help us better understand the dynamics and interactions occurring among CCJR providers furnishing services included within a CCJR episode. For example, these data could help us better understand hospitals' intervention plans as well as how they were implemented and what they achieved. Moreover, in contrast to relying on quantitative methods alone, qualitative approaches would enable us to view program nuances as well as identify factors that are associated with successful interventions and distinguish the effects of multiple interventions that may be occurring within participating providers, such as simultaneous ACO and bundled payment participation.

D. Key Evaluation Research Questions

Our evaluation would assess the impact of the CCJR model on the aims of improved care quality and efficiency as well as reduced health care costs. This would include assessments of patient experience of care, utilization, outcomes, Medicare expenditures, provider costs, quality, and access. Our key evaluation questions would include, but are not limited to, the following:

- PAYMENT. Is there a reduction in total Medicare expenditures in absolute terms or for subcategories of providers (for example, acute vs post-acute providers, providers in certain geographic areas, providers within concentrated vs non-concentrated market areas or in urban vs rural areas)? Do the participants reduce or eliminate variations in utilization and expenditures or both that are not attributable to differences in health status? If so, how have they accomplished these changes?
- UTILIZATION. Are there changes in Medicare utilization patterns overall or for specific types of providers or services? How do these patterns compare to historic patterns, regional variations, and national patterns of care? How are these patterns of changing utilization associated with Medicare payments, patient outcomes and general clinical judgment of appropriate care?
- OUTCOMES/QUALITY. Is there either a negative or positive impact on quality of care and patient experiences of care or both? Did the incidence of complications remain constant or

decrease? Was there a change in beneficiaries' level of pain reduction, functional outcomes or return to independence under the model than relative to appropriate comparison groups? If so, how and for which beneficiaries?

• REFERRAL PATTERNS AND MARKET IMPACT. How, if at all, has the behavior in the selected geographic areas changed under the model? How have the referral patterns changed and for which type(s) of providers? Similarly, does the model have an impact on the number of patients with LEJR procedures and what types of patients are undergoing the procedure? To what extent, if any, is this related to gainsharing activities?

• UNINTENDED CONSEQUENCES. Did the CCJR model result in any unintended consequences, including adverse selection of patients, access problems, cost shifting beyond the agreed upon episode, evidence of stinting on appropriate care, anti-competitive effects on local health care markets, evidence of inappropriate referrals practices? Is so, how, to what extent, and for which beneficiaries or providers?

• POTENTIAL FOR EXTRAPOLATION OF RESULTS. What was the typical patient case mix in the participating practices and how did this compare to regional and national patient populations? What were the characteristics of participating practices and to what extent were they representative of practices treating Medicare FFS beneficiaries? Was the model more successful in certain types of markets? To what extent would the results be able to be extrapolated to similar markets and nationally or both?

• EXPLANATIONS FOR VARIATIONS IN IMPACT. What factors are associated with the patterns of results? Specifically, are the results related to the following?

++ Characteristics of the models including variations by year and factors such as presence of downside risk?

++ The participating hospital's specific features and ability to carry out their proposed intervention?

++ Characteristics and nature of interaction with partner providers including orthopedic surgeons and PAC provider community?

++ Characteristics of the geographic area, such as market concentration or size of city and availability of PAC providers?

++ Characteristics associated with the patient populations served?

E. Evaluation Period and Anticipated Reports

As discussed in section III.A. of this proposed rule, each of the selected participants in the CCJR model would have a 5-year performance period. The evaluation period would encompass this entire 5-year period and up to two years after. We plan to evaluate the CCJR model on an annual basis. We recognize, however, that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while CMS intends to have internal periodic summaries to offer useful insight during the course of the effort, a final analysis after the end of the 5-year performance period will be important for ultimately synthesizing and validating results.

We seek comments on our design, evaluation, data collection methods, and research questions.

V. Collection of Information Requirements

As stated in section1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the the testing and evaluation of models under section 1115A. As a result, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

VII. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 and other laws and Executive Orders requiring economic analysis of the effects of proposed rules.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

A. Statement of Need

This proposed rule is necessary in order to create and test a new payment model under the authority of section 1115A of the Act that allows the Innovation Center to test innovative payment and service delivery models in order to ''reduce program expenditures while preserving or enhancing the quality of care furnished to individuals.'' The underlying issue addressed by the proposed model is that under FFS, Medicare makes separate payments to providers and suppliers for items and services furnished to a beneficiary over the course of a treatment (an episode of care). Because the amount of payment is dependent on the volume of services delivered, this creates incentives for care that are fragmented, unnecessary or duplicative, while impeding the investment in quality improvement or care coordination that would maximize patient benefit. We anticipate the proposed model may reduce costs while maintaining or improving quality where the provision of ''bundled services'' in which all the services needed for a given episode of care are included in a single payment arrangement that provides incentives to promote high quality and efficient care.

This proposed rule would create and test the first bundled care model under the Innovation Center authority in which providers would be required to participate, building on the experience of the current voluntary BPCI and ACE efforts. Testing the model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement quality for common LEJR procedure episodes. This learning could inform future Medicare payment policy.

Under the proposed CCJR model, acute care hospitals in certain selected counties will receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. This proposed rule was developed based on the experiences we gained from the implementation of the Bundled Payments and Care Improvement Initiative and the Medicare Acute Care Episode (ACE) Demonstration to test bundled payments. We believe the model may benefit Medicare beneficiaries through improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in infrastructure and redesigned care processes for high

quality and efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care spectrum spanning the episode of care. It will also provide an opportunity to evaluate the nature and extent of reductions in the cost of treatment by providing financial incentives for providers to coordinate their efforts to provide services to meet patient needs and prevent future costs.

As detailed in Table 18, we estimate a total aggregate impact of $153 million in net Medicare savings over the proposed duration of the model, CYs 2016 through 2020, from the proposed implementation of the CCJR model. These estimated impacts represent the net effect of federal transfers that reward or penalize hospitals for improving care while making it more efficient. Furthermore, the proposed CCJR model may benefit beneficiaries since the model requires participant hospitals to be accountable for 90-day episodes of care for Medicare beneficiaries with a lower extremity joint replacement, improve the coordination of FFS items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrate a dedication and focus toward patient-centered care.

Our analysis of the model's effects shows that this proposed rule would trigger the threshold of ''an annual effect on the economy of $100 million or more'' or any of the other criteria for significant economic effects under E.O. 12866. Accordingly it would also be a major rule under the Congressional Review Act, and we are required to prepare an analysis that presents the costs and benefits of this proposed rule. We have prepared an analysis that address benefits and costs that applies to ''economically significant'' or ''major'' rules. We solicit comment on the assumptions and analysis presented throughout this regulatory impact section.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. As previously stated, this proposed rule triggers these criteria.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, pre-empts state law, or otherwise has federalism implications. We do not believe that there is anything in this proposed rule that either explicitly or implicitly pre-empts any state law, and furthermore we do not believe that this proposed rule will have a substantial direct effect on state or local governments, preempt states law, or otherwise have a federalism implication.

C. Anticipated Effects

1. Overall Magnitude of the Model and Its Effects on the Market

According to Medicare FFS claims data in FY 2014 (October 1, 2013 through September 30, 2014), there were approximately 21,000 discharges for MS–DRG 469 and 406,000 discharges for MS–DRG 470 (these DRG's cover knee and hip replacements, respectively with and without complications) nationally. Based on the same data, we estimate that the participant hospitals cover approximately 111,000 LEJR episodes in this model or about 25 percent of LEJR discharges nationally. The number of such procedures has grown in recent years, due both to the aging of the American population and to advances in medical technology and care that have made these operations less physically burdensome on patients and led to faster recovery times.

More uncertain are the total costs of these procedures. The mean estimated 90-day episode payment for lower extremity joint replacement procedures (defined as discharges for MS–DRG 469 and MS–DRG 470) is about $26,000 based on Medicare claims data for FY 2014 where approximately 55 percent of the spending is attributed to hospital inpatient services, 25 percent of spending is attributed to post-acute services such as physical therapy (either ambulatory and in a facility) and 20 percent to physician, outpatient hospital and other spending.

We have proposed to apply the model in 75 MSAs out of 196 MSAs eligible for selection, as described previously in this proposed rule. Based on this proposed selection methodology, we estimate that the model will cover about 25 percent of all lower extremity joint replacement procedures nationally. We estimate the model will cover about $2.261 billion in episode spending in 2016 and $2.713 billion in episode spending in 2020 as displayed in Table 18 later in this section. As discussed subsequently in this analysis, this is likely to generate approximately a net amount of $153 million in savings to Medicare over the entire duration of the model. Annual reconciliation payments for each performance year may be greater than or less than the net change as detailed in Table 18 later in this section. In years 2019 and 2020 of the proposed model, we estimate a net change that is less than $100 million, but with repayments that may be greater than $100 million, which exceed the $100 million dollar threshold for economic significance.

There may also be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of this model. We believe these are likely to be small, but cannot be certain. These issues are discussed later in the analysis. We welcome comments on our assumptions and calculations.

2. Effects on the Medicare Program

The proposed CCJR model is a model involving an innovative mix of financial incentives for quality of care and efficiency gains within FFS Medicare for lower extremity joint replacement episodes. This model represents a new approach for the Medicare FFS program because it applies bundled payments to hospitals that might not otherwise

participate in Innovation Center models or Medicare demonstrations and tests bundled payment models for episodes of care for LEJR procedures in multiple geographic areas. As such, we are interested in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those providers that may not have decided to engage in programs or models in which Medicare makes payments differently than Medicare FFS.

As described earlier in this proposed rule, episodes would begin with admission to an acute care hospital for an LEJR procedure that is paid under the IPPS through MS–DRG 469 or 470 and extend 90 days following discharge from the acute care hospital. The episode would include the LEJR procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services. Furthermore, we have proposed to designate participant hospitals as the episode initiators and to be financially responsible for episode cost under the proposed CCJR model. We propose to require all hospitals paid under the IPPS and physically located in selected geographic areas to participate in the CCJR model, with limited exceptions. Eligible beneficiaries who receive care at these hospitals will automatically be included in the model. Geographic areas, based on MSAs, are proposed to be selected through a stratified random sampling methodology based on the following criteria: Historical episode wage-adjusted payment quartiles and population size halves. We anticipate the proposed model may have financial and quality of care effects on non-hospital providers that are involved in the care of Medicare beneficiaries with an LEJR episode, improving the coordination of items and services paid for through Medicare FFS, encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care spectrum spanning the episode of care. However, the proposed model attributes episode spending and makes the retrospective reconciliation payment to or repayment from the participant hospital. Accordingly, our analysis examines the proposed effects on participant hospitals, as they are the providers accountable for the episode payment under this model. Additionally, we have proposed to test CCJR for a 5-year period, beginning January 1, 2016, and ending December 31, 2020 and our estimates cover the 5 years of the model.

As described earlier in this proposed rule, we propose to continue paying hospitals and other providers according to the usual Medicare FFS payment systems during all performance years. After the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, would be combined to calculate an actual episode payment. The actual episode payment is the sum of Medicare claims payments furnished to a beneficiary during a CCJR episode. The actual episode payment would then be reconciled against an established CCJR target price, with consideration of additional payment adjustments based on quality performance and post episode spending. The amount of this calculation, if positive, would be paid to the participant hospital if the hospital has met the quality thresholds proposed in this rule. This payment is the reconciliation payment. If negative, the participant hospital would be required to make repayment to Medicare. We also proposed to phase in the requirement that hospitals whose actual episode payments exceed their CCJR target price to pay the difference back to Medicare beginning in performance year 2. Under this proposal, Medicare will not require repayment from hospitals for CCJR episode cost performance above their target price in performance year 1. Lastly, we propose to limit how much a hospital can gain or lose based on its reconciliation calculation with additional policies to further limit the risk of high payment cases for all participant hospitals and for special categories of hospitals.

Based on the mix of financial and quality incentives, the proposed CCJR model could result in a range of possible outcomes for participant hospitals. The effects on hospitals of potential savings and liabilities will have varying degrees.

Table 18 summarizes the estimated impact for the CCJR model. Our model estimates that the Medicare program will save $153 million dollars over the 5 performance years (2016 through 2020). Savings to the Medicare program may be greater if providers are able to improve the coordination of care, invest in infrastructure, and redesign care processes to promote high quality and efficient service delivery. Costs to the Medicare program may increase if providers are able to use waivers provided under the model to increase episode volume among beneficiaries that are expected to be less costly than the hospitals target price without the need for improving the coordination of care. Our analysis to the best of our ability presents the cost and transfer payment effects of this proposed rule. We solicit comment on the assumptions and analysis presented.

a. Assumptions and Uncertainties

We used final action Medicare claims data from January 1, 2012 through December 31, 2014 to simulate the impact that this model would have on Medicare spending for joint replacement episodes. This time period is consistent with the historical period that are proposing to use to calculate target prices for performance years 1 and 2 of the model as described in section III.C of this proposed rule (we note that for performance year 3 through 5, target prices would be calculated based on episodes that start between in the proposed period of January 1, 2014 to December 31, 2016). Specifically we applied the methodology provided in this proposed rule for calculating target prices for all hospitals that would be required to participate in the model, as discussed in section III.A. of this proposed rule, based on their performance from calendar years 2012 through 2014. Specifically, all IPPS hospitals in the selected MSAs not currently participating in Model 1 or Phase II of BPCI Models 2 or 4 for the LEJR clinical episode were included in this analysis. We identified the anchor hospitalizations based on claims with MS–DRG 469 and MS–DRG 470 and included the related spending that occurred 90 days after discharge. We removed payments excluded from the episode as not being associated with joint replacement care, as well as removing the IPPS add-on payments including disproportionate share hospital and indirect medical educational payments, and new technology payments associated with the anchor hospitalization. We note that we have proposed other payment exclusions in the calculation of the episode target price, in comparing actual episode payments with target prices, and in determining whether a reconciliation payment should be made to the hospital or repayment from the hospital should be made as described in section III.C of this proposed rule. For the purpose of this impact analysis, we have only limited our calculations to remove the IPPS add-on payments for disproportionate share hospital and indirect medical educational payments, and new technology payments in calculating estimated target prices and in comparing the target price to actual episode payments. We then excluded

episodes where the anchor hospitalization occurred in hospitals that are not paid under the IPPS. With the remaining episodes, we standardized episode payments to remove the variation in spending due to differences in the hospital's wage index. We trended utilization and prices in 2012 and 2013 to match 2014 national performance, and we incorporated the proposed outlier policy to cap spending for high cost outlier episodes such that payments are capped at the MS–DRG anchor value that is two standard deviations above the mean as described in section III.C of this proposed rule. After we pooled episodes for MS–DRGs 469 and 470, we calculated average episode prices for each hospital and census region, as well as a hospital-specific weight representing a case mix value for each hospital that is dependent only on episode volume for MS–DRGs 469 and 470, and the national anchor factor. We then calculated blended prices for each hospital, with prices set at two-thirds of the hospital's experience and one-third of the region's average experience for performance years 1 and 2 of the model, as one-third of the hospital's experience and two-thirds of the region's experience as used for performance year 3 of the model, and as the region's average experience for performance years 4 and 5 of the model. We made an exception for hospitals with low historical CCJR episode volume defined in this proposed rule as those with fewer than 20 CCJR episodes in total across the 3 historical years, by setting their target price as the region's experience. These average prices were then disaggregated based on the national anchor factor of average episode spending for MS–DRG 470 relative to MS–DRG 469, the computed hospital-specific weight, the hospital's wage index was then applied back to the price, and a 2 percent discount was applied.

After calculating target prices for MS–DRG 469 and 470 for each hospital appropriate for each performance year, we compared these target prices against actual performance in the 2014 calendar year. We capped actual spending for individual episodes based on the methodology in this proposed rule for high cost outlier spending episodes. After incorporating the proposed outlier policy, total Medicare FFS spending in the 2014 calendar year for each hospital was reconciled against the target price and total number of episodes for the hospital. The aggregate impacts were then determined by multiplying by the total episodes for each MS–DRG.

We have proposed that the difference between each CCJR episode's actual payment and the relevant target price (calculated as target price subtracted by CCJR episode actual episode payment) would be aggregated for all episodes for a participant hospital within the performance year, creating the NPRA. Any positive NPRA amount greater than the proposed stop-gain limit would be capped at the stop-gain limit of 20 percent for each performance year of the model, and any negative NPRA amount exceeding the proposed stop-loss limit would be capped at the stop-loss limit as described in section III.C.8.b of this proposed rule. To limit a hospital's overall repayment responsibility under this model, we have proposed a 10 percent repayment limit in performance year 2 and a 20 percent repayment limit in performance year 3 and subsequent years. For rural hospitals, MDHS, SCHs and RRCs, we have proposed a 3 percent repayment limit in performance year 2 and a 5 percent repayment limit in performance year 3 and subsequent years. Furthermore, as described earlier in this proposed rule, in order for a participant hospital to qualify for a reconciliation payment, a hospital must meet or exceed the 30th percentile benchmark for each of the three proposed quality measures in performance years 1 through 3:

- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550)
- Hospital-level 30-day, all-cause risk-standardized readmission rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551)
- HCAHPS Survey (NQF #0166).

In performance years 4 through 5, a hospital must meet or exceed the 40th percentile benchmark for those proposed quality measures.

To simulate the impact for performance year 1 or 2016, we calculated the NPRA assuming no downside risk to hospitals as proposed, and using the target price calculated for performance year 1, that is two-thirds hospital experience and one-third region experience. If the estimated NPRA is negative (that is, in the aggregate, the actual episode payments for all episodes is greater than the target price multiplied by the number of episodes) for performance year 1, Medicare would not require repayment of the NRPA from the hospital because we have proposed no hospital responsibility for repayment for the first performance year. Additionally, as part of this estimate, we accounted for whether a hospital met the quality benchmarks to be eligible for a reconciliation payment. Lastly, we have applied the proposed 20 percent stop-gain limit on the estimated reconciliation payments made to participant hospitals total reconciliation payments reflect what we would expect Medicare to pay hospitals due to normal claims variation, and due to a blended target price which rewards hospitals that already perform better than their regional average.

To simulate the impact in performance year 2, we calculated the NPRA assuming full risk as proposed for this model, rewarding hospitals that perform better than their 2 percent discount that met the 30th percentile threshold for the complications, readmissions and HCAHPs quality metrics, but only requiring repayments from hospitals for total spending that is above a 1 percent discount. For the simulation in performance year 2, we used the target price calculated for performance year 2 that is two-thirds hospital experience and one-third regional experience. A 10 percent stop-loss limit was applied to repayments, and 3 percent stop-loss limit was applied for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers, as proposed, and a 20 percent stop-gain limit was applied.

To simulate the impact in performance year 3, we calculated the NPRA assuming full risk as proposed in the model and rewarding hospitals that perform better than their 2 percent discount and met the 30th percentile thresholds for all three of the quality metrics, and requiring repayments from hospitals for total spending that is above the 2 percent discount. For the simulation in year 3, we used the target price calculated as one-third of the hospital's experience and two-thirds of the regional experience. We included a 20 percent stop-gain limit for all hospitals, a 20 percent stop-loss limit on repayments from acute care hospitals included in this analysis, but used a 5 percent stop-loss limit on reconciliation repayments from rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers, as proposed.

For performance years 4 and 5, the impact estimates were calculated in the same way except that the episode target prices are based on 100 percent of the regional experience, as proposed. Additionally, the impact estimates accounted for the proposal that a hospital must meet or exceed the 40th percentile benchmark for those proposed quality measures in order to be eligible for a reconciliation payment.

In this proposed model, we are selecting a total of 75 MSAs from 8 MSA groupings. IPPS hospitals located within the selected MSAs will be required to participate in this model unless they participate in BPCI as discussed earlier in this proposed rule in section III.A.

Additionally, as described earlier in this proposed rule in section III.C.5, hospitals can qualify for a lower discount applied to their target episode price if they voluntarily submit patient-reported outcome measures data. More specifically, for hospitals that successfully submit patient-reported outcome measures data for episodes beginning in performance year 2, the discount percentage is reduced from 2 percent to 1.7 percent for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price, and reduce the discount percentage from 1 percent to 0.7 percent for purposes of determining the amount Medicare would require the hospital to repay. We modeled the effects of this proposal by re-running the simulation using a 1.7 percent discount for all hospitals in performance years 2 through 5, and in performance year 2 only requiring repayments that are beyond a 0.7 percent discount. We combined the simulations with a 2 percent discount and 1.7 percent discount by assuming that 33 percent of hospitals would submit the patient-reported outcome measures data.

Additionally, we note for these estimates, we did not make assumptions for changes in efficiency or utilization over the course of the model. Over the 5 years of the model, we estimate $153 million dollars in savings to the Medicare program, out of $12.321 billion in total episode spending.

TABLE 18: PROPOSED ESTIMATES OF RECONCILIATION PAYMENTS *

	Year of proposed model					Across all 5 years of the proposed model
	2016	2017	2018	2019	2020	
Total episode spending	$2,261	$2,332	$2,447	$2,568	$2,713	$12,321
Net reconciliation payments**	23	(29)	(43)	(50)	(53)	(153)
Reconciliation amounts	23	24	47	63	66	223
Repayment amounts	0	(53)	(90)	(113)	(120)	(376)
Net reconciliation as a percentage of total episode spend	1.0%	(1.3%)	(1.7%)	(2.0%)	(2.0%)	(1.2%)

* Impact for 75 selected MSAs. All numbers rounded to closest million.
** Sum of reconciliation amount and repayment amount may not add to net reconciliation payment due to rounding.

These estimates contain a significant amount of uncertainty. As a result, this proposed model could produce more significant Medicare savings or could result in additional costs to the Medicare program. The primary source of uncertainty stems from the normal variation in claim cost trends each year coupled with the proposed cap on the repayment made at reconciliation. In addition, this analysis assumes no change in utilization both for the use of services within the bundled episode, as well as no change in total episodes among hospitals. The prospective prices for the proposed CCJR model incorporate price updates from the FFS payment systems, but assume no change in utilization for the performance years. If there is a national increase in utilization within each bundle that is independent of this model, then savings to the Medicare program may increase due to greater repayments paid back to Medicare. If there is a national decrease in utilization within each bundle that is independent of this model then costs to the Medicare program may increase due to greater reconciliation payments paid by Medicare to hospitals. The results will also depend on the cumulative effects over time and across providers on whether and how to change either actual medical procedures or the allocations of payments among service providers. We would expect significant variation among hospitals and among metropolitan areas, but are unable to predict these.

Additionally, although we project savings to Medicare under this proposed model, as stated earlier, we note that under section 1115A(b)(3)(B) of the Act, the Secretary is required to terminate or modify a model unless certain findings can be made with respect to savings and quality after the model has begun. If during the course of testing the model it is determined that termination or modification is necessary, such actions would be undertaken through rulemaking.

b. Analyses

The first performance year of the model is expected to cost the Medicare program $23 million in reconciliation payments made by CMS to hospitals. We have proposed that no repayments from hospitals will be assessed because hospitals are not subject to downside risk in performance year 1. Hospitals that would receive reconciliation payments are the hospitals that provide lower cost care relative to their regional average.

In the second performance year of the model, participant hospitals on net are expected to pay $29 million to CMS. We have proposed a 10 percent stop-loss limit for acute care hospitals, with exception for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral center hospitals which would be subject to a 3 percent stop-loss limit. These limits would cap the total amount of repayments paid by hospitals to CMS.

In the third performance year of the model, net reconciliation payments are expected to be $43 million in savings to the Medicare program. The additional savings in performance year 3 compared to performance year 2 can be attributed to receiving repayments from hospitals for total spending that is above a 1 percent discount in performance year 2, while in performance year 3, we would require repayments from hospitals for total spending that is above a 2 percent discount.

For performance years 4 and 5 of the model, the proposed episode target price will be based on full regional pricing. This creates great variation between the target price and hospital's own experience. Therefore, the stop-gain and stop-loss limits on reconciliation payments are estimated to have a larger impact. As a result, net payments are expected to be $50 million dollars from hospitals to the Medicare program in the fourth year and $53 million in the fifth year. Savings to the Medicare program increases as a higher proportion of hospitals that provide care more efficiently than their regional average will forego reconciliation

payments due to failure to meet the proposed thresholds on all three of the quality of care measures. These estimated savings in years 4 and 5 represent 2.0 percent of total episode spending in those years. The proposed total savings to the Medicare program after 5 years of the model are expected to be $153 million dollars out of $12.321 billion dollars or 1.2 percent in total episode spending. Due to the uncertainty of estimating this model, actual results could be significantly higher or lower than this estimate.

c. Further Consideration

We can use our experience in previous implementation of bundled payment models to help inform our impact analyses. We have previously used our statutory authority to create payment models such as the BPCI initiative and the ACE Demonstration to test bundled payments. Under the authority of section 1866C of the Act, CMS funded a 3-year demonstration, the ACE Demonstration. The demonstration used a prospective global payment for a single episode of care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode of care was defined as a combination of Parts A and B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MS DRGs. The MS DRGs tested included 469 and 470, those proposed for inclusion in the CCJR model. The discounted bundled payments generated an average gross savings to Medicare of $585 per episode for a total of $7.3 million across all episodes (12,501 episodes) or 3.1 percent of the total expected costs for these episodes. After netting out the savings produced by the Medicare Parts A and B discounted payments and some increased post-acute care costs that were observed at two sites, Medicare saved approximately $4 million, or 1.72 percent of the total expected Medicare spending. Additionally, we are currently testing the BPCI initiative. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. Episodes of care under the BPCI initiative begin with either an—(1) inpatient hospital stay; or (2) post-acute care services following a qualifying inpatient hospital stay and include tests of LEJR episodes. The BPCI initiative is evaluating the effects of episode based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. Although there is limited evidence from BPCI and ACE suggesting that providers may improve their performance, both of these demonstrations were voluntary, and the participants that volunteered for these demonstrations may be in a better position to reduce episode spending relative to the average provider. We believe that our experiences with BPCI support the proposed design of the CCJR Model.

3. Effects on Beneficiaries

In 2014, approximately 430,000 Medicare beneficiaries had discharges for lower extremity joint replacements (MS–DRG 469 and MS–DRG 470) nationally. We anticipate that the CCJR model may benefit beneficiaries receiving lower extremity joint replacements because the intent of the model is to test whether providers under this bundled payment system are able to improve the coordination and transition of care, invest in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivize higher value care across the inpatient and post-acute care spectrum spanning the episode of care. We believe the model has a patient-centered focus such that healthcare delivery and communication on the patient and those who are close to the patient and bases the care and communication delivered around the needs of the beneficiary, thus benefitting the beneficiary community.

We have proposed several quality of care and patient experience measures to evaluate participant hospitals in the CCJR model with the intent that it will encourage the provider community to focus on and deliver improved quality care for the Medicare beneficiary. We are proposing to adopt and publicly report three hospital level quality of care measures for the CCJR model. Those measures include a complication measure, readmission measure, and a patient experience survey measure. In addition, we are proposing to voluntarily collect data to develop a hospital-level measure of patient reported outcomes following an elective primary total hip or total knee arthroplasty. We propose to use these measures to test the success of the model and to monitor for beneficiary safety. Additionally, participant hospitals must meet the proposed quality performance standards in order to qualify to receive a reconciliation payment. The accountability of participant hospitals for both quality and cost of care provided for Medicare beneficiaries with an LEJR episode provides the hospitals with new incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the model does not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program guaranteed under section 1802 of the Act. Under the CCJR model, eligible beneficiaries who choose to receive services from a participant hospital would not have the option to opt out of inclusion in the model. Although the proposed model allows hospitals to enter into risk-sharing arrangements with certain other providers and these hospitals may recommended those providers to the beneficiary, hospitals may not prevent or restrict beneficiaries to any list of preferred or recommended providers.

Many controls exist under Medicare to ensure beneficiary access and quality and we have proposed to use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. As described earlier in this proposed rule, given that participant hospitals would receive a reconciliation payment when they are able to reduce average costs per case and meet quality thresholds, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. Furthermore, we also proposed to require providers to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice.

We have proposed to implement several safeguards to ensure that Medicare beneficiaries do not experience a delay in services. We believe that the longer the episode duration, the lower the risk of delaying care beyond the episode duration, and we believe that a 90 day episode is sufficiently long to minimize the risk that any lower extremity joint replacement related care will be delayed beyond the end of the episode. Moreover, we have proposed as part of the payment definition (see section III.C of this proposed rule) that certain outlier costs post-episode payments occurring in the 30 day window subsequent to the end of the 90-day episode will be counted as an

adjustment against savings. Importantly, approaches to saving costs will include taking steps that facilitate patient recovery, that shorten recovery duration, and that minimize post-operative problems that might lead to readmissions. Thus, the model itself rewards better patient care.

Lastly, we note that Medicare payments for services will continue to be made for each Medicare FFS payment system under this model, and will include normal beneficiary copayments, deductibles, and coinsurance. We expect and assume that beneficiary payments will not be affected, as only the hospital will be subject to the reconciliation process. Beneficiaries may benefit if providers are able to systematically improve the quality of care while reducing costs. We welcome public comments on our estimates of the impact of our proposals on Medicare beneficiaries.

4. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, 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 governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities, either by virtue of their nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $7.5 to $38.5 million in any 1 year; NAIC Sector–62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at *http://www.sba.gov/content/small-business-size-standards.*

For purposes of the RFA, we generally consider all hospitals and other providers and suppliers to be small entities. We believe that the provisions of this proposed rule relating to acute care hospitals would have some effects on a substantial number of other providers involved in these episodes of care including surgeons and other physicians, skilled nursing facilities, physical therapists, and other providers.

Although we acknowledge that many of the affected entities are small entities, and the analysis discussed throughout this proposed rule discusses aspects of the model that may or will affect them, we have no reason to assume that these effects will reach the threshold level of 5 percent of revenues used by HHS to identify what are likely to be ''significant'' impacts. Although lower extremity joint replacement procedures (MS–DRGs 469 and 470) are among the most common surgical procedures undergone by Medicare beneficiaries, they are only about 5 percent of all acute hospital discharges.[81] We assume that all or almost all of these entities will continue to serve these patients, and to receive payments commensurate with their cost of care. Such changes occur frequently already (for example, as both hospital affiliations and preferred provider networks change), and we have no reason to assume that this will change significantly under the model.

Accordingly, we have determined that this proposed rule will not have a significant impact on a substantial number of small entities. We solicit public comments on our estimates and analysis of the impact of our proposals on those small entities.

5. Effects on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a proposed rule or final rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, a small rural hospital is defined as a hospital that is located outside of an MSA and has fewer than 100 beds. We note that, according to this definition, the CCJR model would not include any rural hospitals given that the CCJR model would only include hospitals located in MSAs, as proposed in section III.A. However, we also note that as discussed in section III.C.8., for purposes of our proposal to include a more protective stop-loss policy for certain hospitals, we are proposing to define a rural hospital as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103. Thus, the proposed model will affect some rural hospitals, as discussed previously in section III.C.8 of this proposed rule.

Because of our concerns that rural hospitals may have lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes, we have proposed additional financial protections for certain categories of hospitals, including rural hospitals. In performance year 2, a hospital could owe Medicare no more than 10 percent of the target price multiplied by the number of the hospital's LEJR episodes in CCJR as we phase in repayment responsibility under the model. In performance year 3 and beyond when full repayment responsibility is in place, no more than 20 percent of the target price multiplied by the number of the hospital's LEJR episodes in CCJR could be owed by a hospital to Medicare. However, for rural hospitals, Medicare Dependent Hospitals, Rural Referral Centers and Sole Community, we proposed a stop loss limit policy of 3 percent of episode payments for these categories of hospitals. More specifically, in performance year 2, a hospital could owe Medicare no more than 3 percent of the target price multiplied by the number of the hospital's episodes in CCJR. In performance years 3 through 5, a hospital could owe Medicare no more than 5 percent of the target price multiplied by the number of the hospital's episodes. Although we propose these additional protections, we believe that few rural hospitals will be included in the model, and therefore that few will need those protections.

Because lower extremity joint replacement procedures (MS–DRGs 469 and 470) account for only about 5 percent of all discharges, because relatively few of these procedures are performed at small rural hospitals, and because our model is designed to minimize adverse effects on rural hospitals, we do not believe that rural hospitals will experience significant adverse economic impacts. Accordingly, we conclude that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

We are soliciting public comments on our estimates and analysis of the impact of our proposals on those small rural hospitals.

6. Unfunded Mandates

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 2015, that is approximately $144 million. This proposed rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of $144 million in any 1 year.

[81] Medicare Inpatient Claims data from January–December 2014, Chronic Conditions Warehouse.

D. Alternatives

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered, and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. We solicit and welcome comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these. We note that our estimates are limited to the IPPS hospitals that would be selected to participate in this proposed model. This proposed rule will not impinge directly on hospitals that are not participating in the model. However, it may encourage innovations in health care delivery in other areas or in care reimbursed through other payers. For example, a hospital and affiliated providers may choose to extend their arrangements to all joint replacement procedures they provide, not just those reimbursed by Medicare. Alternatively, a hospital and affiliated providers in one city may decide to hold themselves forth as ''centers of excellence'' for patients from other cities, both those included and not included in the model. We welcome comments that address these or other possibilities.

E. Accounting Statement

As required by OMB Circular A–4 under Executive Order 12866 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*) in Table 19, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the provisions in this proposed rule. The accounting statement is based on estimates provided in this regulatory impact analysis. Because of the uncertainties identified in establishing the economic impact estimates, we intend to update the estimates in the final rule. As described in Table 18, we estimate this proposed model will result in savings to the federal government of $153 million over the 5years of the model from 2016 to 2020. The following Table 19 shows the annualized change in (A) net federal monetary transfers, and (B) potential reconciliation payments to participating hospitals net of repayments from participant hospitals that is associated with the provisions of this proposed rule as compared to baseline. In Table 19, the annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $28 million and $30 million respectively.

TABLE 19—ACCOUNTING STATEMENT ESTIMATED IMPACTS

Category	Primary estimate	Source citation (RIA, preamble, etc.)
BENEFITS:		
Annualized monetized transfers: Discount rate: 7%	$28 million	Change from baseline to proposed changes (Table 18).
Annualized monetized transfers: Discount rate: 3%	$30 million.	
From whom to whom?	From Participant IPPS Hospitals to Federal Government.	

F. Conclusion

The preceding analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule with a significant economic effect. As a result of this proposed rule, we estimate of the financial impact of the CCJR model for CYs 2016 through 2020 would be net federal savings of $153 million over a 5 year period. The annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $28 million and $30 million respectively.

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

List of Subjects for 42 CFR Part 510

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at section 1115A of the Social Security Act, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as follows:

■ 1. Revise the heading of Subchapter H to read as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

■ 2. Part 510 is added to Subchapter H to read as follows:

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

Secs.

Subpart A—General Provisions

510.1 Basis and scope.
510.2 Definitions.

Subpart B—Comprehensive Care for Joint Replacement Model Participants

510.100 Episodes being tested.
510.105 Geographic areas.

Subpart C—Scope of Episodes

510.200 Time periods, included services, and attribution.
510.205 Beneficiary inclusion criteria.
510.210 Determination of the episode.

Subpart D—Pricing and Payment

510.300 Determination of episode target prices.
510.305 Determination of the NPRA and reconciliation process.
510.310 Appeals process.
510.315 Quality thresholds for reconciliation payment eligibility.
510.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.
510.325 Allocation of payments for services that straddle the episode.

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

510.400 Quality measures and reporting.
510.405 Beneficiary choice and beneficiary notification.
510.410 Compliance enforcement.

Subpart F—Financial Arrangements and Beneficiary Incentives

510.500 Financial arrangements under the CCJR model.
510.505 Beneficiary incentives under the CCJR model.

Subpart G—Waivers

510.600 Waiver of direct supervision requirement for certain post-discharge home visits.
510.605 Waiver of certain telehealth requirements.
510.610 Waiver of SNF 3-day rule.
510.615 Waiver of certain post-operative billing restrictions.

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

Subpart A—General Provisions

§ 510.1 Basis and scope.

(a) *Basis.* This part implements the test of the Comprehensive Care for Joint Replacement model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, and other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) *Scope.* This part sets forth the following:

(1) The participants in the Comprehensive Care for Joint Replacement model.

(2) The episodes being tested in the model.

(3) The methodology for pricing and payment under the model.

(4) Quality performance standards and quality reporting requirements.

(5) Safeguards to ensure preservation of beneficiary choice and beneficiary notification.

§ 510.2 Definitions.

For the purposes of this part, the following definitions are applicable:

ACO stands for Accountable Care Organization.

Actual episode payment means the sum of Medicare claims payments for items and services that are included in the episode in accordance with § 510.200(b), excluding the items and services described in § 510.200(d) and the incentive programs and add-on payments specified in § 510.320, and subject to the cap described in § 510.300(b)(4).

Alignment payment means a payment from a Comprehensive Care for Joint Replacement collaborator to a participant hospital under a Comprehensive Care for Joint Replacement sharing arrangement.

Anchor hospitalization means the initial hospital stay upon admission for a lower extremity joint replacement.

BPCI stands for the Bundled Payments for Care Improvement initiative.

CCJR stands for Comprehensive Care for Joint Replacement.

CCJR collaborator means one of the following persons or entities that enter into a CCJR sharing arrangement:

(1) Skilled nursing facility.

(2) Home health agency.

(3) Long-term care hospital.

(4) Inpatient rehabilitation facility.

(5) Physician.

(6) Nonphysician practitioner.

(7) Outpatient therapy provider.

(8) Physician group practice.

CCJR-eligible hospital means a hospital that is paid under IPPS and not a participant in BPCI Model 1 or in the risk-bearing period of Models 2 or 4 for LEJR episodes, regardless of whether or not the metropolitan statistical area in which the hospital is located is selected for inclusion in the CCJR model.

CCJR reconciliation report means the report prepared after each reconciliation that CMS provides to each participant hospital notifying the participant hospital of the outcome of the reconciliation.

CCJR sharing arrangement means a financial arrangement between a participant hospital and a CCJR collaborator for the sole purpose of sharing the following:

(1) CCJR reconciliation payments.

(2) The participant hospital's internal cost savings.

(3) The participant hospital's responsibility for repayment to Medicare.

Core-based statistical area (CBSA) means a statistical geographic entity consisting of the county or counties associated with at least one core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties containing the core.

Critical access hospital (CAH) means a hospital designated under subpart F of part 485 of this chapter.

Episode of care (Episode) means all Medicare Part A and B items and services described in § 510.200(b) (and excluding the items and services described in § 510.200(d)) that are furnished to a beneficiary described in § 510.205 during the time period that begins with such beneficiary's admission to an anchor hospitalization and ends 90 days after discharge from the anchor hospitalization.

Episode target price means the amount determined in accordance with § 510.300 and applied to an episode in determining a net payment reconciliation amount.

Gainsharing payment means a payment from a participant hospital to a CCJR collaborator, under a CCJR sharing arrangement, composed of only reconciliation payments or internal cost savings or both.

Historical episode payment means the most recent 3 years of expenditures for an episode in a given participant hospital.

Hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

ICD–CM stands for International Classification of Diseases, Clinical Modification.

Inpatient prospective payment systems (IPPS) means the payment systems for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

Internal cost savings means the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CCJR episodes of care. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital.

Lower-extremity joint replacement (LEJR) means any procedure that is within MS–DRG 469 or 470, including lower-extremity joint replacement procedures or reattachment of a lower extremity.

Medicare severity diagnosis-related group (MS–DRG) means a patient classification system for inpatient discharges and adjusting payments under the IPPS.

Medicare-dependent, small rural hospital (MDH) means a specific type of hospital that meets the classification criteria specified under § 412.108 of this chapter.

Metropolitan Statistical Area (MSA) means a core-based statistical area associated with at least one urbanized area that has a population of at least 50,000.

Net payment reconciliation amount (NPRA) means the amount determined in accordance with § 510.305(e).

NPI stands for National Provider Identifier.

OIG stands for the *Department of Health and Human Services'*, Office of the Inspector General.

Participant hospital means an IPPS hospital (other than those hospitals specifically excepted under § 510.100(b)) that is physically located in one of the geographic areas selected for participation in the CCJR model in accordance with § 510.105, as of the date of selection or any time thereafter during any performance period.

Participation agreement means a written, signed agreement between a CCJR collaborator and a participant hospital that meets the requirements of § 510.500(c).

PBPM stands for per-beneficiary-per-month.

Performance year means one of the calendar years in which the CCJR model will be tested.

Post-episode spending amount means the sum of Medicare Parts A and B payments for items and services that are furnished within 30 days after the end of the episode.

Reconciliation payment means a payment of the NPRA made to a CCJR participant hospital.

Region means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau.

Rural hospital means a hospital that meets one of the following definitions:

(1) Is located in a rural area as defined under § 412.64 of this chapter.

(2) Is located in a rural census tract defined under § 412.103(1) of this chapter.

(3) Has reclassified as a rural hospital under § 412.103 of this chapter.

Rural referral center (RRC) has the same meaning given this term under § 412.96 of this chapter.

Sole community hospital (SCH) means a certain type of hospital that meets the classification criteria specified in § 412.92 of this chapter.

TIN stands for Taxpayer Identification Number.

Total episode payments means the total Medicare FFS Parts A and B claims for an episode.

Subpart B—Comprehensive Care for Joint Replacement Program Participants

§ 510.100 Episodes being tested.

(a) *Initiation of an episode.* An episode is initiated when a participant hospital admits a Medicare beneficiary described in § 510.205 for an anchor hospitalization.

(b) *Exclusions.* A hospital is excluded from being a participant hospital if any of the following conditions apply on or after July 1, 2015:

(1) The hospital is an episode initiator for an LEJR episode in the risk-bearing period of Models 2 or 4 of the BPCI. This exclusion ceases to apply to the hospital upon any termination of its participation as an episode initiator for a lower-extremity joint replacement episode.

(2) The hospital is participating in Model 1 of the BPCI. This exclusion ceases to apply to the hospital upon any termination of its participation in BPCI in Model 1.

§ 510.105 Geographic areas.

(a) *General.* The geographic areas for inclusion in the CCJR model are obtained using a stratified random sampling of certain MSAs in the United States. All counties within each of the selected MSAs are selected for inclusion in the CCJR model.

(b) *Stratification criteria.* Geographic areas in the United States are stratified according to the characteristics that CMS determines are necessary to ensure that the model is tested on a broad range of different types of hospitals that may face different obstacles and incentives for improving quality and controlling costs.

(c) *Exclusions.* CMS excludes from the selection of geographic areas MSAs that met the following criteria between July 1, 2013 and June 30, 2014:

(1) Had fewer than 400 episodes;

(2) Had fewer than 400 non-BPCI episodes;

(3) Had at least 400 non-BPCI episodes, but—

(i) Had more than 50 percent of otherwise qualifying (BPCI or non BPCI) episodes in Phase 2 of BPCI Model 2 or 4 with hospital episode initiators; or

(ii) Had more than 50 percent of otherwise qualifying (BPCI or non-BPCI) episodes treated in a SNF or HHA that were treated in a BPCI Model 3 initiating provider;

(4) Had more than 50 percent of episodes that were paid under the Maryland State Waiver System, if any part of the MSA was located in Maryland.

Subpart C—Scope of Episodes

§ 510.200 Time periods, included services, and attribution.

(a) *Time periods.* All episodes being tested in the CCJR model begin on or after January 1, 2016 and end on or before December 31, 2020.

(b) *Included services.* All Medicare Parts A and B items and services are included in the episode, except as specified in paragraph (d) of this section. These services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services (including hospital readmissions).

(3) Inpatient hospital readmission services.

(4) Inpatient psychiatric facility (IPF) services.

(5) Long-term hospital care (LTCH) services.

(6) Inpatient rehabilitation facility (IRF) services.

(7) Skilled nursing facility (SNF) services.

(8) Home health agency (HHA) services.

(9) Hospital outpatient services.

(10) Independent outpatient therapy services.

(11) Clinical laboratory services.

(12) Durable medical equipment (DME).

(13) Part B drugs and biologicals.

(14) Hospice services.

(15) PBPM payments under models tested under section 1115A of the Act.

(c) *Episode attribution.* All items and services included in the episode (as described in paragraph (b) of this section) are attributed to the participant hospital at which the anchor hospitalization occurs.

(d) *Excluded services.* The following items, services, and payments are excluded from the episode:

(1) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter.

(2) New technology add-on payments, as defined in part 412, subpart F of this chapter.

(3) Items and services unrelated to the anchor hospitalization, as determined by CMS. Such excluded services include, but are not limited to, the following:

(i) Inpatient hospital admissions for MS–DRGs that group to the following categories of diagnoses:

(A) Oncology.

(B) Trauma medical.

(C) Chronic disease surgical, such as prostatectomy.

(D) Acute disease surgical, such as appendectomy.

(ii) Medicare Part B services as identified by the principal ICD–CM diagnosis code, based on the ICD–CM version in use during the performance year, on the claim that group to the following categories of diagnoses:

(A) Acute disease diagnoses, such as severe head injury.

(B) Certain chronic disease diagnoses, as specified by CMS on a diagnosis-by-diagnosis—basis depending on whether the condition was likely to have been affected by the lower-extremity joint replacement procedure and recovery period or whether substantial services were likely to be provided for the chronic condition during the episode. Such chronic disease diagnoses are posted on the CMS Web site and may be revised in accordance with paragraph (e) of this section.

(C) Certain PBPM payments under models tested under section 1115A of the Act. PBPM model payments are excluded if they are determined to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses, as described in this paragraph. The list of excluded PBPM payments is posted on the CMS Web site and is updated consistent with the following. Notwithstanding the foregoing, all PBPM model payments

funded from CMMI's appropriation are excluded from the episode.

(*1*) The list of excluded PBPM payments will be posted on the CMS Web site.

(*2*) On an annual basis, or more frequently as needed, CMS updates the list of excluded PBPM payments.

(*3*) Criteria for exclusion of PBPM payments under certain models tested under section 1115A of the Act. Model PBPM payments are excluded from episode target price and actual episode payments if determined to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses, as described in paragraph (d) of this section.

(*4*) Updating the list of excluded PBPM payments to account for new models.

CMS posts potential new exclusions of PBPM payments to the CMS Web site to allow for public comment and finalize and post to the CMS Web site the updated exclusions list after consideration of public input.

(D) Previous years' reconciliation or repayment amounts are not included in the episode for purposes of calculating episode target prices (§ 510.300) or total episode payments during a performance period.

(e) *Updating the lists of excluded services.* (1) The list of excluded MS–DRGs and ICD–CM diagnosis codes are posted on the CMS Web site.

(2) On an annual basis, or more frequently as needed, CMS updates the list of excluded services to reflect annual coding changes or other issues brought to CMS's attention.

(3) CMS applies the following standards when revising the list of excluded services for reasons other than to reflect annual coding changes:

(i) Items or services that are directly related to the LEJR procedure or the quality or safety of LEJR care would be included in the episode.

(ii) Items or services for chronic conditions that may be affected by the LEJR procedure or post-surgical care would be related and included in the episode.

(iii) Items and services for chronic conditions that are generally not affected by the LEJR procedure or post-surgical care would be excluded from the episode.

(iv) Items and services for acute clinical conditions not arising from existing, episode-related chronic clinical conditions or complications of LEJR surgery would be excluded from the episode.

(4) CMS posts the following to the CMS Web site:

(i) Potential revisions to the exclusion to allow for public comment; and

(ii) An updated exclusions list after consideration of public comment.

§ 510.205 Beneficiary inclusion criteria.

(a) Episodes tested in the CCJR model include only those in which care is furnished to beneficiaries who meet all of the following criteria upon admission to the anchor hospitalization:

(1) The beneficiary is enrolled in Medicare Parts A and Part B.

(2) The beneficiary's eligibility for Medicare is not on the basis of end stage renal disease, as described in § 406.13 of this chapter.

(3) The beneficiary is not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations).

(4) The beneficiary is not covered under a United Mine Workers of America health care plan.

(5) Medicare is the primary payer.

(b) If at any time during the episode the beneficiary no longer meets all of the criteria in this section, the episode is canceled in accordance with § 510.210(b).

§ 510.210 Determination of the episode.

(a) *General.* The episode begins with the admission of a Medicare beneficiary described in § 510.205 to a participant hospital for an anchor hospitalization and ends 90 calendar days after discharge from the anchor hospitalization.

(b) *Cancellation of an episode.* The episode is cancelled and is not included in the determination of NPRA as specified in § 510.305 if the beneficiary does any of the following:

(1) Ceases to meet any criterion listed in § 510.205 at any time during the episode.

(2) Is readmitted to any participant hospital during the episode for another anchor hospitalization;

(3) Initiates an LEJR episode under BPCI

(4) Dies during the anchor hospitalization.

Subpart D—Pricing and Payment

§ 510.300 Determination of episode target prices.

(a) *General.* CMS establishes episode target prices for participant hospitals for each performance year the model as specified in this section. Episode target prices are established according to the following:

(1) MS–DRG assigned at discharge for anchor hospitalization—

(i) MS–DRG 469; or

(ii) MS–DRG 470.

(2) Applicable time period for performance period episode target prices. Episode target prices are be updated to account for midyear payment updates no less than twice per year, for updated episode target prices effective October 1 and January 1, and at other intervals if necessary.

(3) Episodes that straddle performance years or midyear payment updates. Episode target prices apply for the time period in which the date of the anchor hospitalization admission occurs.

(4) Adjustments for quality reporting, as discussed in § 510.305(g).

(b) *Episode target price.* (1) CMS calculates episode target prices based on a blend of each participant hospital's most recent 3 years of expenditures for an episode and the most recent 3 years of expenditures for an episode in the region in which the participant hospital is physically located. Specifically, the blend consists of the following:

(i) Two-thirds of the participant hospital's own historical episode payments and one-third of the regional historical episode payments for performance years 1 and 2.

(ii) One-third of the hospital's own historical episode payments and two-thirds of the regional historical episode payments for performance year 3.

(iii) Regional historical episode payments for performance years 4 and 5.

(2) *Exception for low-volume hospitals.* Episode target prices for participant hospitals with fewer than 20 CCJR episodes in total across the 3 historical years of data used to calculate the episode target price are based on 100 percent regional historical episode payments.

(3) *Exception for recently merged or split or altogether new hospitals.* (i) Hospital-specific historical payments for recently merged or split hospitals would incorporate the historical episodes attributed to their previous entities.

(ii) New hospitals (with new CMS provider agreements) would receive target prices using the same blended approach and low-volume policy for existing hospitals as described in in this section.

(4) *Exception for high episode spending in baseline period.* Historical episode payments are capped at 2 standard deviations above the mean episode payment for purposes of calculating the episode target prices.

(5) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain incentive programs and add-on payments are excluded, as applicable, from target price and total episode payment calculations by using the CMS

Price Standardization methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program.

(6) *Communication of episode target prices.* CMS communicates episode target prices to participant hospitals before the performance period in which they apply for performance years 2 through 5, and before or shortly after the start of performance year 1.

(c) *Discount factor.* A participant hospital's episode target prices incorporate applicable discount factors to reflect Medicare's portion of reduced expenditures from the CCJR model as described in this section.

(1) Except as provided in paragraph (c)(2) of this section, the applicable discount factor is for a participant hospital that—

(i) Does not successfully submit voluntary patient-reported outcome data for that performance year as provided in § 510.400(b) is 2.0 percent.

(ii) Successfully submits voluntary patient-reported outcome data for that performance year as provided in § 510.400(b) is 1.7 percent.

(2) For performance year 2 only, if the participant hospital's NPRA (defined in section § 510.305(e)) would be negative using the applicable discount factor under paragraph (c)(1) of this section, then for purposes of determining the participant hospital's NPRA, the discount factor is applied in lieu of the applicable discount factor under paragraph (c)(1) of this section for a participant hospital that—

(i) Successfully submits the voluntary patient-reported outcomes data for performance year 2 as provided in § 510.400(b) is 0.7 percent.

(ii) Does not successfully submit the voluntary patient-reported outcomes data for performance year 2 as provided in § 510.400(b), is 1 percent.

(d) *Data sharing.* (1) CMS makes available to participant hospitals, through the most appropriate means, data that CMS determines may be useful to participant hospitals to do the following:

(i) Determine appropriate ways to increase the coordination of care.

(ii) Improve quality.

(iii) Enhance efficiencies in the delivery of care.

(iv) Otherwise achieve the goals of the CCJR model described in this section.

(2) *Beneficiary-identifiable data.* (i) CMS makes beneficiary-identifiable data available to a participant hospital in accordance with applicable privacy laws and only in response to the hospital's request for such data for a beneficiary who has been furnished a billable service by the participant hospital corresponding to the episode definitions for CCJR and has not chosen to opt out of claims data sharing.

(ii) The minimum data necessary to achieve the goals of the CCJR model, as determined by CMS, may be provided under this section for a participant hospital's baseline period and as frequently as on a quarterly basis throughout the hospital's participation in the CCJR model.

§ 510.305 Determination of the NPRA and reconciliation process.

(a) *General.* Providers and suppliers furnishing items and services included in the episode bill for such items and services in accordance with existing rules and as if this part were not in effect.

(b) *Reconciliation.* Medicare uses a series of reconciliation processes, which CMS performs as described in paragraphs (d) and (f) of this section after the end of each performance year, to establish final payment amounts to participant hospitals for CCJR episodes for a given performance year. Following the end of each performance year, CMS determines actual episode payments for each episode for the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) and determines the amount of a reconciliation or repayment amount.

(c) *Data used.* CMS uses the most recent claims data available to perform each reconciliation calculation.

(d) *Annual reconciliation.* (1) Two months after the end of each performance year, CMS performs a reconciliation calculation to establish an NPRA for each participant hospital.

(2) CMS—

(i) Calculates the NPRA for each participant hospital in accordance with § 510.305(e) including the adjustments provided for in § 510.305(e)(5); and

(ii) Assesses whether hospitals meet specified quality requirements under § 510.315.

(e) *Calculation of the NPRA.* By comparing the episode target prices described in § 510.300 and the participant hospital's actual episode spending for the performance year and applying the adjustments in paragraph (e)(1)(v) of this section, CMS establishes an NPRA for each participant hospital for each performance year.

(1) *Initial calculation.* In calculating the NPRA for each participant hospital for each performance year, CMS does the following:

(i) Determines actual episode payments for each episode included in the performance year (other than episodes that have been cancelled in accordance with § 510.210(b)) using claims data that is available 2 months after the end of the performance year, in accordance with the adjustments in § 510.300(b)(5).

(ii) Multiplies the participant hospital's applicable episode target price, including necessary adjustments for voluntary reporting of outcome data (§ 510.400(b)) for each type of episode being tested and time period (as determined in accordance with § 510.300) by the number of episodes being tested in the performance year to which that episode target price applies.

(iii) Aggregates the amounts computed in paragraph (e)(1) of this section across all episodes being tested for that participant hospital in that performance year.

(iv) Subtracts the aggregate actual episode payments for all of the participant hospital's episodes being tested in that performance year from the calculated amount from paragraph (e)(2) of this section.

(v) Makes the following adjustments:

(A) *Increases in post-episode spending.* If the average post-episode spending for a participant hospital in any given performance year is greater than 3 standard deviations above the regional average post-episode spending for the same performance year, then this amount would be applied to the NPRA.

(B) *Limit on financial responsibility for high episode payment cases.* Actual episode payments for an episode are capped at 2 standard deviations above the mean episode payment for purposes of calculating the episode target prices (§ 510.300) and for purposes of comparing the actual episode payments with the applicable episode target price to calculate the NPRA.

(C) *Limitation on loss.* The total amount any participant hospital is responsible for repaying to Medicare for a performance year cannot exceed the following:

(*1*) For performance year 2 only, 10 percent of the amount calculated in paragraph (e)(1)(ii) of this section for the performance year.

(*2*) For performance years 3, 4, and 5, 20 percent of the amount calculated in paragraph (e)(1)(ii) of this section for the performance year.

(D) *Limitation on gain.* The total amount of any reconciliation payment Medicare would make to a participant hospital for a performance year cannot exceed 20 percent of the amount calculated in paragraph (e)(1)(ii) of this section for the performance year.

(E) *Financial loss limits for SCHs, MDHs, and RRCs.* If a participant hospital is an SCH, an MDH or RRC, then for—

(*1*) Performance year 2, the total repayment amount for which the participant hospital is responsible cannot exceed 3 percent of amount calculated in paragraph (e)(1)(ii) of this section; and

(*2*) Performance years 3 through 5, the total repayment amount cannot exceed 5 percent of the amount calculated in paragraph (e)(1)(ii) of this section.

(f) *Determination of reconciliation or repayment amount*—(1) *Determination of the reconciliation or repayment amount.* (i) For performance year 1, the reconciliation or repayment amount is equal to the NPRA.

(ii) For performance years 2 through 5, results from the subsequent reconciliation calculation for a prior year's reconciliation, as described in paragraph (i)(3) of this section, are applied to the current year's NPRA in order to determine the reconciliation or repayment amount.

(2) *Reconciliation payment.* If the amount from paragraph (f)(1) of this section is positive and the participant hospital meets or exceeds all of the quality thresholds described in § 510.400, Medicare pays the participant hospital a reconciliation payment an amount equal to the calculation described in paragraph (f)(1) of this section.

(3) *Repayment amount.* If the amount from paragraph (f)(1) of this section is negative, the participant hospital pays to Medicare an amount equal to the calculation described in paragraph (f)(1) of this section. CMS waives this requirement for performance year 1.

(g) *Determination of eligibility for reconciliation based on quality.* (1) CMS assesses each participant hospital's performance on quality metrics, as described in § 510.400, to determine whether the participant hospital is eligible to receive a reconciliation payment for a performance year.

(2) If the hospital meets the quality thresholds as specified in § 510.400, and is determined to have positive NPRA under paragraph (e) of this section, the hospital is eligible for a reconciliation payment.

(3) If the hospital does not meet the thresholds as specified in § 510.400 for a performance year, the hospital is not eligible for a reconciliation payment.

(h) *Reconciliation report.* CMS issues each participant hospital a CCJR reconciliation report for the performance year. Each CCJR reconciliation report contains the following:

(1) Information on whether the participant hospital met or exceeded the quality thresholds specified in § 510.400.

(2) The total actual episode payments for the participant hospital.

(3) The NPRA.

(4) Whether the participant hospital is eligible for a reconciliation payment or must make a repayment to Medicare.

(5) The NPRA and subsequent reconciliation calculation amount for the previous performance year, as applicable.

(6) The reconciliation payment or repayment amount.

(i) *Subsequent reconciliation calculation.* (1) Fourteen months after the end of each performance year, CMS performs an additional calculation, using claims data available at that time, to account for final claims run-out and any additional overlap between the CCJR model and other CMS models and programs as described in paragraph (i)(2) of this section.

(2) The subsequent reconciliation calculation accounts for CCJR episodes that overlap with the following shared savings programs and models in cases where the participant hospital is a participant in the ACO and the beneficiary in the episode is assigned to the ACO:

(*i*) The Pioneer ACO model.

(*ii*) The Medicare Shared Savings Program.

(*iii*) The Next Generation ACO model.

(*iv*) The Comprehensive ESRD Care Initiative (CEC).

(3) The additional calculation occurs concurrently with the reconciliation process for the most recent performance year. If the result of the subsequent calculation is different than zero, CMS applies the stop-loss and stop-gain limits in paragraph (e) of this section to the calculations in aggregate for that performance year (the initial reconciliation and the subsequent calculation) to ensure the amount does not exceed the stop-loss or stop-gain limits. CMS then applies this amount to the NPRA for the most recent performance year in order to determine the reconciliation amount or repayment amount for the most recent performance year. For the performance year 2 reconciliation report only, the subsequent calculation amount (for performance year 1) is applied to the performance year 1 NPRA to ensure that the combined amount is not less than 0. If the combined amount is less than zero, the subsequent calculation amount would be capped at the amount that would result in a net amount of zero for the combination of the performance year 1 NPRA and subsequent calculation amount.

§ 510.310 Appeals process.

(a) *General.* If a participant hospital believes that there is an error in a calculation that involves a matter in any way related to payment, reconciliation amounts, repayment amounts, or determinations associated with quality measures impacting payment, the hospital is required to provide written notice of the error, in a form and manner specified by CMS.

(1) Unless the participant hospital provides such notice, the CCJR reconciliation report is deemed final 30 calendar days after it is issued.

(2) If CMS receives a timely notice of a calculation error as provided in paragraph (d) of this section, CMS responds in writing within 30 calendar days to either confirm or refute the calculation error, although CMS reserves the right to an extension upon written notice to the participant hospital.

(3) If a participant hospital does not submit timely notice of a calculation error in accordance with the timelines and processes specified by CMS, then CMS deems final the CCJR reconciliation report and proceeds with the payment or repayment processes, as applicable, as determined by the NPRA reflected in the CCJR reconciliation report.

(b) Participant hospitals may appeal the NPRA or any calculations impacting NPRA, reconciliation amounts or repayment amounts on the grounds that CMS or its representative made an error in calculating such amounts using the dispute resolution process defined in paragraph (e) of this section.

(c) Only participant hospitals may utilize the dispute resolution process.

(d) To begin the dispute resolution process, a participant hospital must submit a notice of calculation error in a timely manner, as specified by CMS.

(e) *Dispute resolution process.* (1) If the participant hospital is dissatisfied with CMS's response to the notice of a calculation error, the participant hospital may request a reconsideration review in a form and manner as specified by CMS.

(i) The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA in accordance with § 510.305.

(ii) If CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the issue date of CMS's response to the participant hospital's notice of calculation error, then CMS's response

to the calculation error is deemed final and CMS proceeds with reconciliation payment or repayment processes, as applicable, as described in § 510.305.

(iii) Where the participant hospital contests a matter that does not involve an issue contained in, or a calculation which contributes to, a CCJR reconciliation report, a calculation error form is not required. An example of such a matter is termination of the participant hospital from the model. In those instances, if CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with action indicated in the initial determination.

(2)(i) A CMS reconsideration official notifies the participant hospital in writing within 15 calendar days of receiving the participant hospital's review request of the following:

(A) The date, time, and location of the review.

(B) The issues in dispute.

(C) The review procedures.

(D) The procedures (including format and deadlines) for submission of evidence.

(ii) The CMS reconsideration official takes all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of the notification.

(iii) The provisions at § 425.804(b), (c), and (e) of this chapter are applicable to reviews conducted in accordance with the reconsideration review process for CCJR.

(iv) The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

(3) *Limitations on review.* In accordance with section 1115A(d)(2) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

(i) The selection of models for testing or expansion under section 1115A of the Act.

(ii) The selection of organizations, sites, or participants to test those models selected.

(iii) The elements, parameters, scope, and duration of such models for testing or dissemination.

(iv) Determinations regarding budget neutrality under section 1115A(b)(3) of Act.

(v) The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of Act.

(vi) Decisions about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (e)(1) or (2) of this section.

§ 510.315 Quality thresholds for reconciliation payment eligibility.

(a) *General.* Participant hospitals are eligible for a reconciliation payment for a performance year only if they meet or exceed the minimum quality thresholds specified in paragraph (b) of this section for the performance year.

(b) *Quality measure thresholds.* A participant hospital's measure result must be at or above the thresholds in paragraphs (b)(1) and (2) of this section for all three quality measures for each performance year of this model to be eligible for additional payments under the CCJR model.

(1) The 30th percentile of the national hospital measure results calculated for all HIQR-participant hospitals for performance years 1, 2, and 3.

(2) The 40th percentile for performance years 4 and 5.

(c) *Low-volume hospital exception.* A participant hospital with an insufficient volume of episodes on which to determine performance on an individual measure, as determined by CMS, is considered to have met the performance threshold for that quality measure.

§ 510.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.

The CCJR model does not replace any existing Medicare incentive programs or add-on payments. The target price and NPRA for a participant hospital is independent of, and does not affect, any incentive programs or add-on payments under existing Medicare payment systems (as described in § 510.300(b)(5)).

§ 510.325 Allocation of payments for services that straddle the episode.

(a) *General.* Services included in the episode as provided in § 510.200(b) that straddle the episode are prorated so that only the portion attributable to care furnished during the episode are attributed to the calculation of actual episode payments.

(b) *Proration of services.* Payments for services that straddle the episode are prorated using the following methodology:

(1) *Non-IPPS inpatient services and other inpatient services.* Non-IPPS inpatient services, and services furnished by other inpatient providers that extend beyond the end of the episode are prorated according to the percentage of the actual length of stay (in days) that falls within the episode window.

(2) *Home health agency services.* Home health services paid under the prospective payment system in part 484, subpart E of this chapter are prorated according to the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that occur during the fixed duration of the episode. This methodology is applied in the same way if the home health services begin (the start of care date) prior to the start of the episode.

(3) *IPPS services.* IPPS claim amounts that extend beyond the end of the episode are prorated according to the geometric mean length of stay, using the following methodology:

(i) The first day of the IPPS stay is counted as 2 days.

(ii) If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode.

(iv) If the full amount is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (defined in § 510.2).

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

§ 510.400 Quality measures and reporting.

(a) *Reporting of quality measures.* The following quality measures are used for public reporting and for determining whether a participant hospital is eligible for additional payments under the CCJR model, as described in § 510.305:

(1) Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty.

(2) Hospital-level 30-day, all-cause risk-standardized readmission rate following elective primary total hip arthroplasty and/or total knee arthroplasty.

(3) Hospital Consumer Assessment of Healthcare Providers and Systems Survey.

(b) *Requirements for successful data submission of patient reported outcomes.* To be eligible for the discount factors that apply to participant hospitals that successfully submit the voluntary patient reported outcomes data described in § 510.300(c), participant hospitals must submit data

on the hospital-level performance measure(s) of patient-reported outcomes following elective primary total hip and/or total knee arthroplasty, including but not limited to the pre-operative and post-operative data elements, for at least 80 percent of the eligible elective primary total hip and/or total knee arthroplasty beneficiaries within 60 days of the end of the most recent performance period.

(c) *Public reporting.* CMS—

(1) Makes the quality measurement results calculated for the readmission, complication, and patient survey quality measures for each participant hospital in each performance year publicly available on the CMS Web site in a form and manner as determined by CMS.

(2) Shares each participant hospital's quality metrics with the hospital prior to display on the Web site.

(3) Does not publicly report the voluntary patient reported outcome data during this 5 year model.

§ 510.405 Beneficiary choice and beneficiary notification.

(a) *Beneficiary choice.* The CCJR model does not restrict Medicare beneficiaries' ability to choose any Medicare participating provider or supplier, or any provider or supplier who has opted out of Medicare.

(b) *Required beneficiary notification.* (1) Each participant hospital must provide written notice to any Medicare beneficiary that meets the criteria in § 510.205 of his or her inclusion in the CCJR model. The beneficiary notification must contain all of the following:

(i) A detailed explanation of the model and how it might be expected to affect the beneficiary's care.

(ii) Notification that the beneficiary retains freedom of choice to choose providers and services.

(iii) Explanation of how patients can access care records and claims data through an available patient portal, and how they can share access to their Blue Button® electronic health information with caregivers.

(iv) A statement that all existing Medicare beneficiary protections continue to be available to the beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations (QIO) and 1–800–MEDICARE.

(2) A participant hospital must require any physician with whom it has a CCJR sharing arrangement to provide written notice of the existence of such an arrangement to any Medicare beneficiary that meets the criteria for inclusion in the model specified in § 510.205.

(c) *Timing of the required beneficiary notification.* The participant hospital provides the written notice described in paragraph (b) of this section upon the beneficiary's admission for an anchor hospitalization.

§ 510.410 Compliance enforcement.

(a) *General.* Participant hospitals must comply with all of the requirements outlined in this part.

(b) *Failure to comply.* CMS may do one or more of the following if a participant hospital fails to comply with any of the requirements outlined in this part:

(1) Issue a warning letter to the participant hospital.

(2) Require the participant hospital to develop a corrective action plan.

(3) Reduce or eliminate a participant hospital's positive NPRA.

(4) Terminate the participant hospital's participation in the CCJR model, if the participant hospital, or an individual or entity with which the participant hospital has a participation agreement, does any of the following:

(i) Takes any action that threatens the health or safety of patients.

(ii) Avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20 of this chapter.

(iii) Avoids patients on the basis of payer status.

(iv) Is subject to sanctions or final actions of an accrediting organization or federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this part.

(v) Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the CCJR model.

(vi) Is subject to action by the Secretary to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority or similar actions.

Subpart F—Financial Arrangements and Beneficiary Incentives

§ 510.500 Financial arrangements under the CCJR model.

(a) *General.* To assist participant hospitals in aligning the financial incentives of other providers and suppliers caring for beneficiaries in CCJR episodes with the quality and efficiency goals of the CCJR model, participant hospitals may, consistent with applicable law, elect to enter into financial arrangements that contain CCJR sharing arrangements with CCJR collaborators, as defined in this section.

(1) All such financial arrangements must comply with all relevant laws and regulations, including the fraud and abuse laws and all applicable payment and coverage requirements.

(2) CMS reserves the right to review any CCJR sharing arrangement to ensure that it does not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(b) *Required records.* When a participant hospital enters into a CCJR sharing arrangement with a CCJR collaborator, the participant hospital, and all of its CCJR collaborators must maintain copies of the following records:

(1) All original copies of CCJR sharing arrangements that the participant hospital signs with a CCJR collaborator in connection with the hospital's participation in CCJR. Each CCJR sharing arrangement must include, but is not limited to the following:

(i) A specific methodology and accounting formula for calculating and verifying the internal cost savings generated by the participant hospital entering into a CCJR sharing arrangement with a CCJR collaborator based on the care redesign elements specifically associated with the particular CCJR collaborator.

(ii) Specific methodologies for accruing and calculating internal cost savings from the participant hospital, where the hospital intends to share internal cost savings through a CCJR sharing arrangement with a CCJR collaborator. The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles and Government Auditing Standards (The Yellow Book). The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CCJR collaborator or both.

(iii) A description of the methodology and accounting formula for calculating the percentage or dollar amount of a reconciliation payment that will be paid from the participant hospital to the CCJR collaborator.

(iv) A description of the methodology, frequency of distribution, and accounting formula for distributing and verifying any and all gainsharing payments.

(v) A description of the arrangement between the participant hospital and the CCJR collaborator regarding gainsharing payments and alignment payments, including safeguards to ensure that such alignment payments are made solely for purposes related to sharing responsibility for funds need to repay

Medicare in the CCJR model. This description must include the following:

(A) A methodology.

(B) Frequency of payment.

(C) Accounting formula for payment.

(D) Receipt of any and all alignment payments.

(E) Plans regarding care redesign.

(F) Changes in care coordination or delivery that is applied to the participant hospital or CCJR collaborators or both.

(G) Any description of how success will be measured.

(vi) Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out changes to care under the model.

(2) The participant hospital must keep records of the following:

(i) All CCJR collaborators.

(ii) Its process for determining and verifying the eligibility of CCJR collaborators to participate in Medicare.

(iii) Information confirming the organizational readiness of the participant hospital to measure and track internal cost savings.

(iv) Plan to track internal cost savings.

(v) Information on the accounting systems used to track internal cost savings.

(vi) A description of current health information technology, including systems to track reconciliation payments and internal cost savings.

(c) *Participant agreement.* The participant agreement must obligate the parties to comply, and must obligate the CCJR collaborator to require any of its employees, contractors or designees to comply, without limitation, to the following:

(1) An individual or entity's participation in the CCJR sharing arrangement is voluntary, and there is no penalty for nonparticipation.

(2) Any gainsharing payments made under the CCJR sharing arrangement may be made only from the participant hospital to the entity or individual with whom the participant hospital has a signed CCJR sharing arrangement.

(3) Any alignment payments made in accordance with a CCJR sharing arrangement may be made only to the participant hospital from the entity or individual with whom the participant hospital has signed a participation agreement containing a CCJR sharing arrangement. A CCJR collaborator entering into a CCJR sharing arrangement must be in compliance with all Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI.

(4) Any internal cost savings or reconciliation payments that the participant hospital seeks to share through CCJR sharing arrangements must meet the requirements set forth in this part and must be administered by the participant hospital in accordance with generally accepted accounting principles.

(i) The participant hospital may not distribute any amounts that are not comprised of dollars that are either internal cost savings or a reconciliation payment, as those terms are defined in this part.

(ii) All amounts deemed internal cost savings by the participant hospital must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital in the manner described in this section.

(iii) Internal cost savings may not reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

(5) Any alignment payments that the participant hospital receives through a CCJR sharing arrangement must meet the requirements set forth in this section and be administered by the participant hospital in accordance with generally accepted accounting principles. In no event may the participant hospital receive any amounts from a CCJR collaborator under a CCJR sharing arrangement that are not alignment payments.

(6) Provisions that require CCJR collaborators to share all records related to a CCJR Sharing Arrangement, including at a minimum the following:

(i) Each participation agreement between the participant hospital and a CCJR collaborator must obligate the CCJR collaborator to provide the participant hospital and CMS with access to the CCJR collaborator's records, information, and data for purposes of monitoring and reporting and any other lawful purpose.

(ii) Records, information, and data demonstrating compliance with the gainsharing payment must—

(A) Have sufficient detail to verify compliance with all material terms of the CCJR sharing arrangement; and

(B) Be fully substantiated and documented, as to both statements and numbers.

(7) Participation agreements must require all CCJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees for the purposes of operating the CCJR model.

(d) *Gainsharing payment and alignment payment conditions and restrictions.* Participant hospitals must adhere to the following conditions and restrictions concerning gainsharing payments and alignment payments made under a CCJR sharing arrangement:

(1) No entity or individual, as a party to a participation agreement or not, may condition the opportunity to receive gainsharing payments in CCJR on the volume or value of past or anticipated referrals or other business generated to, from, or among the participant hospital and any CCJR collaborators.

(2) Participant hospitals are not required to share reconciliation payments, internal cost savings, or responsibility for repayment to CMS with other providers and suppliers.

(i) If a participant hospital elects to engage in those activities, such activities are limited to the terms of this section.

(ii) Gainsharing payments, if distributed, must be distributed on an annual basis.

(iii) Alignment payments from a CCJR collaborator to a participant hospital may be made at any interval that is agreed upon by both parties, and must—

(A) Be clearly identified;

(B) Comply with all provisions in this section;

(C) Comply with all applicable laws, statutes, and rules.

(3) No entity or individual, as a party to a participation agreement or not, may condition the opportunity to send or receive alignment payments in CCJR on the volume or value of past or anticipated referrals or other business generated to, from, or among the participant hospital and any CCJR collaborators.

(4) In a calendar year, the aggregate amount of the total gainsharing payments distributed by a participant hospital that are derived from a CCJR reconciliation payment may not exceed the amount of the reconciliation payment the participant hospital receives from CMS.

(5) In a calendar year, the aggregate amount of the total alignment payments received by the participant hospital may not exceed 50 percent of the participant hospital's repayment amount due to CMS. If no repayment amount is due, then no alignment payments may be received by the participant hospital.

(6) The participant hospital must retain at least 50 percent of its responsibility for repayment, pursuant to the repayment amount reflected in a reconciliation report, under the CCJR model to CMS.

(7) A single CCJR collaborator may not make an alignment payment to a participant hospital that represents an amount greater than 25 percent of the

repayment amount reflected on a reconciliation report.

(8) Gainsharing payments and alignment payments must not induce any of the following parties to reduce or limit medically necessary services to any Medicare beneficiary:

(i) The participant hospital.

(ii) CCJR collaborators.

(iii) Employees, contractors, or designees of the participant hospital or CCJR collaborators.

(9) Individual physician and nonphysician practitioners must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(10) Methodologies for calculating gainsharing payments and alignment payments must not directly account for volume or value of referrals, or business otherwise generated, between or among the participant hospital and CCJR collaborators.

(11) Gainsharing payments must be derived solely from reconciliation payments or internal cost savings or both.

(12) The total amount of gainsharing payments for a calendar year paid to an individual physician or nonphysician practitioner who is a CCJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital's CCJR beneficiaries during a CCJR episode by that physician or nonphysician practitioner.

(e) *Documentation and maintenance of records.* All participant hospitals and CCJR collaborators who enter into CCJR sharing arrangements must:

(1) Provide to CMS, the OIG, and the Comptroller General or their designee(s) scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality performance measures, billings, and CCJR sharing arrangements related to CCJR) sufficient to enable the audit, evaluation, inspection, or investigation of the participant hospital's compliance, as well as the compliance of any CCJR collaborator that has a CCJR sharing arrangement with the participant hospital, with CCJR requirements, the participation agreement, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, or the calculation or both, distribution, receipt, or recoupment of gainsharing payments or alignment payments.

(2) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CCJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital at least 30 calendar days before the normal disposition date; or

(ii) There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CCJR collaborator, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

(f) *Compliance responsibility.* Notwithstanding any CCJR sharing arrangements between the participant hospital and CCJR collaborators, the participant hospital must have ultimate responsibility for adhering to and otherwise fully complying with all provisions of the CCJR model.

(g) *OIG authority.* OIG authority is not limited or restricted by the provisions of the CCJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CCJR collaborators, or any other person or entity or their records, data, or information, without limitation.

(h) *Other authorities.* None of the provisions of the CCJR model limits or restricts any other government authority permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CCJR collaborators, or any other person or entity or their records, data, or information, without limitation.

§ 510.505 Beneficiary incentives under the CCJR model.

(a) *General.* Participant hospitals may choose to provide in-kind patient engagement incentives to beneficiaries in CCJR episodes for free or below fair market value, subject to the following conditions:

(1) The incentive must be provided to the beneficiary during a CCJR episode of care.

(2) The item or service provided must be reasonably connected to the beneficiary's medical care, as well as be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (b) of this section, for a beneficiary in a CCJR episode by engaging the beneficiary in better managing his or her own health.

(b) *Goals of the CCJR model.* The following are the particular clinical goals of the CCJR model, which may be advanced through beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to follow up care plan or care.

(3) Reduction of readmissions and complications resulting from lower-extremity joint replacement procedures.

(4) Management of chronic diseases and conditions that may be affected by the lower-extremity joint replacement procedure.

(c) *Beneficiary incentives.* Participant hospitals are required to maintain a list of items and services furnished as beneficiary incentives that exceed $10, including the following:

(1) The date the incentive is provided.

(2) The identity of the beneficiary to whom the item or service was provided.

(d) *Technology provided to a beneficiary.* (1) Items or services involving technology provided to a beneficiary may not exceed $1,000 in value for any one beneficiary in any one CCJR episode.

(2) Items of technology exceeding $50 must—

(i) Remain the property of the participant hospital; and

(ii) Be retrieved from the beneficiary at the end of the CCJR episode. The participant hospital must maintain documentation of the date of retrieval.

Subpart G—Waivers

§ 510.600 Waiver of direct supervision requirement for certain post-discharge home visits.

(a) *General.* CMS waives the requirement in § 410.26(b)(5) of this chapter that services and supplies furnished incident to a physician's service must be furnished under the direct supervision of the physician (or other practitioner) to permit home visits as specified in this section. The services furnished under this waiver are not be considered to be ''hospital services,'' even when furnished by the clinical staff of the hospital.

(b) *General supervision of qualified personnel.* The waiver of the direct supervision requirement in § 410.26(b)(5) of this chapter applies only in the following circumstances:

(1) The home visit is furnished during the episode to a beneficiary who has been discharged from an anchor hospitalization.

(2) The home visit is furnished at the beneficiary's home or place or residence.

(3) The beneficiary does not qualify for home health services under sections 1835(a) and 1814(a) of the Act at the time of any such home visit.

(4) The visit is furnished by a licensed clinician, either employed by a hospital

or not, under the general supervision of a physician employee or a contractor of the participant hospital.

(5) No more than 9 visits are furnished to the beneficiary during the episode.

(c) *Payment.* Up to 9 post-discharge home visits per CCJR episode may be billed under Part B by the physician or nonphysician practitioner or by the participant hospital to which the supervising physician has reassigned his or her billing rights.

(d) *Other requirements.* All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.

§ 510.605 Waiver of certain telehealth requirements.

(a) *Waiver of the geographic site requirements.* CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for all episodes being tested in the CCJR model, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the episode in accordance with § 510.200(b).

(b) *Waiver of the originating site requirements.* CMS waives originating site requirements under section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act for all episodes being tested in the CCJR model to permit a telehealth visit to originate in the beneficiary's home or place of residence, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the CCJR episode in accordance with § 510.200(b). The facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home.

(c) *Other requirements.* All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

§ 510.610 Waiver of SNF 3-day rule.

(a) *Waiver of the SNF 3-day rule.* For all episodes being tested in the CCJR model in performance years 2 through 5, CMS waives the SNF 3-day rule for coverage of a SNF stay for a beneficiary following the anchor hospitalization, but only if the SNF is rated an overall of 3 stars or better in the Five-Star Quality Rating System for SNFs on the Nursing Home Compare Web site (*www.medicare.gov/NursingHome Compare/*).

(b) *Other requirements.* All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

§ 510.615 Waiver of certain post-operative billing restrictions.

(a) *Waiver to permit certain services to be billed separately during the 90-day post-operative global surgical period.* CMS waives the billing requirements for global surgeries to allow the separate billing of certain post-discharge home visits, including those related to recovery from the surgery, as described in paragraph (b) of this section, for all episodes being tested in the CCJR model.

(b) *Services to which the waiver applies.* Up to 9 post-discharge home visits, including those related to recovery from the surgery, per CCJR episode may be billed separately under Part B by the physician or nonphysician practitioner, or by the participant hospital to which the physician or nonphysician practitioner has reassigned his or her billing rights.

(c) *Other requirements.* All other Medicare rules for global surgery billing during the 90-day post-operative period continue to apply.

Dated: July 1, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 6, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–17190 Filed 7–9–15; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 80 Tuesday,

No. 134 July 14, 2015

Part IV

Department of the Treasury

Internal Revenue Service

26 CFR Part 54

Department of Labor

Employee Benefits Security Administration

29 CFR Parts 2510 and 2590

Department of Health and Human Services

45 CFR Part 147

Coverage of Certain Preventive Services Under the Affordable Care Act; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9726]

RIN 1545–BJ58, 1545–BM37, 1545–BM39

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Parts 2510 and 2590

RIN 1210–AB67

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9940–F]

RIN 0938–AS50

Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document contains final regulations regarding coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. These regulations finalize provisions from three rulemaking actions: Interim final regulations issued in July 2010 related to coverage of preventive services, interim final regulations issued in August 2014 related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services, and proposed regulations issued in August 2014 related to the definition of ''eligible organization,'' which would expand the set of entities that may avail themselves of an accommodation with respect to the coverage of contraceptive services.

DATES: *Effective Date:* These final regulations are effective on September 14, 2015.

Applicability Date: These final regulations are applicable beginning on the first day of the first plan year (or, for individual health insurance coverage, the first day of the first policy year) that begins on or after September 14, 2015.

FOR FURTHER INFORMATION CONTACT: David Mlawsky, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786–1565; Amy Turner or Elizabeth Schumacher, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; or Karen Levin, Internal Revenue Service (IRS), Department of the Treasury, at (202) 927–9639.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's Web site (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. These statutes are collectively known as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage of certain specified preventive services without cost sharing. These preventive services include:

- Evidence-based items or services that have in effect a rating of ''A'' or ''B'' in the current recommendations of the United States Preventive Services Task Force (Task Force) with respect to the individual involved.
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee) with respect to the individual involved. A recommendation of the Advisory Committee is considered to be ''in effect'' after it has been adopted by the Director of the Centers for Disease Control and Prevention (CDC). A recommendation is considered to be for ''routine use'' if it appears on the Immunization Schedules of the CDC.
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).
- With respect to women, preventive care and screenings provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force), including all Food and Drug Administration (FDA)-approved contraceptives, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).[1]

The complete list of recommendations and guidelines that are required to be covered under these final regulations can be found at: *https://www.healthcare.gov/preventive-care-benefits.* Together, the items and services described in these recommendations and guidelines are referred to in this preamble as ''recommended preventive services.''

The Departments of Labor, Health and Human Services, and the Treasury (the Departments)[2] have issued rulemaking to implement these requirements:

[1] The HRSA Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

[2] Note, however, that in sections under headings listing only two of the three Departments, the term ''Departments'' generally refers only to the two Departments listed in the heading.

• Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations), implemented the preventive services requirements of PHS Act section 2713;

• Interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621, provided HRSA with the authority to exempt group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with those plans) from the requirement to cover contraceptive services consistent with the HRSA Guidelines; [3]

• Final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations), finalized the definition of religious employer in the 2011 amended interim final regulations without modification; [4]

• An advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501, solicited comments on how to provide for coverage of recommended preventive services, including contraceptive services, without cost sharing, while simultaneously ensuring that certain nonprofit organizations with religious objections to contraceptive coverage would not be required to contract, arrange, pay, or refer for that coverage;

• Proposed regulations on February 6, 2013, at 78 FR 8456, proposed to simplify and clarify the definition of ''religious employer'' for purposes of the religious employer exemption, and proposed accommodations for group health plans established or maintained by certain nonprofit religious organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with those plans) and for insured student plans arranged by certain nonprofit religious organizations that are institutions of higher education with religious objections to contraceptive coverage;

• Final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations), simplified and clarified the definition of religious employer for purposes of the religious employer exemption and established accommodations for health coverage established or maintained or arranged by eligible organizations; [5]

• Interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations), amended the July 2013 final regulations in light of the United States Supreme Court's interim order in connection with an application for an injunction in *Wheaton College* v. *Burwell* (Wheaton interim order),[6] and provided an alternative process that an eligible organization may use to provide notice of its religious objection to the coverage of contraceptive services; and

• Proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations), proposed potential changes to the definition of ''eligible organization'' in light of the United States Supreme Court's decision in *Burwell* v. *Hobby Lobby Stores, Inc.*[7]

In addition to these regulations, the Departments released six sets of Frequently Asked Questions (FAQs) regarding the preventive services coverage requirements. The Departments released FAQs about Affordable Care Act Implementation Parts II, V, XII, XIX, XX, and XXVI to answer outstanding questions, including questions related to the coverage of preventive services. These FAQs provided guidance related to compliance with the 2010 and 2014 interim final regulations, and addressed issues related to specific services required to be covered without cost sharing, subject to reasonable medical management, under recommendations and guidelines specified in section 2713 of the PHS Act. Information on related safe harbors, forms, and model notices is available at *http://www.dol.gov/ebsa/healthreform* and *http://www.cms.gov/cciio/resources/regulations-and-guidance/index.html.*

After consideration of the comments and feedback received from stakeholders, the Departments are publishing these final regulations,[8] which finalize the July 2010 interim final regulations related to coverage of recommended preventive services, the August 2014 interim final regulations related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services, and the August 2014 proposed regulations related to the definition of eligible organization.

II. Overview of the Final Regulations

A. Coverage of Recommended Preventive Services Under 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130

(i) Scope of Recommended Preventive Services

Section 2713 of the PHS Act, as added by the Affordable Care Act, requires that a non-grandfathered group health plan or a health insurance issuer offering non-grandfathered group or individual health insurance coverage provide, without cost sharing, coverage for recommended preventive services, as outlined above. The July 2013 final regulations finalized the requirement to provide coverage without cost sharing with respect to those preventive services provided for in the HRSA Guidelines for women. These regulations finalize the requirement to provide coverage without cost sharing with respect to the other three categories of recommendations and guidelines specified in section 2713 of the PHS Act: Evidence-based items or services that have in effect a rating of ''A'' or ''B''

[3] On the same date, HRSA exercised this authority in the HRSA Guidelines to exempt group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) from the HRSA Guidelines with respect to contraceptive services.

[4] Contemporaneous with the issuance of the 2012 final regulations, HHS, with the agreement of the Departments of Labor and the Treasury, issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments for group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans) originally issued on February 10, 2012, and reissued on August 15, 2012, and June 28, 2013; available at: *http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf.* The guidance clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. *See* Student Health Insurance Coverage, 77 FR 16457 (Mar. 21, 2012).

[5] A contemporaneously re-issued HHS guidance document extended the temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This guidance included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary enforcement safe harbor. In addition, HHS and the Department of Labor (DOL) issued a self-certification form, EBSA Form 700, to be executed by an organization seeking to be treated as an eligible organization for purposes of an accommodation under the July 2013 final regulations. This self-certification form was provided for use with the accommodation under the July 2013 final regulations, after the expiration of the temporary enforcement safe harbor (that is, for plan years beginning on or after January 1, 2014). *See http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf.*

[6] 134 S. Ct. 2806 (2014).

[7] 134 S. Ct. 2751 (2014).

[8] The Department of the Treasury/Internal Revenue Service published temporary regulations and proposed regulations with the text of the temporary regulations serving as the text of the proposed regulations as part of each of the joint rulemaking interim final rules listed above. The Departments of Labor and HHS published their rules as interim final rules and are finalizing their interim final rules. The Department of the Treasury/Internal Revenue Service is finalizing its proposed rules.

in the current recommendations of the Task Force, immunizations for routine use that have in effect a recommendation from the Advisory Committee, and evidence-informed preventive care and screenings for infants, children, and adolescents, provided for in guidelines supported by HRSA. The complete list of recommendations and guidelines can be found at: *https://www.healthcare.gov/preventive-care-benefits.*

Commenters requested additional clarity on the specific items and services required to be covered without cost sharing. The Departments previously released FAQs about Affordable Care Act Implementation Parts XII [9] and XIX [10] to provide guidance related to the scope of coverage required under the recommendations and guidelines, including coverage of aspirin and other over-the-counter medication, colonoscopies, BRCA testing, well-woman visits, screening and counseling for interpersonal and domestic violence, HIV and HPV testing, contraception, breastfeeding and lactation counseling, and tobacco cessation interventions. Moreover, on May 11, 2015, the Departments issued FAQs about Affordable Care Act Implementation [11] to address specific coverage questions related to BRCA testing, contraception, sex-specific recommended preventive services, services for dependents covered under the plan or policy, and colonoscopies. If additional questions arise regarding the application of the preventive services coverage requirements, the Departments may issue additional subregulatory guidance.

(ii) Office Visits

The July 2010 interim final regulations clarified the cost-sharing requirements applicable when a recommended preventive service is provided during an office visit through the use of the ''primary purpose'' test: First, if a recommended preventive service is billed separately (or is tracked as individual encounter data separately) from an office visit, a plan or issuer may impose cost sharing with respect to the office visit. Second, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of the recommended preventive service, a plan or issuer may not impose cost sharing with respect to the office visit. Finally, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of the recommended preventive service, a plan or issuer may impose cost sharing with respect to the office visit. The reference to tracking individual encounter data was included to provide guidance with respect to plans and issuers that use capitation or similar payment arrangements that do not bill individually for items and services.

Several commenters supported the primary purpose test, while other commenters were concerned that the test provides too much discretion to providers or issuers to determine the primary purpose of the visit. Some commenters stated that many individuals only seek medical care from their physician when they are sick, and physicians must be able to provide preventive services, along with other treatment, in a single office visit. Other commenters recommended that the Departments eliminate the primary purpose test. Some of these commenters recommended that cost sharing be prohibited if any recommended preventive service is provided during the visit.

These final regulations continue to provide that when a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit, plans and issuers must look to the primary purpose of the office visit when determining whether they may impose cost sharing with respect to the office visit. Nothing in these requirements precludes a health care provider from providing preventive services, along with other treatment, in a single office visit. These rules only establish the circumstances under which an office visit that includes a recommended preventive service may be subject to cost sharing. The Departments anticipate that the determination of the primary purpose of the visit will be resolved through normal billing and coding activities, as they are for other services. If questions arise regarding the application of this rule to common medical scenarios, the Departments may issue additional subregulatory guidance.

(iii) Out-of-Network Providers

With respect to a plan or health insurance coverage that maintains a network of providers, the July 2010 interim final regulations provided that the plan or issuer is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. The plan or issuer may also impose cost sharing for recommended preventive services delivered by an out-of-network provider.

Several commenters requested the rule be amended to require that preventive services be provided without cost sharing when services are provided out-of-network in all instances. Other commenters suggested that the rule be amended to require out-of-network coverage if an in-network provider is not available to the individual, or if the services are not available to a material segment of the plan's population. One commenter asked that, in a situation where preventive services are obtained from a network provider with the assistance of medical professionals who are out-of-network, all of the services be treated as in-network services, and thus not subject to cost sharing. Several commenters stated that cost sharing for recommended preventive services received from out-of-network providers should not be higher than cost sharing for other ambulatory health services provided on an out-of-network basis.

In response to comments, the Departments issued an FAQ clarifying that, if a plan or issuer does not have in its network a provider who can provide a particular recommended preventive service, then, consistent with the statute and July 2010 interim final regulations, the plan or issuer must cover, without cost sharing, the item or service when performed by an out-of-network provider.[12] These final regulations adopt the rule of the July 2010 interim final regulations with respect to out-of-network providers, with one clarification. These final regulations incorporate the clarification that a plan or issuer that does not have in its network a provider who can provide a particular recommended preventive service is required to cover the preventive service when performed by an out-of-network provider, and may

[9] *See* FAQs about Affordable Care Act Implementation Part XII, available at *http://www.dol.gov/ebsa/faqs/faq-aca12.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.*

[10] *See* FAQs about Affordable Care Act Implementation Part XIX, available at *http://www.dol.gov/ebsa/faqs/faq-aca19.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html.*

[11] See FAQs about Affordable Care Act Implementation Part XXVI, available at *www.dol.gov/ebsa/faqs/faq-FAQs/Downloads/aca_implementaton_faqs26.pdf.* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.*

[12] *See* FAQ about Affordable Care Act Implementation Part XII, Q3 at *http://www.dol.gov/ebsa/faqs/faq-aca12.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.*

not impose cost sharing with respect to the preventive service.

(iv) Reasonable Medical Management

The July 2010 interim final regulations included a provision on reasonable medical management. Specifically, if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer may use reasonable medical management techniques to determine any coverage limitations.

The Departments received a number of comments related to the use of reasonable medical management techniques. Some commenters were concerned that the July 2010 interim final regulations did not clearly outline what constitutes reasonable medical management techniques, and requested that the Departments provide greater clarity, particularly with respect to a situation where a patient's attending provider determines that the frequency, method, treatment, or setting of a particular item or service is medically appropriate for a particular patient. The Departments issued an FAQ clarifying that, under the July 2010 interim final regulations, to the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for the provision of a recommended preventive service.[13] These final regulations incorporate the clarification of the July 2010 interim final regulations set forth in the FAQ.

On May 11, 2015, the Departments issued FAQs to provide further guidance on the extent to which plans and issuers may utilize reasonable medical management when providing coverage for recommended women's contraception services in the HRSA guidelines.[14] If further questions arise regarding the permissible application of reasonable medical management techniques, the Departments may issue additional subregulatory guidance.

Other commenters cited the importance of flexibility to permit plans and issuers to maintain programs that are cost-effective, negotiate treatments with high-quality providers at reduced costs, and reduce fraud and abuse. Commenters requested guidance on how plans and issuers may employ value-based insurance designs (VBID) in a manner that complies with the preventive services coverage requirements.[15] Some commenters requested that the final regulations permit plans and issuers to impose cost sharing on non-preferred network tiers for VBIDs. Another commenter requested the Departments permit cost sharing for preventive care delivered at centers of excellence. On December 22, 2010, the Departments issued an FAQ to provide guidance regarding VBID related to the coverage of preventive services.[16] If questions arise regarding VBID and the preventive services coverage requirements, the Departments may issue additional subregulatory guidance. Several commenters stated that plans and issuers should be required to use and identify credible references or sources supporting their medical management techniques. The Departments recognize the importance of having access to information relating to medical management techniques that a plan or issuer may apply. Several provisions applicable to plans and issuers address these concerns. ERISA section 104 and the Department of Labor's implementing regulations [17] provide that, for plans subject to ERISA, the plan documents and other instruments under which the plan is established or operated must generally be furnished by the plan administrator to plan participants [18] upon request. In addition, the Department of Labor's claims procedure regulations [19] (applicable to ERISA plans), as well as the Departments' internal claims and appeals and external review regulations under the Affordable Care Act (applicable to all non-grandfathered group health plans and health insurance issuers in the group and individual markets),[20] set forth rules regarding claims and appeals, including the right of claimants (or their authorized representatives), upon appeal of an adverse benefit determination (or a final internal adverse benefit determination), to be provided by the plan or issuer, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. Other Federal and State law requirements may also apply, as applicable.

(v) Services Not Described

The July 2010 interim final regulations clarified that a plan or issuer may cover preventive services in addition to those required to be covered by PHS Act section 2713. These final regulations continue to provide that for the additional preventive services, a plan or issuer may impose cost sharing at its discretion, consistent with applicable law. Moreover, a plan or issuer may impose cost sharing for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

(vi) Timing

The July 2010 interim final regulations provided that plans and issuers must provide coverage for new recommended preventive services for plan years (in the individual market, policy years) beginning on or after the date that is one year after the date the relevant recommendation or guideline under PHS Act section 2713 is issued. Some commenters encouraged the Departments to adopt a shorter implementation timeframe. With respect to the Advisory Committee recommendations, one commenter requested that the effective date for any new recommendation be either the publication of the committee's provisional recommendations or the publication of the official CDC immunization schedules, whichever occurs first. Other commenters expressed support for the implementation timeframe set forth in the July 2010 interim final regulations. The statute requires the Departments to establish an interval of not less than one year between when recommendations or guidelines under PHS Act section

[13] *See* FAQs about Affordable Care Act Implementation Part II, Q8 available at *http://www.dol.gov/ebsa/faqs/faq-aca2.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.*

[14] *See* FAQs about Affordable Care Act Implementation Part XXVI, available at *www.dol.gov/ebsa/faqs/faq-aca26.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.*

[15] The Departments first solicited comments on value-based insurance designs in the July 2010 interim final regulations. 75 FR 41726, 41729. Subsequently, the Departments published a request for information (RFI) related to value-based insurance design on December 28, 2010. 75 FR 81544.

[16] *See* FAQs about Affordable Care Act Implementation Part V, Q1, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.*

[17] 29 CFR 2520.104b–1.

[18] ERISA section 3(7) defines a ''participant'' to include any employee or former employee who is or may become eligible to receive a benefit of any type from an employee benefit plan or whose beneficiaries may be eligible to receive any such benefit. Accordingly, employees who are not enrolled but are, for example, in a waiting period for coverage, or who are otherwise shopping among benefit package options during open season, generally are considered plan participants for this purpose.

[19] 29 CFR 2560.503–1(h)(2)(iii).

[20] 29 CFR 2590.715–2719(b)(2)(i) and 45 CFR 147.136(b)(2)(i).

2713(a)[21] are issued, and the plan year (in the individual market, policy year) for which coverage of the services addressed in the recommendations or guidelines must be in effect.

To provide plans and issuers adequate time to incorporate changes or updates to recommendations and guidelines, as provided in the July 2010 interim final regulations, these final regulations continue to provide that a recommendation or guideline of the Task Force is considered to be issued on the last day of the month on which the Task Force publishes or otherwise releases the recommendation; a recommendation or guideline of the Advisory Committee is considered to be issued on the date on which it is adopted by the Director of the CDC; and a recommendation or guideline in the comprehensive guidelines supported by HRSA is considered to be issued on the date on which it is accepted by the Administrator of HRSA or, if applicable, adopted by the Secretary of HHS.

Several commenters supported the policy that plans and issuers should not need to check the recommendations or guidelines for changes during the plan or policy year in order to determine coverage requirements and should not be required to implement changes during the plan or policy year. The Departments adopted this approach in the July 2010 interim final regulations with respect to new recommendations or guidelines that impose additional preventive services coverage requirements, but adopted a different standard for changes in recommendations or guidelines, allowing plans and issuers to eliminate coverage for preventive services that are no longer recommended during the plan or policy year, consistent with other applicable federal and state law. We agree with those commenters who stated that changes in coverage should not occur during the plan or policy year, and are implementing an approach with respect to changes in recommendations or guidelines that narrow or eliminate coverage requirements for previously recommended services that is similar to the one adopted in the July 2010 interim final regulations for new recommendations or guidelines. Furthermore, participants and beneficiaries of group health plans (and enrollees and dependents in individual market coverage) may make coverage choices based on the benefits offered at the beginning of the plan or policy year. Plan years (and individual market policy years) vary and recommendations and guidelines may be issued at any time during a plan or policy year. These final regulations protect against disruption and provide certainty in coverage (including cost-sharing requirements) for the duration of the plan or policy year. Accordingly, these final regulations state that a plan or issuer that is required to provide coverage for any recommended preventive service on the first day of a plan or policy year under a particular recommendation or guideline must generally provide that coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is eliminated during the plan or policy year.

However, there are limited circumstances under which it may be inadvisable for a plan or issuer to continue to cover preventive items or services associated with a recommendation or guideline that was in effect on the first day of a plan year or policy year (for example, due to safety concerns). Therefore, these final regulations establish that if, during a plan or policy year, (1) an ''A'' or ''B'' recommendation or guideline of the Task Force that was in effect on the first day of a plan or policy year is downgraded to a ''D'' rating (meaning that the Task Force has determined that there is strong evidence that there is no net benefit, or that the harms outweigh the benefits, and therefore discourages the use of this service), or (2) any item or service associated with any preventive service recommendation or guideline specified in 26 CFR 54.9815–2713(a)(1) or 29 CFR. 2590.715–2713(a)(1) or 45 CFR 147.130(a)(1) that was in effect on the first day of a plan or policy year is the subject of a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate that item or service, there is no requirement under this section to cover these items and services through the last day of the plan or policy year. Should such circumstances arise, the Departments expect to issue subregulatory guidance to this effect with respect to such preventive item or service.

Other requirements of federal or state law may apply in connection with ceasing to provide coverage or changing cost-sharing requirements for any item or service. For example, PHS Act section 2715(d)(4) and its implementing regulations state that if a group health plan or health insurance issuer makes any material modification in any of the terms of the plan or coverage involved that would affect the content of the Summary of Benefits and Coverage (SBC), that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification to enrollees not later than 60 days prior to the date on which the notification will become effective.

A list of the recommended preventive services is available at *https://www.healthcare.gov/preventive-care-benefits.* We intend to update this list to include the date on which the recommendation or guideline was accepted or adopted. New recommendations and guidelines will also be reflected on this site. Plans and issuers need not make changes to coverage and cost-sharing requirements based on a new recommendation or guideline until the first plan year (in the individual market, policy year) beginning on or after the date that is one year after the new recommendation or guideline goes into effect. Therefore, by visiting this site once per year, plans or issuers should have access to all the information necessary to identify any additional items or services that must be covered without cost sharing, or to identify any items or services that are no longer required to be covered.

B. Accommodations in Connection With Coverage of Preventive Health Services—26 CFR 54.9815–2713A, 29 CFR 2510.3–16 and 2590.715–2713A, and 45 CFR 147.131.

(i) The Process an Eligible Organization Uses To Provide Notice of Its Religious Objection to the Coverage of Contraceptive Services

After issuing the July 2013 final regulations, the Departments issued August 2014 interim final regulations in light of the Supreme Court's *Wheaton* interim order concerning notice to the federal government that an eligible

[21] Section 2713(b)(1) refers to an interval between ''the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.'' While the first part of this statement does not mention guidelines under subsection (a)(4), it is the Departments' view that it would not be reasonable to treat the services covered under subsection (a)(4) any differently than those in subsections (a)(1), (a)(2), and (a)(3). First, the statement refers to ''the requirement described in subsection (a),'' which would include a requirement under subsection (a)(4). Secondly, the guidelines under (a)(4) are from the same source as those under (a)(3), except with respect to women, rather than infants, children and adolescents; and other preventive services involving women are addressed in subsection (a)(1), so it is reasonable to treat the guidelines under subsection (a)(4) similarly. Third, without this clarification, it would be unclear when such services would have to be covered. The July 2010 interim final regulations and these final regulations accordingly apply the intervals established therein to services under section 2713(a)(4).

organization has a religious objection to providing contraceptive coverage, as an alternative to the EBSA Form 700 method of self-certification, and to preserve participants' and beneficiaries' (and, in the case of student health insurance coverage, enrollees' and dependents') access to coverage for the full range of FDA-approved contraceptives, as prescribed by a health care provider, without cost sharing.

These final regulations continue to allow eligible organizations to choose between using EBSA Form 700 or the alternative process consistent with the *Wheaton* interim order. The alternative process provides that an eligible organization may notify HHS in writing of its religious objection to covering all or a subset of contraceptive services. The notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to covering some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers.[22] A model notice to HHS that eligible organizations may, but are not required to, use is available at: *http://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Prevention.* If there is a change in any of the information required to be included, the organization must provide updated information to HHS.

The content required for the notice represents the minimum information necessary for the Departments to determine which entities are covered by the accommodation, to administer the accommodation, and to implement the policies in the July 2013 final regulations.[23] Comments on the August 2014 interim final regulations did not identify any way to administer the accommodation without this information, or any alternative means the Departments can use to obtain the required information. Nothing in this alternative notice process (or in the EBSA Form 700 notice process) provides for a government assessment of the sincerity of the religious belief underlying the eligible organization's objection. The notice to HHS, and any subsequent updates, should be sent electronically to: *marketreform@cms.hhs.gov,* or by regular mail to: Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 200 Independence Avenue SW., Washington, DC 20201, Room 739H.

When an eligible organization that establishes or maintains a self-insured plan subject to ERISA provides a notice to HHS, the Department of Labor (DOL) (working with HHS) will send a separate notification to each third party administrator of the ERISA plan. The DOL notification will inform each third party administrator of the eligible organization's religious objection to funding or administering some or all contraceptive coverage, will list the contraceptive services to which the employer objects, will describe the obligations of the third party administrator(s) under 29 CFR 2590.715–2713A and 26 CFR 54.9815–2713A, and will designate the relevant third party administrator(s) as plan administrator under section 3(16) of ERISA for those contraceptive benefits that the third party administrator would otherwise manage on behalf of the eligible organization. The DOL notification will be an instrument under which the plan is operated, and will supersede any earlier designation. In establishing and implementing this alternative process, DOL is exercising its broad rulemaking authority under title I of ERISA, which includes the ability to interpret and apply the definition of a plan administrator under ERISA section 3(16)(A).

If an eligible organization that establishes or maintains an insured group health plan or insured student health plan provides a notice to HHS under this alternative process, HHS will send a separate notification to each health insurance issuer of the plan. HHS's notification will inform each health insurance issuer of the eligible organization's religious objection to funding or administering some or all contraceptive coverage, will list the contraceptive services to which the organization objects, and will describe the obligations of the issuer(s) under 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A, and 45 CFR 147.131. Issuers remain responsible for compliance with the statutory and regulatory requirement to provide coverage for contraceptive services without cost sharing to participants and beneficiaries of insured group health plans, and to enrollees and dependents of insured student health plans, notwithstanding that the policyholder is an eligible organization with a religious objection to contraceptive coverage that will not have to contract, arrange, pay, or refer for the coverage.

Several comments addressed oversight and enforcement to monitor the accommodation. The Departments will use their established oversight processes, applicable to all the Affordable Care Act market reforms of PHS Act title XXVII, part A to monitor compliance with the requirement to arrange for or provide separate payments for contraceptive services without cost sharing.[24]

(ii) Definition of a Closely Held for-Profit Entity

(a) General Structure of a Closely Held for-Profit Entity

After issuing the July 2013 final regulations, the Departments issued August 2014 proposed regulations in light of the Supreme Court's ruling in *Hobby Lobby,* that, under the Religious Freedom Restoration Act of 1993 (RFRA),[25] the requirement to provide contraceptive coverage could not be applied to certain closely held for-profit entities that had a religious objection to providing coverage for some or all the FDA-approved contraceptive methods. The proposed regulations solicited comments on a number of different approaches for defining a closely held for-profit entity for purposes of qualifying as an eligible organization that can avail itself of an accommodation, and solicited comments on a number of other related issues.

[22] Church plans are exempt from ERISA pursuant to ERISA section 4(b)(2). As such, a third party administrator of a self-insured church plan established or maintained by an eligible organization does not become the plan administrator by operation of 29 CFR 2510.3–16, although such third party administrators may voluntarily provide or arrange separate payments for contraceptive services and seek reimbursement for associated expenses under the process set forth in 45 CFR 156.50.

[23] An accommodation cannot be effectuated until all of the necessary information is submitted. If HHS receives a notice that does not include all of the required information, HHS will attempt to notify the organization of the incompleteness, so the organization can submit additional information to make its notice complete.

[24] The Departments' oversight and enforcement role with respect to the market reforms under the Affordable Care Act builds upon their respective roles with respect to the market reforms under title I of HIPAA. For a description of the latter, *see* Notice of Signing of a Memorandum of Understanding among the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services at 64 FR 70165 (Dec. 15, 1999).

[25] 42 U.S.C. 2000bb *et. seq.*

The Departments received more than 75,000 comments in response to the August 2014 proposed regulations. Numerous comments addressed matters outside the scope of the proposed regulations (for example, many comments expressed support for or disagreement with the Supreme Court's *Hobby Lobby* decision, contraception in general, or different methods of contraception), and are not addressed in this preamble. To the extent comments addressed matters that were within the scope of the proposed regulations, those portions of the comments were considered, and all significant comments related to matters within the scope of the proposed regulations are discussed in this preamble. Many commenters expressed support for or disagreement with the general requirement to provide coverage for contraceptive services without cost sharing. Some commenters expressed support for the notion that any employer that has religious objections to covering contraceptive services should either be exempt from doing so, or should be able to avail itself of the accommodation. Other commenters stated that women should have access to contraceptive services without cost sharing, regardless of where they work, and that employers should not be permitted to deny them coverage, whether the employer's decision is for religious or other reasons. Many commenters suggested that the set of closely held for-profit entities eligible for the accommodation be defined as narrowly as possible.

The August 2014 proposed regulations would extend the availability of the accommodation to closely held for-profit entities. The preamble proposed two possible approaches to defining a closely held for-profit entity. Under the first proposed approach, a qualifying closely held for-profit entity would be a for-profit entity where none of the ownership interests in the entity are publicly traded, and where the entity has fewer than a specified number of shareholders or owners (the Departments did not propose a specific number, but solicited comment on what the number should be). As explained in the preamble to the August 2014 proposed regulations, there is precedent in other areas of federal law for limiting the definition of closely held entities to those with a relatively small number of owners.[26] Under the second proposed approach, a qualifying closely held entity would be a for-profit entity in which the ownership interests are not publicly traded, and in which a specified fraction of the ownership interest is concentrated in a limited and specified number of owners (the Departments did not propose a specific level of ownership concentration but solicited comment on what that level should be). As explained in the preamble to the August 2014 proposed regulations, this approach also has precedent in federal law, which limits certain tax treatment to entities that are more than 50 percent owned by or for not more than five individuals.[27] The Departments invited comments on the appropriate scope of the definition of a qualifying closely held for-profit entity.

As explained in more detail below, these final regulations extend the accommodation to a for-profit entity that is not publicly traded, is majority-owned by a relatively small number of individuals, and objects to providing contraceptive coverage based on its owners' religious beliefs. This definition includes for-profit entities that are controlled and operated by individual owners who are likely to have associational ties, are personally identified with the entity, and can be regarded as conducting personal business affairs through the entity. Those entities appear to be the types of closely held for-profit entities contemplated by *Hobby Lobby,* which involved two family-owned corporations that were operated in accordance with their owners' shared religious beliefs.[28] The Departments also believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. That assessment is supported by the comments received on the proposed regulation. As explained below, the Departments sought comment on a definition similar to the one adopted here, and we believe that no commenter identified an entity that would want to avail itself of the accommodation but that would be excluded by the definition. In addition, based on the available information, it appears that the definition adopted in these final regulations includes all of the for-profit entities that have as of the date of issuance of these regulations challenged the contraceptive coverage requirement in court.

The Departments believe that the definition adopted in these regulations complies with and goes beyond what is required by RFRA and *Hobby Lobby.* The Departments have extended the accommodations to the specified class of for-profit entities in order to provide additional protection to entities that may have religious objections to providing contraceptive coverage, and because the Departments believe that eligibility for the accommodations should be based on a rule that has origins in existing law.

Under the August 2014 proposed regulations and these final regulations, the first prong that an eligible organization (whether it be a nonprofit entity or a closely held for-profit entity) must meet in order to avail itself of the accommodation is that the entity must oppose providing coverage for some or all of any contraceptive item or service required to be covered, on account of religious objections. This requirement remains unchanged in these final regulations. (In the case of a for-profit entity, the entity must be opposed to providing these services on account of its owners' religious objections).

Many commenters supported excluding publicly traded entities from the definition of a closely held for-profit entity. However, a few commenters stated that a publicly traded entity should not be disqualified from the accommodation. Although the entities in *Hobby Lobby* were not publicly traded, one commenter noted that the Court did not expressly preclude publicly traded corporations from the protections of RFRA. Another commenter stated that if a publicly traded corporation could provide evidence of a sincere religious objection to providing contraceptive coverage, it should not be precluded from the accommodation.

These final regulations exclude publicly traded entities from the definition of an eligible organization. *Hobby Lobby* did not involve RFRA's application to publicly traded companies, and the Supreme Court emphasized that ''the idea that unrelated shareholders—including institutional investors with their own sets of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable.'' [29]

Many commenters favored limiting the number of owners to ''a handful,'' without specifying a maximum number. One commenter urged the Departments to establish a limit on the maximum number of shareholders for closely held entities of 999.

One commenter favored limiting the number of owners, but stated that any particular limit could lead to anomalous

[26] *See* discussion of definition of S corporations under section 1361 of the Tax Code, at 79 FR 51122.

[27] See discussion of several Tax code provisions, including 26 U.S.C. 856(h), 542(a)(2), and 469(j)(1), at 79 FR 51122.

[28] *See* 134 S. Ct. at 2764–2768.

[29] 134 S. Ct. at 2744.

results for entities with more than the permitted number of owners that seek the accommodation. The commenter noted, for example, that if the maximum number of shareholders or owners is ten, non-publicly traded companies with eleven shareholders would have to provide contraceptive coverage, no matter how sincerely held the religious objections of the owners. Another commenter who favored the approach stated that the definition should be limited to entities that have ten or fewer shareholders, and that shareholders should be counted based upon the definitions under subchapter S—that is, individuals should be counted along with certain trusts and estates. This would account for Qualified Subchapter S Trusts, but would not allow for other partnerships or corporations to be shareholders. This commenter also urged that members of the same family be counted as separate shareholders. Another commenter explained that a closely held company is commonly understood to be one that chooses S-corporation status or has fewer than 100 shareholders, and that many are privately held and owned by family members. Beyond these characteristics, the commenter urged, the size of the company should not matter. One commenter suggested following the close corporation definition from the applicable state or, in the absence of a corporate form, following the definition of a close corporation under Delaware law.

A few commenters supported a test that would be aligned with one of the federal tax law's definitions of a ''closely held corporation.'' For example, commenters supported a definition that provides that the corporation may not have ownership interests that are publicly traded, that more than 50 percent of the outstanding ownership interests in the corporation must be owned (directly or indirectly) by five or fewer individuals at any time during the last half of the tax year, and that the corporation may not be a personal service corporation. The commenters favored identifying closely held entities through an approach based on this definition because such an approach would be easy to apply and already familiar to corporations that apply similar concepts under the Code.

Other commenters were generally opposed to a limited ownership-concentration test. One commenter observed that under this approach, a corporation would be able to concentrate a fraction of ownership, for example 50 percent, in a specified number of owners, such as ten people. The commenter observed that those ten individuals, who might comprise fewer than half of the total number of owners, would be able to direct the corporation to seek the accommodation, potentially against the wishes of the minority shareholders.

Several commenters suggested that basing the definition either on the number of owners, or upon a concentration of ownership, would be inappropriate. One commenter stated that there is no basis in the *Hobby Lobby* decision to restrict the definition based on measures such as shareholder numbers, fractions of ownership, or tax rules. Another commenter stated that each of the proposed definitions of a ''closely held corporation'' is based on an arbitrary metric unrelated to the religious beliefs of the owners of the corporation. Another commenter stated that any rule that defines ''closely held'' in a narrow manner, such as by limiting the number, kind, or percentage control of a share of its owners, or by adopting definitions used in the Code, will violate RFRA and the *Hobby Lobby* decision. One commenter stated that a numerical test of shareholders will be both under- and over-inclusive, capturing corporations that meet the numerical test but whose shareholders are not expressing a religious belief through the corporation, and failing to capture corporations with a relatively large number of shareholders united in their religious interests. Another commenter believed that basing the definition of ''closely held entity'' solely on the number of owners would not limit eligibility to those types of entities addressed in the *Hobby Lobby* case.

One commenter believed that, for purposes of qualifying for the accommodation, an entity should only employ individuals who adhere to the owners' religious beliefs. The Departments do not believe this is a necessary characteristic for an entity to qualify as an eligible organization that can avail itself of the accommodation, and in *Hobby Lobby* the court granted relief to companies that did not possess this feature. Additionally, while the Departments have noted that exempting churches and their integrated auxiliaries (which the regulations refer to as ''religious employers'') from the requirement to provide contraceptive coverage does not impermissibly undermine the government's compelling interests in promoting public health and ensuring that women have equal access to health care because churches are more likely to hire co-religionists,[30] the exemption to the contraceptive coverage requirement was provided against the backdrop of the longstanding governmental recognition of a particular sphere of autonomy for houses of worship, such as the special treatment given to those organizations in the Code.[31] This exemption for churches and houses of worship is consistent with their special status under longstanding tradition in our society and under federal law, and is not a mere product of the likelihood that these institutions hire coreligionists. Hiring coreligionists is not itself a determinative factor as to whether an organization should be accommodated or exempted from the contraceptive requirements.

Another commenter stated that ownership of the entity should be limited to family members. The Departments do not believe that ownership of a closely held for-profit entity eligible for the accommodation should be limited to members of one family. Although many closely held corporations are family-owned, existing state and federal definitions of closely held or close corporations do not typically include this requirement. As stated below, however, for purposes of these final regulations, an individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family, meaning brothers and sisters (including half-brothers and half-sisters), spouses, ancestors, and lineal descendants. The Departments agree with the commenters who urged us to define a closely held entity, for purposes of these regulations, based on an existing federal definition. The Departments believe that this approach will minimize confusion for entities seeking the accommodation.

At the same time, the Departments also recognize the need for flexibility in the definition for purposes of the accommodation. Therefore, the Departments are adopting in these regulations a definition that is generally based on—but is more flexible than—the definition of a closely held corporation found in the Code[32] (which we refer to as the tax-law definition). Under the tax-law definition, a closely

[30] 78 FR 39887.

[31] 26 U.S.C. 6033(a)(3)(A).

[32] Code section 469(j)(1) states the ''term 'closely held C corporation' means any C corporation described in section 465(a)(1)(B).'' Section 465(a)(1)(B) provides ''a C corporation with respect to which the stock ownership requirement of paragraph (2) of section 542(a) is met.'' Section 542(a)(2) provides that the applicable stock ownership requirement is met if ''[a]t any time during the last half of the taxable year more than 50 percent in value of its outstanding stock is owned, directly or indirectly, by or for not more than 5 individuals.'' Similarly, section 856(h)(1)(A) provides ''a corporation, trust, or association is closely held if the stock ownership requirement of section 542(a)(2) is met.''

held corporation is a corporation that has more than 50 percent of the value of its outstanding stock owned (directly or indirectly) by five or fewer individuals at any time during the last half of the tax year, and is not a personal service corporation.[33] The definitions for closely held corporation in various Code provisions reference the ownership test for personal holding companies contained in Code section 542(a)(2), which generally has the effect of identifying those corporations that are controlled by a small group of individuals and closely affiliated with their owners.

Drawing on the tax-law definition, with appropriate modifications to reflect the context here, these regulations establish that to be eligible for the accommodation, a closely held, for-profit entity must, among other criteria, be an entity that is not a nonprofit entity, and have more than 50 percent of the value of its ownership interests owned directly or indirectly by five or fewer individuals, or must have an ownership structure that is substantially similar.

As previously stated, for purposes of defining a closely held for-profit entity in these regulations, the Departments are using a definition that is more flexible than the tax-law definition of closely held corporation. Because the Departments believe that the tax-law definition might exclude some entities that should be considered to be closely held for purposes of the accommodation, and because some for-profit entities may have unusual or non-traditional ownership structures not readily analyzed under the 5/50 test, the definition under these final regulations also includes, as stated above, entities with ownership structures that are ''substantially similar'' to structures that satisfy the 5-owner/50-percent requirement.

For example, an entity where 49 percent of the value of the outstanding ownership interests are owned directly by six individuals could also qualify as a closely held for-profit entity because it has an ownership structure that is substantially similar to one in which five or fewer individuals hold at least 50 percent of the value of the outstanding ownership interests.

As another example, an entity owned by a series of corporate parents, where among the ultimate stockholders are a nonprofit entity and a for-profit corporation with three individual owners, who collectively own 45 percent of the outstanding ownership interests, also has a substantially similar ownership structure.

We note, however, that a publicly traded entity would not qualify as having a substantially similar ownership structure.

For purposes of the accommodation, the value of the ownership interests in the entity, whether the total ownership interests or those owned by five or fewer individuals, should be calculated based on all ownership interests, regardless of whether they have associated voting rights or any other privileges. This is consistent with how the tax-law definition of a closely held corporation is applied.

Because the accommodation will be sought on a prospective basis, the Departments do not believe it appropriate to incorporate, from the tax-law definition, the time interval over which the test is measured—that the given ownership structure be in place during the last half of the tax year—and instead adopt a test that is measured as of the date of the entity's self-certification or notice of its objection to provide contraceptive services on account of religious objections.

The tax-law definition of ''closely held corporation'' excludes certain ''personal services corporations,'' such as accounting firms, actuarial science firms, architecture firms, and law firms. Although there are legitimate reasons for excluding personal service firms from the definition of ''closely held corporation'' for purposes of taxation, the Departments do not believe the distinction is necessary in this context. Therefore, a personal services corporation may qualify as a closely held for-profit entity under these final regulations, provided it satisfies the other criteria.

Following the tax-law definition, to determine if more than 50 percent of the value of the ownership interests is owned by five or fewer individuals, the following rules apply:

- Ownership interests owned by or for a corporation, partnership, estate, or trust are considered owned proportionately by the entity's shareholders, partners, or beneficiaries. For example, if a for-profit entity is 100 percent owned by a partnership, and the partnership is owned 100 percent by four individuals, the for-profit entity, for purposes of these regulations, is considered to be owned 100 percent by those four individuals.
- An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. The ''family'' includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants. Accordingly, the family members count as a single owner for purposes of these final regulations.
- If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at *accommodation@cms.hhs.gov.* If the entity does not receive a response from HHS to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure, it will be considered to meet the requirement set forth in 26 CFR 54.9815–2713A(a)(4)(iii), 29 U.S.C. 2590.715–2713A(a)(4)(iii), and 45 CFR 147.131(b)(4)(iii). However, an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity.

Based on the information available, it appears that the definition of closely held for-profit entity set forth in these final regulations includes all the for-profit corporations that have filed lawsuits alleging that the contraceptive coverage requirement, absent an accommodation, violates RFRA.

One commenter stated that the definition should include any for-profit entity that is controlled directly or indirectly by a nonprofit eligible organization. The Departments agree, because in this case the nonprofit entity will represent one shareholder that owns more than 50 percent of the ownership interests in the for-profit entity.[34] The same facts and circumstances that are considered in determining whether a given for-profit entity qualifies as an eligible for-profit organization under these final regulations will also apply when one or more of its owners is a nonprofit organization. For purposes of the ownership concentration test set forth in these final regulations that applies to for-profit entities, a nonprofit organization that has an ownership interest in a for-profit entity will be considered one individual owner of the for-profit entity, and the non-profit organization's percentage ownership in the for-profit entity will be attributed to that nonprofit organization.

[33] *See http://www.irs.gov/Help-&-Resources/Tools-&-FAQs/FAQs-for-Individuals/Frequently-Asked-Tax-Questions-&-Answers/Small-Business,-Self-Employed,-Other-Business/Entities/Entities-5.*

[34] *See* EBSA Form 700.

(b) The Process for Making the Decision To Object To Covering Contraceptive Services

The August 2014 proposed regulations proposed that a closely held for-profit entity's objection to covering some or all of the contraceptive services otherwise required to be covered on account of its owners' sincerely held religious beliefs must be made in accordance with the organization's applicable rules of governance, consistent with state law. Some comments proposed alternative or additional criteria for how the decision must be made. One criterion suggested by many commenters was unanimity among all owners regarding opposition to contraception. However, one commenter objected to this requirement, stating that the regulations should not require unanimous shareholder consent because neither the *Hobby Lobby* decision nor state corporate law imposes such a requirement.

Some commenters favored requiring each equity holder to certify, under penalty of perjury, that he or she has a religious objection to the entity providing contraceptive coverage. These final regulations do not adopt a requirement that the owners unanimously decide that the entity will not offer contraceptive coverage based on a religious objection, or that any equity holder certify under penalty of perjury that he or she has a religious objection to the entity providing the coverage. The Departments believe that either requirement would be unduly restrictive, and would unnecessarily interfere with for-profit entities' decision-making processes. Instead, these final regulations provide that the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by the owners) must adopt a resolution (or take other similar action consistent with the organization's applicable rules of governance and with state law) establishing that the organization objects to covering some or all of the contraceptive services on account of its owners' sincerely held religious beliefs.

(c) Documentation of the Decision To Assert a Religious Objection to Contraceptive Coverage

In the August 2014 proposed regulations, the Departments sought comments on whether a for-profit entity seeking the accommodation should be required to document its decision-making process for objecting to coverage for some or all contraceptive services on account of religious objections (as opposed to merely disclosing the fact that it made such a decision). Many comments supported a requirement that the decision-making process be documented, and that the entity submit, to its third party administrator or health insurance issuer, as applicable, and to the federal government, documentation of the entity's decision. These final regulations require that a for-profit entity seeking the accommodation must make the decision pursuant to a resolution (or other similar action), as described above. However, the Departments are not requiring that this resolution be provided as a matter of course to the federal government or any other party. Generally, the Departments believe it is sufficient that the fact of the decision itself, as opposed to documentation of the decision, be communicated as set forth in August 2014 interim final regulations and these final regulations. However, with respect to documentation of the decision, record retention requirements under section 107 of ERISA apply directly to ERISA-covered plans and, with respect to other plans or coverage subject to these final regulations, by operation of these final regulations, which incorporate the record retention requirements under ERISA section 107 by reference. This approach is consistent with document standards for nonprofit entities seeking the accommodation.

(d) Disclosure of the Decision To Assert a Religious Objection to Contraceptive Services

In the August 2014 proposed regulations, the Departments sought comments on whether a for-profit entity seeking the accommodation should be required to disclose publicly or to its employees its decision not to cover some or all contraceptive services on account of religious objections. This requirement would be in addition to the requirement that an eligible organization that is a for-profit entity that seeks the accommodation make its self-certification or notice of objection to providing contraceptive coverage on account of religious objections available for examination upon request by the first day of the plan year to which the accommodation applies, and be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

Many commenters suggested that the entity should be required to notify HHS of its decision to object (even if it chooses to self-certify and send the self-certification to its issuer or third party administrator). A few commenters stated that all employees and prospective employees (or student enrollees and their covered dependents) must be made aware of their employer's (or educational institution's) refusal to offer contraceptive coverage. One commenter stated that a closely held for-profit entity should disclose the following to its shareholders and employees: (A) The reasons the decision was made, (B) the changes that will take place as a result of the decision, and (C) the number of people that will be affected by the decision. Another commenter stated that entities availing themselves of the accommodation should be required to publicize their justifications for denying women access to coverage of medications that serve purposes other than contraception. One commenter noted the need of employees to know by the employer's annual open enrollment period whether the employer is availing itself of the accommodation.

These final regulations do not establish any additional requirements to disclose the decision. The Departments believe that the current notice and disclosure standards afford individuals eligible for or enrolled in group health plans (and students eligible for or enrolled in student health insurance) with an accommodation adequate opportunity to know that the employer (or educational institution) has elected the accommodation for its group health plan (or insurance coverage), and that they are entitled to separate payment for contraceptive services from another source without cost sharing. Those standards require that, for each plan year to which the accommodation applies, a third party administrator that is required to provide or arrange payments for contraceptive services, and a health insurance issuer required to provide payment for these services, provide to plan participants and beneficiaries (or student enrollees and their covered dependents) written notice of the availability of separate payments for these services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment or re-enrollment in health coverage. Model language for this notice is provided in the regulations.

(e) Sincerity of the Owners' Religious Beliefs

Many commenters suggested that, for a closely held for-profit entity to be eligible for an accommodation, it should not be sufficient that the entity's owners object to providing contraceptive coverage. Rather, the commenters proposed that owners should also be required to agree to operate the entity in a manner consistent with religious

principles, and in fact to so operate the entity. Some commenters pointed out that the July 2013 final regulations require non-profit religious organizations that avail themselves of the accommodation to ''hold themselves out'' as religious organizations.

The Departments have not adopted such a criterion for for-profit entities. The Supreme Court's decision in *Hobby Lobby* discussed the application of RFRA in connection with the religious beliefs of the owners of a closely held corporation.[35] These final regulations similarly focus on the religious exercise of the owners of the closely held entity and provide that the entity, in advancing the religious objection, represent that it does so on the basis of the religious beliefs of the owners. The Departments do not believe it is also necessary that the entity itself demonstrate by its bylaws, mission statement, or other documents or practices that it has a religious character. Non-profit entities ordinarily do not have owners in the same way as do for-profit entities, and thus the religious character of a non-profit entity would be reflected in how it holds itself out.

(f) Other Steps the Departments Should Take To Ensure Contraceptive Coverage With No Cost Sharing

The August 2014 proposed regulations solicited comments on other steps the Departments should take to help ensure that participants and beneficiaries (in the case of student health insurance coverage, enrollees and dependents) in plans subject to an accommodation are able to obtain, without cost, the full range of FDA-approved contraceptives without cost sharing. Many commenters stated that a government enforcement body should be established to monitor compliance by plan sponsors, third party administrators, and health insurance issuers, of their respective obligations associated with the accommodation. At this time, the Departments do not believe that an independent body need be established, although as stated above, the Departments will use their established oversight processes, applicable to all the Affordable Care Act market reforms of title XXVII of the PHS Act to monitor compliance with the requirement to provide contraceptive services without cost sharing. As part of those processes, the Departments will work with non-compliant parties to bring them into compliance, and will take enforcement action as appropriate.

Other commenters stated that the federal government should ensure that no barriers to contraceptive coverage exist due to an enrollee's cultural background, English proficiency, disability, or sexual orientation. The Departments agree that no barriers should exist. The same federal and applicable state laws that would prohibit discrimination by employers, group health plans, third party administrators, and health insurance issuers generally would also apply with respect to the entities arranging for or providing separate payments for contraceptive services for women in group health plans and student health insurance subject to an accommodation.

Other commenters urged that the separate payments for contraceptive services be provided in the same manner in which the group health plan or student health insurance would have otherwise covered these services had they not had an accommodation, or in the same manner in which the plan or coverage subject to an accommodation covers other, non-contraceptive benefits. The Departments, however, maintain the view that reasonable differences in the way services are paid for or provided would not necessarily be inappropriate, provided those differences do not create barriers to accessing payments for contraceptive services. Another commenter stated that health insurance issuers of plans subject to an accommodation should not be permitted to require enrollees to have two insurance cards, one for contraceptive benefits, and one for other benefits. The Departments do not believe that this practice, in of itself, would constitute a barrier to accessing separate payments for contraceptive services.

(g) Other Comments That Relate to the July 2013 Final Regulations

In the August 2014 proposed regulations and interim final regulations, the Departments sought comment on other potential changes to the July 2013 final regulations in light of the proposed change to the definition of eligible organization. In particular, the Departments sought comment on applying the approach set forth in the July 2013 final regulations in the context of the expanded definition of eligible organization. The July 2013 final regulations provide for separate payments for contraceptive services for participants and beneficiaries in self-insured group health plans of eligible organizations in a manner that enables these organizations to completely separate themselves from administration and payment for contraceptive coverage. Specifically, the third party administrator must provide or arrange the payments, and the third party administrator can seek reimbursement for the costs (including an allowance for administrative costs and margin) by making an arrangement with a participating issuer—that is, an issuer offering coverage through a Federally-facilitated Exchange (FFE). The participating issuer can receive an adjustment to its FFE user fees to finance these costs.

One commenter suggested that the federal government set up a program to dispense these services using contractors. Another commenter suggested that pharmaceutical companies could provide certain contraceptives directly by mail to persons who are told at a dispensing pharmacy that their plan has denied coverage. Additionally, the pharmaceutical companies could directly supply doctors who prescribe birth control, who in turn could dispense directly to patients who are not covered under their employer-sponsored group health plan or student health insurance coverage. One commenter suggested making contraception available for any woman free of charge through a doctor. One commenter suggested providing contraceptive care through Medicaid.

The Departments have not adopted the proposals advanced by these comments for two reasons. First, the Departments do not have the legal authority to require pharmaceutical companies or doctors to provide contraceptives directly, nor do they have the authority to implement the other alternative arrangements proposed by these commenters. Second, these alternatives raise obstacles to access to seamless coverage. Consistent with the statutory objective of promoting access to contraceptive coverage and other preventive services without cost sharing, plan beneficiaries and enrollees should not be required to incur additional costs—financial or otherwise—to receive access and thus should not be required to enroll in new programs or to surmount other hurdles to receive access to coverage. The Departments believe that the third party administrators and health insurance issuers already paying for other medical and pharmacy services on behalf of the women seeking the contraceptive services are better placed to provide seamless coverage of the contraceptive services, than are other providers that may not be in the insurance coverage network, and that lack the coverage administration infrastructure to verify the identity of women in accommodated

[35] *See* 134 S. Ct. at 2768.

health plans and provide formatted claims data for government reimbursement.

Some commenters suggested other changes to the July 2013 regulations, with respect to how separate payments for contraceptive services provided under the accommodation are funded. One commenter expressed concern that the August 2014 proposed regulations are silent as to possible funds for reimbursement of costs incurred for contraception services where there is no FFE operating in the state. This commenter also noted that the regulations do not consider the possibility that the cost for contraceptive services may exceed the issuer's FFE user fee, nor do they address how a third party administrator would be reimbursed if the issuer is no longer a participating issuer in the FFE. The commenter suggested the Departments consider several different financing options: The user fee for the risk adjustment program; the CMS program management fund; the user fee for the Medicare Part D program; the Prevention and Public Health Fund; medical loss ratio rebates; CMS innovation funding; and the health insurance provider fee.

Another commenter recommended that HHS provide for an expedited process of adjusting FFE user fees in case the volume of contraceptive claims is greater than expected. This commenter also suggested that the Departments also consider alternative means of generating funding for this purpose, such as allowing an issuer to charge a premium of at least an amount equal to the pro rata share of the rate the eligible organization would have paid had it not elected the accommodation, or directly subsidize the cost of contraception using funding provided by the Prevention and Public Health Fund.

One commenter stated that the Departments should evaluate the limitations of current funding arrangements with respect to the current accommodation for eligible non-profit entities, given the additional demands of the proposal to expand the accommodation to certain for-profit entities. The commenter suggested allowing a separate government funded reimbursement mechanism for enrollees in both insured and self-funded plans as an alternative approach to funding the program. If the current funding approach is continued, the commenter recommended a reassessment of the limitations of the approach for third party administrators. If third party administrators remain responsible for providing or arranging separate payments for contraceptive services, the commenter recommended a broadening of the pool available for reimbursement beyond individually negotiated arrangements with issuers participating in the FFE, including potentially establishing a single pool for reimbursement or finding an alternative, simpler financing mechanism for third party administrators, including offsets from federal income taxes, and offsets to amounts due from other lines of business operated by the third party administrator.

At this time, the Departments are not adopting an alternative approach to funding separate payments for contraceptive services with respect to costs incurred for women in plans subject to an accommodation, although the Departments will continue to explore the feasibility of different ideas, including those proposed in the comments.

One commenter suggested that issuers should be permitted to treat the cost of providing separate payments for contraceptive services for women in plans subject to an accommodation as an adjustment to claims costs for purposes of calculating their medical loss ratios, while still being allowed to treat such payments as an administrative cost spread across the issuer's entire risk pool.[36] With respect to calculating medical loss ratios, HHS has previously stated in rulemaking that an insurer of an accommodated insured group health or student plan may include the cost of the actual payments it makes for contraceptive services in the numerator of its medical loss ratio.[37]

Several commenters asked whether, in light of the fact that the accommodation was proposed to be expanded to a new set of entities, if the Department's discussion in the preamble to the July 2013 final regulations about the extent to which the accommodation has an effect on other laws, continues to apply.[38] The Departments explained in that discussion that state insurance laws that provide greater access to contraceptive coverage than federal standards are unlikely to be preempted, and that, in states with broader religious exemptions and accommodations with respect to health insurance issuers than those in the regulations, plans are still required to comply with the federal standard. These principles continue to apply.

One commenter stated that the *Hobby Lobby* decision applies to every form of medical care, not just contraception, and that the regulations should reflect that. However, in *Hobby Lobby,* the Court stated:

> In any event, our decision in these cases is concerned solely with the contraceptive mandate. Our decision should not be understood to hold that an insurance-coverage mandate must necessarily fail if it conflicts with an employer's religious beliefs. Other coverage requirements, such as immunizations, may be supported by different interests (for example, the need to combat the spread of infectious diseases) and may involve different arguments about the least restrictive means of providing them.[39]

Regarding fully insured plans, one commenter noted that the July 2013 final regulations permit issuers that are providing separate payments for contraceptive services under the accommodation, to pay for all FDA-approved contraceptive services, or only for those services to which the eligible organization objects to covering on religious grounds. The commenter noted that this approach simplifies the operational issues associated with implementing the accommodation across multiple employers, and sought clarification that this approach is available to third party administrators as well. The Departments clarify that this option is available to third party administrators with respect to self-insured plans.

One commenter requested that notices of objection to covering contraceptive services on religious grounds be provided with at least 60 days' advance notice, and that any change in objection status based on change of ownership of the employer not be implemented until the next plan year or policy year. The Departments do not adopt this suggestion. Instead, the Departments are extending, to closely held for-profit entities, the same timeframes that have been in effect for non-profit eligible organizations, that is, a plan sponsor can provide such notice, and implement plan benefit changes associated with the accommodation, at any time. For group health plans subject to ERISA, existing notice and timeframe requirements under ERISA apply.

Another commenter stated that health insurance issuers and third party administrators should only be required to provide or arrange for separate payments for contraceptive services for eligible organizations that have invoked an accommodation no earlier than the

[36] *See* Discussion of how an issuer may achieve cost neutrality in the preamble to the July 2013 final regulations, at 78 FR 39878.

[37] *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015 (Mar. 11, 2014), at 79 FR 13809.

[38] 78 FR 39888.

[39] 134 S. Ct. at 2783.

first day of the first plan year that follows publication of these final regulations. To provide employers, institutions of higher education, third party administrators, and health insurance issuers adequate time to comply, these final regulations apply beginning on the first day of the first plan year (or, in the individual market, the first policy year) after these regulations are effective. Accordingly these final regulations are effective beginning on the first day of the first plan year (or, in the individual market, the first policy year) that begins on or after September 14, 2015.

Several commenters stated that the decision to not cover some or all contraceptives on religious grounds should be made annually. The Departments do not believe such a requirement is appropriate or necessary.

One commenter asked for clarification as to how a notice of objection would be provided by employers purchasing coverage through the Small Business Health Options Program (SHOP) and whether there will be a mechanism in place that permits an eligible organization to select a small group plan and provide a notice of objection. With respect to employers purchasing coverage through the SHOP, health insurance issuers selling policies through it, and participants and beneficiaries in such plans, all of the rights and obligations that are associated with these regulations apply no differently than if the employer were to purchase coverage outside of the SHOP.

One commenter stated that providing separate payments for contraceptive services is not cost-neutral for an issuer, and that it is not appropriate for an issuer of a student health insurance plan to be required to make separate payments for contraceptive services for enrollees in student health plans subject to an accommodation, and suggested that the Marketplaces should instead offer free individual market policies covering contraception to those who desire such coverage, or that such individuals get such services through existing clinics. In the alternative, the commenter proposed an ''above the line'' deduction on their federal income taxes for all costs incurred for separate payments made for contraceptive services for enrollees in a student health plan subject to an accommodation. The Departments do not adopt the comment. For the reasons stated in the July 2013 final regulations, the Departments believe that covering contraceptive services is cost-neutral for an issuer at risk for the enrollees in a plan subject to an accommodation. With respect to student health insurance plans, these regulations finalize a clarification proposed in the August 2014 proposed regulations under which a reference to the definition of ''institution of higher education'' found in 20 U.S.C. 1002 is added to 45 CFR 147.131(f), to clarify that both nonprofit and closely held for-profit institutions of higher education, with respect to their insured student health plans, may qualify as eligible organizations.

III. Economic Impact and Paperwork Burden

A. Executive Orders 12866 and 13563—Department of Health and Human Services and Department of Labor

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a proposed rule—(1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below, the Departments anticipate that these regulations—most notably the policies first established in the 2010 interim final rule—are likely to have economic impacts of $100 million or more in any one year, and therefore meet the definition of ''significant rule'' under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with these final regulations. In accordance with the provisions of Executive Order 12866, these final regulations were reviewed by the OMB.

1. Need for Regulatory Action

These final regulations finalize the July 2010 interim final regulations related to coverage of recommended preventive services, the August 2014 interim final regulations related to the process an eligible organization uses to provide notice of its religious objections to the coverage of contraceptive services, and the August 2014 proposed regulations related to the definition of eligible organization.

As discussed later in the RIA, historically there has been an underutilization of preventive services, as health insurance issuers have had little incentive to cover these services. Currently, there is still an underutilization of some preventive services due to a number of barriers, including costs, ethnic/gender disparities,[40] and a general lack of knowledge by those with medical coverage.[41] While many of these factors are being addressed through the Affordable Care Act and these final regulations, the current underutilization of preventive services stems from three main factors. First, due to turnover in the health insurance market, health insurance issuers have historically lacked incentives to cover preventive services, whose benefits may only be realized in the future when an individual may no longer be enrolled with that issuer. Second, many preventive services generate benefits that do not accrue immediately to the individual that receives the services, making the individual less likely to avail themselves of the services, especially in the face of direct, immediate costs. Third, some of the benefits of preventive services accrue to society as a whole, and thus do not get factored into an individual's decision making over whether to obtain such services.

[40] Call, K. T., McAlpine, D. D., Garcia, C. M., Shippee, N., Beebe, T., Adeniyi, T. C., & Shippee, T. (2014). Barriers to Care in an Ethnically Diverse Publicly Insured Population. *Medical Care.*

[41] Reed, M. E., Graetz, I., Fung, V., Newhouse, J. P., & Hsu, J. (2012). In consumer-driven health plans, a majority of patients were unaware of free or low-cost preventive care. *Health Affairs, 31*(12), 2641–2648.

The July 2010 interim final regulations and these final regulations address these market failures through two avenues. First, the regulations require coverage of recommended preventive services by non-grandfathered group health plans and health insurance issuers in the group and individual markets, thereby overcoming plans' lack of incentive to invest in these services. Second, the regulations eliminate cost-sharing requirements, thereby removing a barrier that could otherwise lead an individual to not obtain such services, given the long-term and partially external nature of these benefits.

The August 2014 interim final regulations provided an alternate process that eligible organizations can use to provide notice of their religious objections to providing coverage for some or all of the contraceptive services to HHS, instead of providing the EBSA Form 700 to the issuers or third party administrators of their group health plan. The provisions of those interim final regulations are being finalized without any changes.

These final regulations also amend the definition of an eligible organization to include a closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered by the group health plan or student health insurance plan established, maintained, or arranged by the organization.

These final regulations are necessary in order to provide rules that plan sponsors and issuers can continue to use to determine how to provide coverage for certain recommended preventive services without the imposition of cost sharing, to ensure women's ability to receive those services, and to respect the religious beliefs of qualifying eligible organizations with respect to their objection to covering contraceptive services.

2. Summary of Impacts

In accordance with OMB Circular A–4, Table III.1 below depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action. It is expected that all non-grandfathered plans are already complying with the provisions of the July 2010 and August 2014 interim final regulations. Therefore, benefits related to those regulations have been experienced and costs have already been incurred. The Departments are providing an assessment of the impacts of existing provisions already experienced and expected in the future, in addition to the anticipated impacts of new provisions in these final regulations.

TABLE III.1—ACCOUNTING TABLE

Benefits:
Qualitative: * Increased access to and utilization of recommended preventive services, leading to the following benefits: (1) Prevention and reduction in transmission of illnesses as a result of immunization and screening of transmissible diseases; (2) delayed onset, earlier treatment, and reduction in morbidity and mortality as a result of early detection, screening, and counseling; (3) increased productivity and reduced absenteeism; and (4) savings from lower health care costs. * Benefits to eligible for-profit entities from not being required to facilitate access to or pay for services that contradict their owners' religious beliefs.
Costs:
Qualitative: * New costs to the health care system when individuals increase their use of preventive services in response to the changes in coverage and cost-sharing requirements of preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand and the percentage change in prices facing those with reduced cost sharing or newly gaining coverage. * Administrative cost to eligible for-profit entities to provide self-certification to issuers or third party administrators or notice to HHS. * Administrative cost to issuers and third party administrators for plans sponsored by eligible closely held for-profit entities to provide notice to enrollees.
Transfers:
* Costs previously paid out-of-pocket for certain preventive services are now covered by group health plans and issuers. * Risk pooling in the group market will result in sharing expected cost increases across an entire plan or employee group as higher average premiums for all enrollee. However, not all of those covered will utilize preventive services to an equivalent extent. As a result, these final regulations create a small transfer from those paying premiums in the group market utilizing less than the average volume of preventive services in their risk pool to those whose utilization is greater than average. To the extent there is risk pooling in the individual market, a similar transfer will occur. * Transfer of costs related to certain preventive services from eligible self-funded closely held for-profit entities to third party administrators and issuers that provide (or arrange) separate payments for contraceptive services. Third party administrators can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs, and the issuer offering coverage through the FFE can receive an adjustment to the FFE user fee.

3. Estimated Number of Affected Entities

For purposes of this analysis, the Departments have defined a large group health plan as an employer plan with 100 or more workers and a small group plan as an employer plan with less than 100 workers. The Departments estimate that there are approximately 140,000 large and 2.2 million small ERISA-covered group health plans with an estimated 93.2 million participants in large group plans and 36 million participants in small group plans. The Departments estimate that there are approximately 128,000 governmental plans with 39 million participants in large plans and 2.8 million participants in small plans.[42] In 2013, approximately

[42] All participant counts and the estimates of individual policies are from the U.S. Department of

Continued

12.26 million participants were covered by individual health insurance policies.[43]

Group health plans and health insurance issuers offering group and individual health insurance coverage that are not grandfathered health plans will be affected by these regulations. There are an estimated 500 issuers offering group and individual health insurance coverage.[44] The number of employer-sponsored grandfathered plans has been decreasing steadily since 2010. Thirty-seven percent of employers offering health benefits offered at least one grandfathered health plan in 2014, compared to 54 percent in 2013 and 72 percent in 2011. Therefore, more and more enrollees in employer-sponsored plans have gained access to preventive services without cost sharing. Twenty-six percent of covered workers were enrolled in a grandfathered health plan in 2014, as compared to 36 percent in 2013 and 56 percent in 2011.[45] In the individual market, it is expected that a large proportion of individual policies are not grandfathered. In addition, enrollees in qualified health plans purchased through the Marketplaces have non-grandfathered policies. At the end of the second enrollment period, nearly 11.7 million individuals selected or were automatically reenrolled into a 2015 health insurance plan through the Marketplaces.[46]

It is uncertain how many closely held for-profit entities have religious objections to providing coverage for some or all of the contraceptive services otherwise required to be covered. Based on litigation and communication received by HHS, the Departments estimate that at least 87 closely held for-profit eligible organizations will seek the religious accommodation provided in these final regulations. Health insurance issuers (or third party administrators for self-insured plans) for the group health plans established or maintained by these eligible organizations (and health insurance issuers of closely held for-profit institutions of higher education) will assume sole responsibility for providing (or arranging) separate payments for contraceptive services directly for plan participants and beneficiaries (and for student enrollees and dependents), without cost sharing, premium, fee, or other charge to plan participants or beneficiaries (or student enrollees and dependents) or to the eligible organization or its plan. In addition, based on litigation, the Departments estimate that at least 122 non-profit eligible organizations will have the option to provide notice of their religious objections to HHS, instead of providing the EBSA Form 700 to the issuer or third party administrator of their group health plan. These numbers are likely to underestimate the number of eligible organizations that will seek the accommodation. However, these are the best estimates available to the Departments at this time.

4. Benefits

In the July 2010 interim final regulations, the Departments anticipated several types of benefits that will result from expanding coverage and eliminating cost sharing for recommended preventive services. First, individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease. Second, healthier workers and children will be more productive with fewer missed days of work or school. Third, some of the recommended preventive services will result in savings due to lower health care costs.

As stated in the July 2010 interim final regulations, preventive service coverage is limited to those recommended by the Task Force (grade of A or B), an applicable Advisory Committee, and HRSA.[47] These final regulations can be expected to continue to increase access to and utilization of these services, which have been historically underutilized. For example, 27.7 percent of adults aged 50 to 75 have never been screened for colorectal cancer (such as sigmoidoscopy and/or colonoscopy).[48] In 2012, the median percentage of women over the age of 18 that have not had a pap test in the past 3 years was 22 percent.[49] The CDC recently found that in adults over 50, fewer than 30 percent are up-to-date with core preventive services.[50]

As explained in the July 2010 interim final regulations, numerous studies have shown that improved coverage, or reduced costs, of preventive services results in higher utilization of these services[51] leading to potentially substantial benefits. Research suggests there are significant health benefits associated with a number of newly covered preventive services required under the statute and these final regulations. The National Council on Preventive Priorities (NCPP) has estimated that achieving a utilization rate of 90 percent for eight clinical preventive services would save more than 150,000 lives each year in the U.S., including 42,000 if smokers were offered medication or other cessation assistance (Table III.2).[52] From an economic viewpoint, many preventive services offer high economic value[53] resulting in an estimated savings of $3.7 billion.[54] Even if a rate of 90 percent utilization is not achieved due to a variety of barriers, including financial, service accessibility, and socioeconomic disparities, the Departments expect that utilization will increase among those individuals in plans subject to the regulations because the provisions eliminate cost sharing and require coverage for these services. It is expected that the increased utilization

Labor, EBSA calculations using the March 2013 Current Population Survey Annual Social and Economic Supplement and the 2012 Medical Expenditure Panel Survey and the 2012 Census of Government.

[43] This estimate includes enrollment in student health insurance plans. Source: Data from Medical Loss Ratio submissions for 2013 reporting year, available at *http://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[44] Source: Data from Medical Loss Ratio submissions for 2013 reporting year.

[45] *See* Kaiser Family Foundation and Health Research and Education Trust, Employer Health Benefits 2014 Annual Survey (2014), available at *http://kff.org/private-insurance/report/2014-employer-health-benefits-survey/;* and Employer Health Benefits 2011 Annual Survey (2011) available at *http://kff.org/health-costs/report/employer-health-benefits-annual-survey-archives/.*

[46] This estimate represents the number of individuals who have selected, or been automatically reenrolled into a 2015 plan through the Marketplaces, with or without payment of premium. *See* ASPE, Health Insurance Marketplaces 2015 Open Enrollment Period: March Enrollment Report, available at *http://aspe.hhs.gov/health/reports/2015/MarketPlaceEnrollment/Mar2015/ib_2015mar_enrollment.pdf.*

[47] *See http://www.ahrq.gov/research/findings/final-reports/uspstf/uspstfeval.pdf* for details of the Task Force grading and *http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/* for current recommendations.

[48] CDC. Vital Signs: colorectal cancer screening test use—United States, 2012. MMWR 2013;62:881–888.

[49] Behavioral Risk Factor Surveillance System Numbers (2012), *http://apps.nccd.cdc.gov/BRFSS/page.asp?cat=CC&yr=2012&state=All#CC.*

[50] CDC Focuses on Need for Older Adults To Receive Clinical Preventive Services, brief released by CDC (2012), *http://www.cdc.gov/aging/pdf/cps-clinical-preventive-services.pdf.*

[51] *See e.g.,* Meeker D, Joyce GF, Malkin J, et al. Coverage and preventive screening. Health Serv Res. 2011; 46:173–184. Study found that patients responded to the exclusion of preventive services from deductibles and reducing cost sharing resulted in increased utilization of lipid screening, pap smears, and other services. See *e.g.,* Jill Bernstein, Deborah Chollet, and G. Gregory Peterson, Encouraging Appropriate Use of Preventive Health Services, Issue Brief *Mathematica Policy Research Inc.,* Princeton, NJ (May 2010) Number 2.

[52] National Commission on Prevention Priorities. *Preventive Care: A National Profile on Use, Disparities, and Health Benefits.* Partnership for Prevention, August 2007. *http://www.prevent.org/data/files/initiatives/ncpppreventivecarereport.pdf.*

[53] Woolf, Steven. A Closer Look at the Economic Argument for Disease Prevention. *JAMA* 2009; 301(5):536–538.

[54] Maciosek, Michael V., Coffield, Ashley B., Flottemesch, *et al.,* Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost. *Health Affairs* 2010, 29(9) 1656–1660.

of these services will lead providers to increase their use of these services knowing that they will be covered without cost sharing.

TABLE III.2—LIVES SAVED FROM INCREASING UTILIZATION OF SELECTED PREVENTIVE SERVICES

Preventive service	Population group	Percent utilization (2005)	Lives saved annually if 90 percent utilization
Regular aspirin use	Men 40+/Women 50+	40	45,000
Smoking cessation (medication and advice)	All adult smokers	28	42,000
Colorectal cancer screening	Adults 50+	48	14,000
Influenza vaccination	Adults 50+	37	12,000
Cervical cancer screening (in past 3 years)	Women 18–64	83	620
Cholesterol screening	Men 35+/Women 45+	79	2,450
Breast cancer screening (in past 2 years)	Women 40+	67	3,700
Chlamydia screening	Women 16–25	40	30,000

Source: National Commission on Prevention Priorities, 2007.

Studies comparing the utilization of preventive services among adults show utilization rates range from as high as 89 percent for blood pressure checks to only 40 percent for annual flu vaccinations.[55] Under the Affordable Care Act, there have been significantly higher usage rates of several preventive services in young adults and women, including blood pressure tests, cholesterol screening, and contraceptive services.[56] Numerous studies have shown that improved coverage, or reduced costs, of preventive services results in higher utilization of these services[57] leading to potentially substantial benefits. The Departments expect that utilization of preventive services will continue to increase over time among those individuals in plans affected by these regulations because the provisions eliminate cost sharing and require coverage for these services.

Some recommended preventive services have both individual and public health value. Vaccines have reduced or eliminated serious diseases that, prior to vaccination, routinely caused serious illnesses or deaths. Maintaining high levels of immunization in the general population protects the un-immunized from exposure so that individuals who cannot receive, or who do not have a sufficient immune response to the vaccine, are indirectly protected.[58]

A second type of benefit of these final regulations is improved workplace productivity and decreased absenteeism for school children. A study by *Gallup* has found that among workers working at least 30 hours a week, those considered overweight or obese with one or more chronic condition will miss one to 3.5 days of work a month.[59] With an estimated 450 million days lost to absenteeism, the cost of lost productivity due to personal health or the inability to concentrate due to their own or a family member's illness is estimated to be between $153 and $260 billion annually.[60]

Illness and poorly controlled chronic disease also contribute to increased absenteeism among school children. Recent data indicates that in the 2011–2012 academic year, 6.2 percent of children aged 6 through 17 missed 11 or more days of school.[61] Studies have shown that student health and well-being have been positively linked to students' academic outcomes, including attendance, grades, test scores, and high school graduation.[62] As discussed in the July 2010 interim final rules, studies show that reduced cost sharing and increased access to care can improve productivity in both schools and the labor market. Thus, it is expected that these final regulations can have a substantial benefit to the children in the nation's education system and the labor market, both current and future.

A third type of benefit from some preventive services is cost savings. Increasing the provision of preventive services is expected to reduce the incidence or severity of illness, and, as a result, reduce expenditures on treatment of illness. As discussed in the July 2010 interim final regulations and elsewhere,[63] childhood vaccinations have been found to generate considerable benefit and savings to both individuals and society. Employing a decision analysis cohort model of U.S. children born during 1994–2013, researchers at CDC analyzed the economic impact of DTaP (diphtheria and tetanus toxoids and acellular Pertussis), Hib (*Haemophilus influenza* type b), Polio (OPV then IPV), MMR (measles, mumps and rubella), Hepatitis B, varicella, pneumococcal disease (PCV, 7-valent and 13-valent), and rotavirus vaccines in children aged ≤6

[55] The Commonwealth Fund. ''Current Trends in Health Coverage and the Effects of Implementing the Affordable Care Act'' (2013). *http://www.commonwealthfund.org/~/media/files/publications/fund-report/2013/apr/1681_collins_insuring_future_biennial_survey_2012_final.pdf.*

[56] *See. e.g.,* Lau JS, Adams SH, Park MJ, Boscardin WJ, Irwin CE. Improvement in preventive care of young adults after the affordable care act: the affordable care act is helping. *JAMA Pediatr.* 2014; 168(12):1101–1106. *See e.g.,* Sonfield, A., Tapales, A., Jones RK., Finer, LB. Impact of the federal contraceptive coverage guarantee on out-of-pocket payments for contraceptives: 2014 update. *Contraception,* 2015: 91(1): 44–48.

[57] *See e.g.,* Meeker D, Joyce GF, Malkin J, et al. Coverage and preventive screening. Health Serv Res. 2011; 46:173–184. Study found exclusion of deductibles from, and reduced cost sharing of preventive services resulted in increased utilization of lipid screening, pap smears, and other services. *See e.g.,* Jill Bernstein, Deborah Chollet, and G. Gregory Peterson, Issue Brief Mathematica Research Policy Inc., Princeton, NJ (May 2010) Number 2.

[58] *See* Modern Infectious Disease Epidemiology by Johan Giesecke 1994, Chapter 18, The Epidemiology of Vaccination.

[59] Unhealthy U.S. Workers' Absenteeism Costs $153 Billion. Well-Being, Gallop October 17, 2011 at *http://www.gallup.com/poll/150026/Unhealthy-Workers-Absenteeism-Costs-153-Billion.aspx.*

[60] Ibid, *see e.g.,* Health and Productivity Among U.S. Workers, Karen Davis, Ph.D., Sara R. Collins, Ph.D., Michelle M. Doty, Ph.D., Alice Ho, and Alyssa L. Holmgren, The Commonwealth Fund, August 2005. *http://www.commonwealthfund.org/publications/issue-briefs/2005/aug/health-and-productivity-among-u-s-workers.*

[61] Children Who Missed 11 or More Days of School per Year Due to Illness or Injury, Kids Count Data Center at *http://datacenter.kidscount.org/data/tables/5202-children-who-missed-11-or-more-days-of-school-per-year-due-to-illness-or-injury?loc=1&loct=2#detailed/1/any/false/1021,18,14/691,30,18/11683.*

[62] Vaughn, B., Princiotta, D., Barry, M., Fish, H., & Schmitz, H. (2013). Safe Supportive Living Brief: Schools and The Affordable Care Act. *https://safesupportivelearning.ed.gov/sites/default/files/1953_Schools%20Affordable%20Care%20Brief_d3%20lvr.pdf.*

[63] *See e.g.* Maciosek, Michael V., Coffield, Ashley B., Flottemesch, *et al.,* Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost. *Health Affairs* 2010 29(9) 1656–1660. *See* eg. Zhou F, Santoli J, Messonnier ML, et al. Economic Evaluation of the 7-Vaccine Routine Childhood Immunization Schedule in the United States, 2001. *Arch Pediatr Adolesc Med.* 2005; 159(12):1136–1144.

years. The study estimates that among the 78.6 million children born during this period, these routine immunizations will prevent 322 million illnesses and 21 million hospitalizations, averting 732,000 premature deaths over their lifetime. Furthermore, it was estimated that these routine vaccinations will potentially avert $402 billion in direct costs and $1.5 trillion in societal costs and a net savings of $295 billion and $1.38 trillion for payers and society, respectively (in 2013 dollars).[64]

As with immunizations, other preventive services have been estimated to have cost-savings benefits. As discussed in the July 2010 interim final regulations, aspirin use with high risk adults and tobacco cessation and screening can both yield net savings. For example, in Massachusetts, the availability of tobacco cessation treatments combined with promotional campaigns resulted in a ten percent decline in Medicaid enrolled smokers, a $3.12 savings for every dollar spent on the benefit.[65] As discussed in more detail in the July 2010 interim final regulations, another area where prevention can achieve savings is obesity prevention and reduction. Based on recent guidelines, up to 116.1 million American adults are candidates for both pharmaceutical and behavioral treatments for weight loss, and up to 32 million are eligible for bariatric surgery.[66] According to the CDC, from 2011–2012, 16.9 percent of children 2 through 19 years of age and 34.9 percent of adults aged 20 and over were obese (defined as having a body mass index (BMI) greater than or equal to the age and sex-specific 95th percentiles of the 200 CDC growth charts).[67] One study used the number of obese and overweight twelve-year olds in 2005 to simulate a cohort over their lifetimes, indicating that a sustained one-percentage-point decrease in the prevalence of obesity over the lifetime of this cohort would result in an estimated savings of $260.4 million in total medical expenditures.[68] These final regulations are expected to increase the take-up rate of preventative services counseling for obesity and other conditions among patients, and lead physicians to increase appropriate referrals for such services. The effect of these final regulations is expected to be magnified due to the numerous public and private sector initiatives dedicated to combating the obesity epidemic and smoking cessation.

Eligible closely held for-profit entities that seek the accommodation to exclude coverage for contraceptive services from health coverage offered to their employees and students, and eligible organizations that opt to provide notice to HHS, will benefit from not being required to facilitate access to or pay for coverage that are contrary to their owners' religious beliefs. Women enrolled in plans under this accommodation will have continued access to contraceptive services without cost sharing.

5. Costs and Transfers

The changes in how plans and issuers continue to cover the recommended preventive services resulting from these final regulations will result in changes in covered benefits and premiums for individuals in plans and health insurance coverage subject to these final regulations. New costs to the health system result when individuals increase their use of preventive services in response to the changes in coverage of those services. Cost sharing, including coinsurance, deductibles, and copayments, divides the costs of health services between the plan or issuer and the enrollees. The removal of cost sharing increases the quantity of services demanded by lowering the direct cost of the service to consumers. Therefore, the Departments expect that the statute and these final regulations will continue to increase utilization of the covered preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand.

Several studies have found that individuals are sensitive to prices for health services.[69] CDC researchers who studied out-of pocket costs of immunizations for privately insured children up to age 5 (in families in Georgia in 2003) found that a one percent increase in out-of-pocket costs for routine immunizations (DTaP, IPV, MMR, Hib, and Hep B) was associated with a 0.07 percent decrease in utilization.[70]

Eligible closely held for-profit entities that seek the accommodation for contraceptive services will incur administrative costs to provide self-certifications to issuers or third party administrators or notices to HHS. Issuers and third party administrators for health plans sponsored by these eligible organizations will also incur administrative costs to provide notifications to enrollees. The costs related to these information collection requirements are estimated in section D below.

Along with new costs of induced utilization, there are transfers associated with these final regulations. A transfer is a change in who pays for the services, where there is not an actual change in the level of resources used. For example, costs that were previously paid out-of-pocket for certain preventive services will now be covered by plans and issuers under these final regulations. Such a transfer of costs could be expected to lead to an increase in premiums.

In the July 2010 interim final regulations, the Departments analyzed the impact of eliminating cost sharing, increases in services covered, and induced utilization on the average insurance premium using a model to evaluate private health insurance plans against a nationally representative population. In the July 2010 interim final regulations, the Departments analyzed Medical Expenditure Panel Survey (MEPS) data and determined the average person with employer-sponsored insurance (ESI) would have $264 in covered preventive service expenses, of which $240 would be paid by insurance and $24 paid out-of-pocket.[71] When preventive services are covered with zero copayment, the Departments estimated the average preventive benefit (holding utilization constant) would increase by $24, or a 0.6 percent increase in insurance benefits and premiums for plans that have relinquished their grandfather

[64] Whitney, CG., Zhou, F., Singleton, J., Schuchat, A. Benefits from Immunization During the Vaccines of Children Program Era—United States, 1994–2013. MMWR 2014;63(16):352–355.

[65] McAfee, T., Babb, S., McNabb, S., Fiore, MC. *N Engl J Med* 2015; 372:5–7.

[66] Stevens, J., Oakkar, EE., Cui, Z., Cai, J., Truesdale, KP. US adults recommended for weight reduction by 1998 and 2013 obesity guidelines, NHANES 2007–2012, 2015 *Obesity* 23(3) 527–531.

[67] Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of Childhood and Adult Obesity in the United States, 2011–2012. *JAMA.* 2014; 311(8):806–814.

[68] Trasande, L., 2010, How Much Should We Invest in Preventing Childhood Obesity? Health Affairs, 29, no. 3:372–378.

[69] Liu, S., and Chollet, D., Price and Income Elasticity of the Demand for Health Insurance and Health Care Services: A Critical Review of the Literature, *Mathematica Policy Research Inc.,* (March 2006) *http://www.mathematica-mpr.com/~/media/publications/PDFs/priceincome.pdf. See e.g.,* Ringel, JS., Hosek, SD., Vollaard, BA., and S. Mahnovski (2002), The elasticity of demand for health care; A review of the literature and its application to the military health system, National Defense Research Institute, RAND Health. *http://www.rand.org/content/dam/rand/pubs/monograph_reports/2005/MR1355.pdf.*

[70] *See e.g.,* Noelle-Angelique Molinari et al., ''Out-of-Pocket Costs of Childhood Immunizations: A Comparison by Type of Insurance Plan,'' Pediatrics, 120(5) pp. e1148–e1156 (2007).

[71] The model does not distinguish between recommended and non-recommended preventive services, and so this likely represents an overestimate of the insurance benefits for preventive services.

status. Furthermore, in the July 2010 interim final regulations, the Departments estimated that additional coverage for genetic screening, depression screening, lead testing, autism testing, and oral health screening would result in a total average increase in insurance benefits on these services to be 0.12 percent, or just over $4 per insured person. This increase represented a mixture of new costs and transfers, dependent on whether beneficiaries previously purchased these services on their own. Impacts were expected to vary depending on baseline benefit levels, and grandfathered health plans were not expected to experience any impact from those interim final regulations.

As discussed in the July 2010 interim final regulations, the Departments used the standard actuarial ''induction formula'' 1/(1+alpha*P), where alpha is the ''induction parameter'' and P is the average fraction of the cost of services paid by consumers to estimate behavioral changes to estimate the induced demand for preventive services.[72] Removing cost sharing for preventive services lowers the direct cost to consumers of using preventive services, which induces additional utilization, estimated with the model above to increase covered expenses and benefits by approximately $17, or 0.44 percent in insurance benefits in group health plans. A similar, but larger, effect was anticipated in the individual market because individual health insurance policies generally had less generous benefits for preventive services than group health plans.

When eligible closely held for-profit entities seek the accommodation, health insurance issuers (or third party administrators for self-insured plans) for the group health plans established or maintained by the eligible organizations (and health insurance issuers of student health plans arranged by eligible organizations that are institutions of higher education) will assume sole responsibility for providing (or arranging) separate payments for contraceptive services directly for plan participants and beneficiaries (or student enrollees and dependents), without cost sharing, premium, fee, or other charge to plan participants or beneficiaries (or student enrollees and dependents) or to the eligible organization or its plan. The Departments continue to believe that issuers will find that providing contraceptive coverage is at least cost neutral because they will be insuring the same set of individuals under both the group or student health insurance policies for whom they will also be making the separate payments for contraceptive services and, as a result, will experience lower costs from improvements in women's health, healthier timing and spacing of pregnancies, and fewer unplanned pregnancies. Several studies have estimated that the costs of providing contraceptive coverage are balanced by cost savings from lower pregnancy-related costs and from improvements in women's health.[73] A third party administrator can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs (including an allowance for administrative costs and margin). The issuer offering coverage through the FFE can receive an adjustment to the FFE user fee, and the issuer is expected to pass on a portion of that adjustment to the third party administrator to account for the costs of providing or arranging payments for contraceptive services.

B. Regulatory Alternatives

Several provisions in these final regulations involved policy choices. One was whether to allow a plan or issuer to impose cost sharing for an office visit when a recommended preventive service is provided in that visit. Sometimes a recommended preventive service is billed separately from the office visit; sometimes it is not. The Departments decided that the cost-sharing prohibition of these final regulations applies to the specific preventive service as recommended by the guidelines. Therefore, if the preventive service is billed separately (or is tracked as individual encounter data separately) from the office visit, it is the preventive service that has cost sharing waived, not the entire office visit.

A second policy choice was, if the preventive service is not billed separately (or is not tracked as individual encounter data separately) from the office visit, whether these final regulations should prohibit cost sharing for any office visit in which any recommended preventive service was administered, or whether cost sharing should be prohibited only when the preventive service is the primary purpose of the office visit. Prohibiting cost sharing for office visits when any recommended preventive service is provided, regardless of the primary purpose of the visit, could lead to an overly broad application of these final regulations; for example, a person who sees a specialist for a particular condition could end up with a zero copayment simply because his or her blood pressure was taken as part of the office visit. This could create financial incentives for consumers to request preventive services at office visits that are intended for other purposes in order to avoid copayments and deductibles. The increased prevalence of the application of zero cost sharing would lead to increased premiums compared with the chosen option, without a meaningful additional gain in access to preventive services.

A third issue involves health plans that have differential cost sharing for services provided by in-network vs. out-of-network providers. These final regulations provide that a plan or issuer generally is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. The plan or issuer generally may also impose cost sharing for recommended preventive services delivered by an out-of-network provider. However, if the plan or issuer does not have in its network a provider who can provide the recommended preventive service, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service. The Departments considered that requiring coverage by out-of-network providers with no cost sharing would result in higher premiums. Plans and issuers negotiate allowed charges with in-network providers as a way to promote effective, efficient health care, and allowing differences in cost sharing in- and out-of-network enables plans to encourage use of in-network providers. Allowing zero cost sharing for out-of-network providers could reduce providers' incentives to participate in insurer networks. The Departments decided that permitting cost sharing for recommended preventive services provided by out-of-network providers

[72] Standard formula best described in ''Quantity-Price Relationships in Health Insurance'', Charles L Trowbridge, Chief Actuary, Social Security Administration (DHEW Publication No. (SSA) 73–11507, November 1972).

[73] Bertko, J., Glied, S., et al. The Cost of Covering Contraceptives Through Health Insurance (February 9, 2012), *http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml;* Washington Business Group on Health, Promoting Healthy Pregnancies: Counseling and Contraception as the First Step, Report of a Consultation with Business and Health Leader (September 20, 2000), Campbell, K.P., Investing in Maternal and Child Health: An Employer's Toolkit, National Business Group on Health (2007) *http://www.businessgrouphealth.org/healthtopics/maternalchild/investing/docs/mch_toolkit.pdf;* Trussell, J., et al. The Economic Value of Contraception: A Comparison of 15 Methods, American Journal Public Health, 1995; 85(4):494–503, Revenues of H.R. 3162, the Children's Health and Medicare Protection Act, for the Rules Committee (August 1, 2007).

(except in cases where the recommended service is only available from an out-of-network provider) is the appropriate option to preserve a choice of providers for individuals, while avoiding potentially larger increases in costs and transfers as well as potentially lower quality care.

As discussed previously in the preamble, the Departments also considered different ways to define a closely held for-profit entity. Under one approach, a qualifying closely held for-profit entity would have been defined as a for-profit entity where none of the ownership interests in the entity is publicly traded and where the entity has fewer than a specified number of shareholders or owners.

Under the second approach, a qualifying closely held for-profit entity would have been defined as a for-profit entity in which the ownership interests are not publicly traded, and in which a specified fraction of the ownership interest is concentrated in a limited and specified number of owners. Within the second approach, the Departments considered adopting the IRS test to define a closely held corporation. The definition adopted in these final rules, although based on the IRS test, is more flexible and ensures that it does not exclude some entities that should be considered to be closely held for the purposes of these final regulations.

Under a third approach, the Departments considered a test under which none of the ownership interests in the entity is publicly traded, without any other restrictions on the number of owners or on ownership concentration. The Departments believe, however, that such a test would be excessively broad.

C. Special Analyses—Department of Treasury

For purposes of the Department of the Treasury, it has been determined that this rule is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this rule. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the regulations merely modify the definition of eligible organization to include certain closely held for-profit entities. This modification, as adopted, will not increase costs to or burdens on the affected organizations. Pursuant to section 7805(f) of the Code, the proposed rule preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business and no comments were received.

D. Paperwork Reduction Act—Department of Health and Human Services

These final regulations contain information collection requirements that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

1. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*).

2. Information Collection Requirements (ICRs)

a. ICRs Regarding Self-Certification (§ 147.131(b)(3))

All eligible organizations will have the option of either providing a self-certification (EBSA Form 700) to the issuers or third party administrators of the plans that would otherwise arrange for or provide coverage for the contraceptive services, or providing a notice to HHS. For the purpose of estimating burdens, HHS is assigning the burden of the self-certification to eligible for-profit entities and the burden of notice to HHS to eligible non-profit organizations.

The July 2013 final regulations require an eligible organization that seeks an accommodation to self-certify that it meets the definition of an eligible organization using the EBSA Form 700 and provide it directly to each third party administrator or issuer of the plan that would otherwise arrange for or provide coverage for the contraceptive services. These final regulations continue to allow eligible organizations to use EBSA Form 700 to notify their third party administrators and issuers, as set forth in the July 2013 final regulations and guidance.

The Departments received comments that HHS underestimated the number of closely held for-profit eligible organizations that may seek the accommodation. Some commenters noted that it would be difficult to estimate this number. One commenter estimated that about 1.3 million S-corporations offer health insurance to their employees and, based on this data, objection rates of 1 percent of S-corporations would result in 13,000 objecting firms, an objection rate of 2 percent would result in 26,000 objecting firms and an objection rate of 5 percent would result in 65,000 objecting firms. However, the Departments have no indication that such large numbers of closely held for-profit entities would seek the accommodation. The Departments also note that the definition of a qualifying closely held for-profit entity adopted in these final regulations differs from the definition of an S-corporation. In the proposed rules, based on the number of plaintiffs that are for-profit employers in recent litigation objecting on religious grounds to the provision of contraceptive services, HHS estimated that 71 closely held for-profit entities would seek the accommodation. In the final regulations, based on updated information, HHS is revising the estimate to 87. Even though this may underestimate the number of eligible closely held for-profit entities that will seek the accommodation, this is the best estimate available to the Departments at this time.

For each eligible organization, it is assumed that clerical staff will gather and enter the necessary information, send the self-certification to its issuer(s) or third party administrator(s) or the notice to HHS, and retain a copy for recordkeeping. A manager and legal counsel will subsequently review the information, and a senior executive will execute it. It is estimated that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of $30 per hour, 10 minutes for a manager at a cost of $102 per hour, 5 minutes for legal counsel at a cost of $127 per hour, and 5 minutes for a senior executive at a cost of $121 per hour) to execute the self-certification. Therefore, the total one-time burden for preparing and providing the information in the self-certification is estimated to be approximately $53 for each eligible organization. The certification may be electronically transmitted to the issuer

or third party administrator at minimal cost or mailed. For purposes of this analysis, HHS assumes that all notices will be mailed. It is estimated that mailing each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.54.

Based on this estimate of 87 affected entities and the individual burden estimates of 50 minutes and a cost of $53, we estimate the total hour burden to be 72.5 hours with an equivalent cost of $4,611. The total paper filing cost burden for the notices is approximately $47. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 36.25 burden hours at an equivalent cost of approximately $2,306 and a paper filing cost burden of approximately $23, with approximately 44 respondents.

b. ICRs Regarding Notice to HHS (§ 147.131(b)(3))

These final regulations provide an organization seeking to be treated as an eligible organization under the August 2014 interim final regulations an alternative process, consistent with the Supreme Court's interim order in *Wheaton College,* under which an eligible organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services. The eligible organization must maintain the notice to HHS in its records. The burden related to this alternate notice is currently approved under OMB Control Number 0938–1248.

Based on litigation, HHS believes that at least 122 eligible non-profit organizations will have the option to provide the alternative notice to HHS rather than their third party administrators or issuers. Even though this likely underestimates the number of eligible non-profit organizations that will seek the accommodation, this is the best estimate available to the Departments at this time. In order to complete this task, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the notice. HHS assumes that a compensation and benefits manager and inside legal counsel will review the notice and a senior executive will execute it. HHS estimates that an eligible organization will spend approximately 50 minutes (30 minutes of clerical labor at a cost of $30 per hour, 10 minutes for a compensation and benefits manager at a cost of $102 per hour, 5 minutes for legal counsel at a cost of $127 per hour, and 5 minutes by a senior executive at a cost of $121 per hour) preparing and sending the notice and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately $53 for a total hour burden of 102 hours with an equivalent cost of $6,425. As HHS and DOL share jurisdiction, they are splitting the hour burden so each will account for 51 burden hours with an equivalent cost of $3,213, with a total of 61 respondents.

Notices to HHS may be sent electronically at minimal cost or by mail. For purposes of this analysis, HHS assumes that all notices will be mailed. It is estimated that mailing each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) with a total postage and materials cost for each notice sent via mail of $0.54. The total cost burden for the notices is approximately $66. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $33 of the cost burden.

c. Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(d))

As required by the July 2013 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers may, but are not required to, use the model language set forth in the July 2013 final regulations or substantially similar language.

As mentioned, HHS is anticipating that at least 122 non-profit and 87 closely held for-profit entities will seek an accommodation. It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 209. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at $30 per hour) and 15 minutes of management review (at $102 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately $56. The total burden for all issuers or third party administrators will be 261.25 hours, with an equivalent cost of $11,600. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 130.63 burden hours with an equivalent cost of $5,800, with approximately 105 respondents.

d. Letter to HHS Regarding Ownership Structure (§ 147.131(b)(4)(v))

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at *accommodation@cms.hhs.gov.* However, an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity.

As stated earlier in the preamble, the Departments believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. In addition, it appears based on available information that the definition adopted in these final regulations includes all of the for-profit entities that have, as of the date of issuance of these regulations, challenged the contraceptive coverage requirement in court. Therefore, the Departments anticipate that fewer than 10 entities will submit a letter to HHS. Under 5 CFR 1320.3(c)(4), this provision is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

3. Summary of Proposed Annual Burden Estimates

TABLE III.3—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB Control No.	Respondents	Total responses	Burden per response (hours)	Total annual burden (hours)	Burden cost per respondent ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
Self-Certification (§ 147.131(b)(3)).	New	44	44	0.83	36.25	$53	$2,306	$23	$2,329
Notice to HHS (§ 147.131(b)(3)).	0938–1248	61	61	0.83	51	53	3,213	33	3,246
Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(d)).	New	105	105	1.25	130.63	56	5,800	0	5,800
Total	.....	210	210	.....	217.88	.....	$11,319	$56	$11,375

4. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

E. Paperwork Reduction Act—Department of Labor

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)), the Department submitted an information collection request (ICR) to OMB in accordance with 44 U.S.C. 3507(d), contemporaneously with the publication of the interim final regulation, for OMB's review under the emergency PRA procedures.[74] OMB approved the ICR on August 27, 2014 under OMB Control Number 1210–0150 through February 28, 2015. Contemporaneously with the publication of the emergency ICR, the Department published a separate **Federal Register** notice informing the public that it intends to request OMB to extend the approval for 3 years and soliciting comments on the ICR.[75] The Department submitted the extension request to OMB on February 27, 2015. OMB approved the ICR extension on April 14, 2015, which currently is scheduled to expire on April 30, 2018.

The Department also submitted an ICR to OMB in accordance with 44 U.S.C. 3507(d), for the ICR contained in the August 2014 proposed regulations contemporaneously with the publication of the proposal that solicited public comments on the ICR. OMB filed a comment regarding the proposed ICR on October 16, 2014, stating that it was not approving the ICR associated with the proposed rule at the proposed rule stage and requesting the Department to resubmit the ICR at the final rule stage after taking into account public comments. OMB assigned OMB Control Number 1210–0152 to the proposed ICR.

Although no public comments were received in response to the ICRs contained in the August 2014 interim final and proposed regulations that specifically addressed the paperwork burden analysis of the information collections, the comments that were submitted, and which are described earlier in this preamble, contained information relevant to the costs and administrative burdens attendant to the proposals. The Department took into account the public comments in connection with making changes to the proposal, analyzing the economic impact of the proposals, and developing the revised paperwork burden analysis summarized below.

In connection with publication of this final rule, the Department submitted ICRs to OMB as a revision to OMB Control Number 1210–0150 for eligible non-profit organizations and under new OMB Control Number 1210–0152 for eligible for-profit organizations and received OMB approval for both ICRs.

A copy of the ICRs may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov.* PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

1. ICRs Regarding Self-Certification (29 CFR 2590.2713A(b) or (c))

Under these final regulations, all eligible organizations will have the option of either providing (1) a self-certification (EBSA Form 700) to the issuers or third party administrators of the plans that would otherwise arrange for or provide coverage for the contraceptive services or (2) a notice to HHS. For the purpose of estimating burdens, the Department is assigning the burden of the self-certification to eligible for-profit entities and the burden of notice to HHS to eligible non-profit organizations.

The July 2013 final regulations require an eligible organization that seeks an accommodation to self-certify that it meets the definition of an eligible organization using the EBSA Form 700 and provide it directly to each third party administrator or issuer of the plan that would otherwise arrange for or provide coverage for the contraceptive services. These final regulations continue to allow eligible organizations to use EBSA Form 700 to notify their third party administrators and issuers, as set forth in the July 2013 final regulations and guidance.

In response to the public comment solicitation for the ICRs in the August 2014 proposed regulations, the Departments received comments that they underestimated the number of closely held for-profit eligible organizations that may seek the accommodation. Some commenters noted that it would be difficult to estimate this number. One commenter estimated that about 1.3 million S-corporations offer health insurance to their employees and, based on this data, objection rates of 1 percent of S-corporations would result in 13,000 objecting firms, an objection rate of 2 percent would result in 26,000 objecting firms and an objection rate of 5 percent

[74] 5 CFR 1320.13.

[75] 79 FR 51197 (Aug. 27, 2014).

would result in 65,000 objecting firms. However, the Departments have no indication that such large numbers of closely held for-profit entities would seek the accommodation. The Departments also note that the definition of a qualifying closely held for-profit entity adopted in these final regulations differs from the definition of an S-corporation. In the proposed rules, based on the number of plaintiffs that are for-profit employers in recent litigation objecting on religious grounds to the provision of contraceptive services, the Departments estimated that 71 closely held for-profit entities would seek the accommodation. In these final regulations, based on updated information, the Departments are revising the estimate to 87. Even though this may underestimate of the number of eligible closely held for-profit entities that will seek the accommodation, this is the best estimate available to the Departments at this time.

For each eligible organization, the Departments assume that clerical staff will gather and enter the necessary information, send the self-certification to its issuer(s) or third party administrator(s) or the notice to HHS, and retain a copy for recordkeeping. A manager and legal counsel will subsequently review the information, and a senior executive will execute it. It is estimated that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of $30 per hour,[76] 10 minutes for a manager at a cost of $102 per hour,[77] 5 minutes for legal counsel at a cost of $127 per hour,[78] and 5 minutes for a senior executive at a cost of $121 per hour [79]) to execute the self-certification. Therefore, the Departments estimate that the total one-time burden for preparing and providing the information in the self-certification is estimated to be approximately $53 for each eligible organization. The certification may be electronically transmitted to the issuer or third party administrator at minimal cost or mailed. For purposes of this analysis, the Departments assume that all notices will be mailed. The Departments estimate that mailing each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.54.

Based on this estimate of 87 affected entities and the individual burden estimates of 50 minutes and a cost of $53, the Departments estimate the total hour burden associated with the ICR to be 72.5 hours with an equivalent cost of $4,611. The total paper filing cost burden for the notices is approximately $47. The hour burden associated with the ICR is allocated equally between DOL and HHS, because the agencies share jurisdiction of preventive health services resulting in an hour burden for each agency of 36.25 burden hours at an equivalent cost of approximately $2,306 and a paper filing cost burden of approximately $23, with approximately 44 respondents.

2. ICRs Regarding Notice to HHS (29 CFR 2590.2713A(b) or (c))

These final regulations provide an organization seeking to be treated as an eligible organization under the August 2014 interim final regulations with an alternative process, consistent with the Supreme Court's interim order in *Wheaton College,* under which an eligible organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services. The eligible organization must maintain the notice to HHS in its records. The burden related to this alternate notice is currently approved under OMB Control Number 1210–0150.

Based on litigation, the Departments estimate that at least 122 eligible non-profit organizations will have the option to provide the alternative notice to HHS rather than their third party administrators or issuers. Even though this may underestimate the number of eligible non-profit organizations that will seek the accommodation, it is the best estimate available to the Departments at this time. In order to complete this task, the Departments assume that clerical staff for each eligible organization will gather and enter the necessary information and send the notice. The Departments assume that a compensation and benefits manager and inside legal counsel will review the notice and a senior executive will execute it. The Departments estimate that an eligible organization will spend approximately 50 minutes (30 minutes of clerical labor at a cost of $30 per hour, 10 minutes for a compensation and benefits manager at a cost of $102 per hour, 5 minutes for legal counsel at a cost of $127 per hour, and 5 minutes by a senior executive at a cost of $121 per hour) preparing and sending the notice and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately $53 for a total hour burden of 102 hours with an equivalent cost of $6,425. As HHS and DOL share jurisdiction, they are splitting the hour burden so each will account for 51 burden hours with an equivalent cost of $3,213, with a total of 61 respondents.

Notices to HHS may be sent electronically at minimal cost or by mail. For purposes of this analysis, the Departments assume that all notices will be mailed. It is estimated that mailing each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) with a total postage and materials cost for each notice sent via mail of $0.54. The total cost burden for the notices is approximately $66. As DOL and HHS share jurisdiction, they are sharing the cost burden equally and each is attributed $33 of the cost burden.

3. Notice of Availability of Separate Payments for Contraceptive Services (29 CFR 2590.2713A(d))

As required by the July 2013 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries (or student enrollees and covered dependents) in insured plans of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers may, but are not required to, use the model language set forth in the July 2013 final regulations or substantially similar language.

As mentioned, the Departments anticipate that at least 122 non-profit and 87 closely held for-profit entities will seek an accommodation. It is unknown how many issuers or third party administrators provide health

[76] Secretaries, Except Legal, Medical, and Executive (43–6014): $16.13(2012 BLS Wage rate)/0.679(ECEC ratio) *1.2(Overhead Load Factor) *1.019(Inflation rate) −2(Inflated 2 years from base year) = $29.60

[77] Compensation and Benefits Manager (11–3041): $50.92(2012 BLS Wage rate)/0.697(ECEC ratio) *1.35(Overhead Load Factor) *1.019(Inflation rate) −2(Inflated 2 years from base year) = $102.41

[78] Legal Professional (23–1011): $62.93(2012 BLS Wage rate)/0.697(ECEC ratio) *1.35(Overhead Load Factor) *1.019(Inflation rate) −2(Inflated 2 years from base year) = $126.56

[79] Financial Managers (11–3031): $59.26(2012 BLS Wage rate)/0.689(ECEC ratio) *1.35(Overhead Load Factor) *1.019(Inflation rate) −2(Inflated 2 years from base year) = $120.57

insurance coverage or services in connection with health plans of eligible organizations, but that for the purposes of the analysis, the Departments assume at least 209 do. The Departments assume that each issuer or third party administrator will need approximately one hour of clerical labor (at $30 per hour) and 15 minutes of management review (at $102 per hour) to prepare the notices. Therefore, the Departments estimate that the total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately $56. The total burden for all issuers or third party administrators will be 261.25 hours, with an equivalent cost of $11,600. The cost burden associated with this ICR is allocated equally between DOL and HHS, because the agencies share jurisdiction under the provision. Therefore, the hour burden for each is 130.63 burden hours with an equivalent cost of $5,800 for approximately 105 respondents.

4. Letter to HHS Regarding Ownership Structure (29 CFR 2590.2713A(a)(4)(v))

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at *accommodation@cms.hhs.gov.* However, an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity.

As stated earlier in the preamble, the Departments believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. In addition, it appears based on available information that the definition adopted in these final regulations includes all of the for-profit entities that have, as of the date of issuance of these regulations, challenged the contraceptive coverage requirement in court. Therefore, the Departments anticipate that fewer than 10 entities will submit a letter to HHS. Under 5 CFR 1320.3(c)(4), this provision is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

F. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (RFA) requires agencies that issue a rule to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as—(1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a non-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000 (states and individuals are not included in the definition of ''small entity''). The Departments use as their measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 percent to 5 percent.

As discussed in the Web Portal interim final rule with comment period published on May 5, 2010 (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis it was determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for ''small'' business established by the SBA (currently $38.5 million in annual receipts for health insurance issuers).[80] In addition, analysis of data from Medical Loss Ratio annual report submissions for the 2013 reporting year was used to develop an estimate of the number of small entities that offer comprehensive major medical coverage. It is estimated that 141 out of 500 issuers of health insurance coverage nationwide had total premium revenue of $38.5 million or less. This estimate may overstate the actual number of small health insurance companies that would be affected, since 77 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding $38.5 million. For these reasons, the Departments expect that these final regulations will not affect a significant number of small issuers.

The provisions of these final regulations affect small employers with self-insured group health plans by requiring them to include coverage under their group health plans for recommended preventive services without cost sharing. However, small employers also benefit from having healthier employees and reduced absenteeism. Small employers are less likely to be self-insured compared to large employers; only about 13.3 percent of employers with less than 100 employees that offer a group health plan have a self-funded plan.[81]

With respect to contraceptive coverage, some eligible organizations that seek the accommodation may be small entities and will incur costs to provide the self-certification to issuers or third party administrators or notice to HHS. However, the related administrative costs are expected to be minimal.

Third party administrators for self-insured group health plans established or maintained by eligible organizations will incur administrative costs to send notices to enrollees and arrange for separate payments for contraceptive services. It is unknown how many third party administrators impacted by this requirement have revenues below the size thresholds for ''small'' business established by the SBA (currently $32.5 million for third party administrators). However, a third party administrator can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for the third party administrator's costs.

G. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. In the Departments' view, these final regulations have federalism implications, but the federalism implications are substantially mitigated because, with respect to health insurance issuers, 45 states are either enforcing the requirements related to coverage of specified preventive services (including contraception) without cost sharing pursuant to state law or otherwise are working collaboratively with HHS to ensure that issuers meet these standards. In five states, HHS ensures that issuers comply with these requirements. Therefore, the final regulations are not likely to require substantial additional oversight of states by HHS.

[80] ''Table of Small Business Size Standards Matched To North American Industry Classification System Codes,'' effective July 14, 2014, U.S. Small Business Administration, available at *http://www.sba.gov.*

[81] Source: Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2013 Medical Expenditure Panel Survey-Insurance Component.

In general, section 514 of ERISA provides that state laws are superseded to the extent that they relate to any covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. ERISA also prohibits states from regulating a covered plan as an insurance or investment company or bank. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting state requirements on group health insurance coverage. States may continue to apply state law requirements but not to the extent that such requirements prevent the application of the federal requirement that group health insurance coverage provided in connection with certain group health plans (or student health insurance issuers) provide coverage for specified preventive services without cost sharing. HIPAA's Conference Report states that the conferees intended the narrowest preemption of state laws with regard to health insurance issuers (H.R. Conf. Rep. No. 104–736, 104th Cong. 2d Session 205, 1996). State insurance laws that are more stringent than the federal requirement are unlikely to ''prevent the application of'' the preventive services coverage provision, and therefore are unlikely to be preempted. Accordingly, states have significant latitude to impose requirements on health insurance issuers that are more restrictive than those in federal law.

Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 (62 FR 16904) and December 30, 2004 (69 FR 78720), and these final regulations implement the preventive services coverage provision's minimum standards and do not significantly reduce the discretion given to states under the statutory scheme.

The PHS Act provides that states may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but that the Secretary of HHS will enforce any provisions that a state does not have authority to enforce or that a state has failed to substantially enforce. When exercising its responsibility to enforce provisions of the PHS Act, HHS works cooperatively with the state to address the state's concerns and avoid conflicts with the state's exercise of its authority. HHS has developed procedures to implement its enforcement responsibilities, and to afford states the maximum opportunity to enforce the PHS Act's requirements in the first instance. In compliance with Executive Order 13132's requirement that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of states, the Departments have engaged in numerous efforts to consult and work cooperatively with affected state and local officials.

In conclusion, throughout the process of developing these final regulations, to the extent feasible within the specific preemption provisions of ERISA and the PHS Act, the Departments have attempted to balance states' interests in regulating health insurance coverage and health insurance issuers, and the rights of individuals intended to be protected in the PHS Act, ERISA, and the Code.

H. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by state, local or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold level is approximately $144 million.

UMRA does not address the total cost of a regulatory action. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs. These final regulations include no mandates on state, local, or tribal governments. Health insurance issuers, third party administrators and eligible organizations would incur costs to comply with the provisions of these final regulations. However, consistent with policy embodied in UMRA, these final regulations have been designed to be the least burdensome alternative while achieving the objectives of the Affordable Care Act.

I. Congressional Review Act

These final rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and have been transmitted to Congress and the Comptroller General for review.

IV. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2510

Employee benefit plans, Pensions.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Approved: July 8, 2015.

John Dalrymple,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: July 8, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 7th day of May 2015.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: May 7, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 20, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read in part as follows:

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

* * * * *

Section 54.9815–2713 also issued under 26 U.S.C. 9833;

■ **Par.2.** Section 54.9815–2713 is amended by adding paragraphs (a)(1)(i), (ii), and (iii), and revising paragraphs (a)(2), (3), (4), and (5), (b), and (c) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) * * *

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

* * * * *

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1,* the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1* of this section. As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2,* because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3,* the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4,* the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement with respect to the office visit.

(3) *Out-of-network providers.* (i) Subject to paragraph (a)(3)(ii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost-sharing with respect to the item or service.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency,

method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year must provide coverage through the last day of the plan year, even if the recommendation or guideline changes is or is no longer described in paragraph (a)(1) of this section, during the plan year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year is downgraded to a ''D'' rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the item or service during a plan year, there is no requirement under this section to cover these items and services through the last day of the plan year.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

■ **Par. 3.** Section 54.9815–2713A is amended by revising paragraphs (a), (b), (c)(1), and (c)(2)(i) introductory text to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under § 54.9815–2713(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (a)(4) of this section, and the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization's applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owner's sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary of Labor or provide notice to the Secretary of Health and Human Services as described in paragraph (b) or (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) A closely held for-profit entity is an entity that—

(i) Is not a nonprofit entity;

(ii) Has no publicly traded ownership interests, (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and

(iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity's self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (a)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity's shareholders, partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to the Department of Health and Human Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (a)(4)(iii) of this section.

(b) *Contraceptive coverage—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis complies for one or more plan years with any requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if all of the requirements of this paragraph (b)(1) are satisfied:

(i) The eligible organization or its plan contracts with one or more third party administrators.

(ii) The eligible organization provides either a copy of the self-certification to each third party administrator or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and agrees to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, the third party administrator shall provide or arrange payments for contraceptive services using one of the following methods—

(i) Provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(c) * * *

(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan provides either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage for all or a subset of contraceptive services.

(i) When a copy of the self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713. An issuer may not require any further documentation from the eligible organization regarding its status as such.

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section.

(2) * * *

(i) A group health insurance issuer that receives a copy of the self-certification or notification described in paragraph (c)(1)(ii) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under § 54.9815–2713(a)(1)(iv) must—

* * * * *

§ 54.9815–2713AT [REMOVED]

■ **Par. 4.** Section 54.9815–2713AT is removed.

§ 54.9815–2713T [REMOVED]

■ **Par. 5.** Section 54.9815–2713T is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, under the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012)

the Department of Labor adopts as final the interim rules amending 29 CFR part 2590 published on July 19, 2010 (75 FR 41726) and amending 29 CFR parts 2510 and 2590 published August 27, 2014 (79 FR 51092) and further amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 12(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (January 9, 2012).

■ 7. Section 2590.715–2713 is amended by revising paragraphs (a)(3) and (4) and (b)(2) to read as follows:

§ 2590.715–2713 Coverage of preventive health services

(a) * * *

(3) *Out-of-network providers*—(i) Subject to paragraph (a)(3)(ii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

* * * * *

(b) * * *

(2) *Changes in recommendations or guidelines.* (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year must provide coverage through the last day of the plan year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the plan year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year is downgraded to a ''D'' rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the item or service during a plan year, there is no requirement under this section to cover these items and services through the last day of the plan year.

* * * * *

■ 8. Section 2590.715–2713A is amended by revising paragraph (a) to read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under § 2590.715–2713(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (a)(4) of this section, and the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization's applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owners' sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary or provide notice to the Secretary of Health and Human Services as described in paragraph (b) or (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) A closely held for-profit entity is an entity that—

(i) Is not a nonprofit entity;

(ii) Has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and

(iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity's self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (a)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity's shareholders, partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for-profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to the Department of Health and Human Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive

a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (a)(4)(iii) of this section.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, under the authority contained in Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended), the Department of Health and Human Services adopts as final the interim rules amending 45 CFR part 147 published on July 19, 2010 (75 FR 41726) and amending 45 CFR part 147 published August 27, 2014 (79 FR 51092) and further amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 9. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 10. Section 147.130 is amended by revising paragraphs (a)(3) and (4) and (b)(2) to read as follows:

§ 147.130 Coverage of preventive health services

(a) * * *

(3) *Out-of-network providers*—(i) Subject to paragraph (a)(3)(ii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

* * * * *

(b) * * *

(2) *Changes in recommendations or guidelines.* (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year (in the individual market, policy year) must provide coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the plan or policy year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year (in the individual market, policy year) is downgraded to a ''D'' rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the plan or policy year.

* * * * *

■ 11. Section 147.131 is amended by revising paragraphs (b) and (f) to read as follows:

§ 147.131 Exemption and accommodations in connection with coverage of preventive health services.

* * * * *

(b) *Eligible organizations.* An eligible organization is an organization that meets the criteria of paragraphs (b)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under § 147.130(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (b)(4) of this section, and the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization's applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owners' sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary of Labor or provide notice to the Secretary of Health and Human Services as described in paragraph (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) A closely held for-profit entity is an entity that—

(i) Is not a nonprofit entity;

(ii) Has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and

(iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity's self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (b)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity's shareholders, partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for-profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to the Department of Health and Human Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (b)(4)(iii) of this section.

* * * * *

(f) *Application to student health insurance coverage.* The provisions of this section apply to student health insurance coverage arranged by an eligible organization that is an institution of higher education as defined in 20 U.S.C. 1002 in a manner comparable to that in which they apply to group health insurance coverage provided in connection with a group health plan established or maintained by an eligible organization that is an employer. In applying this section in the case of student health insurance coverage, a reference to ''plan participants and beneficiaries'' is a reference to student enrollees and their covered dependents.

[FR Doc. 2015–17076 Filed 7–10–15; 11:15 am]

BILLING CODE 6325–64–P; 4150–28–P; 4120–01–P

FEDERAL REGISTER

Vol. 80 Tuesday,

No. 134 July 14, 2015

Part V

Department of Transportation

Federal Highway Administration

23 CFR Part 650

National Tunnel Inspection Standards; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 650

[Docket No. FHWA–2008–0038]

RIN 2125–AF24

National Tunnel Inspection Standards

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule establishes the National Tunnel Inspection Standards (NTIS) for highway tunnels. The NTIS require tunnel owners to establish a program for the inspection of highway tunnels, to maintain a tunnel inventory, to report the inspection findings to FHWA, and to correct any critical findings found during these inspections.

DATES: This final rule is effective August 13, 2015. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of August 13, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Hartmann, Office of Bridges and Structures, 202–366–4599; or Mr. Robert Black, Office of the Chief Counsel, 202–366–1359, Federal Highway Administration, 1200 New Jersey Ave. SE., Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., eastern time, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Executive Summary

I. Purpose of the Regulatory Action

The purpose of this final rule is to establish the NTIS for tunnel inspections consistent with the provisions of the Moving Ahead for Progress in the 21st Century Act (MAP–21), which includes requirements for establishing a highway tunnel inspection program, maintaining a tunnel inventory, and reporting to FHWA of inspection results and, in particular, critical findings, which are any structural or safety-related deficiencies that require immediate follow-up inspection or action. The NTIS apply to all structures defined as highway tunnels on all public roads, on and off Federal-aid highways, including tribally and federally owned tunnels.

Routine and thorough inspections of our Nation's tunnels are necessary to maintain safe operation and prevent structural, geotechnical, and functional failures. Data on the condition and operation of our Nation's tunnels is necessary in order for tunnel owners to make informed investment decisions as part of an asset management program for maintenance and repair of their tunnels. Recognizing that the safety and security of our Nation's tunnels are of paramount importance, Congress declared in MAP–21 that it is in the vital interest of the U.S. to inventory, inspect, and improve the condition of the Nation's highway tunnels. As a result of this declaration and the MAP–21 mandate found in 23 U.S.C. 144, FHWA establishes the NTIS.

II. Summary of the Major Provisions of the Regulatory Action in Question

The NTIS require the establishment of a National Tunnel Inventory (NTI); routine inspections of tunnels on all public roads, on and off Federal-aid highways, including tribally and federally owned tunnels; written reports to FHWA of critical findings, as defined in 23 CFR 650.305; training for tunnel inspectors; a national certification program for tunnel inspectors; and the timely correction of any deficiencies.

Section 650.503 establishes the applicability of the NTIS to all highway tunnels on all public roads as authorized by MAP–21.

Section 650.507 describes the organizational responsibilities associated with successful implementation of the NTIS. Tunnel inspection organizations are required to develop and maintain inspection policies and procedures, ensure that inspections are conducted in accordance with the proposed standards, collect and maintain inspection data, and maintain a registry of nationally certified tunnel inspection staff.

Section 650.509 establishes certain minimum qualifications for tunnel inspection personnel. A Program Manager shall be a registered Professional Engineer (P.E.) or have 10 years of tunnel or bridge inspection experience, and be a nationally certified tunnel inspector. The Team Leader shall be a nationally certified tunnel inspector and either be a registered P.E. with 6 months of tunnel or bridge inspection experience, or have 5 years of tunnel or bridge inspection experience or an appropriate combination of education and experience as detailed in the referenced section. This section also describes the requirements for national certification of inspection staff.

Section 650.511 establishes a minimum inspection frequency of 24 months for routine tunnel inspections. An owner is permitted to increase the frequency of inspection based on a risk analysis approach that considers such factors as tunnel age, traffic characteristics, geotechnical conditions, and known deficiencies. An owner does not need FHWA approval to increase the frequency of inspection. An owner is permitted to decrease the frequency of inspection after a written request that considers tunnel age, time from last major rehabilitation, tunnel complexity, traffic characteristics, geotechnical conditions, functional systems, and known deficiencies has been reviewed and commented on by FHWA.

Section 650.513 requires the establishment of a statewide, Federal agencywide, or tribal governmentwide procedure to ensure that critical findings, as defined in 23 CFR 650.305, are addressed in a timely manner. Owners are required to notify FHWA within 24 hours of identifying a critical finding and the actions taken to resolve or monitor that finding. This section also discusses inspection procedures for complex tunnels and functional systems, load rating of tunnels, quality assurance, and quality control.

Section 650.515 requires certain inventory data to be collected and reported for all tunnels subject to the NTIS within 120 days of the effective date of this rule. This data will be used to create a national inventory of tunnels that will provide a more accurate assessment of the number and condition of the Nation's tunnels.

III. Costs and Benefits

The FHWA anticipates that the benefits associated with this rulemaking will significantly outweigh the costs. The FHWA has only limited data regarding the number of highway tunnels in the Nation and the frequency and cost of their inspection. The FHWA received some data from a 2003 informal survey of tunnel owners.[1] Throughout this rulemaking, FHWA relied on the data received from that survey to develop estimates of the costs and benefits of this final rule. The FHWA expects that there may be some tunnels that could be covered by the expanded scope of this rulemaking that were not included in the survey's limited data set; however, we believe that those tunnels would be only a small fraction of the total cost and that the 2003 survey data provides a sufficient basis for FHWA's analysis.

The FHWA expects that the overall increase in tunnel inspection costs across the Nation will be modest, as the vast majority of tunnel owners already inspect at the 24-month interval required by the NTIS. The FHWA does

[1] See Background section II.D. for more information.

not have any information regarding the cost of fixing critical findings that are uncovered as a result of provisions in this rulemaking. Based on current data, only two tunnel owners, that together own 15 tunnels (bores), would be required to increase their current inspection frequency as a result of this final rule. The FHWA is taking this action because ensuring timely inspections of highway tunnels not only enhances the safe passage of the traveling public, but also protects investments in key infrastructure, as early detection of problems in tunnels will likely increase their longevity and lead to lower repair costs than problems found later. Inspections are vital to preventing tunnel collapses and closures, which often result in millions of dollars in repair and user fee costs.

Electronic Access and Filing

This document, the 2008 advance notice of proposed rulemaking (ANPRM), the 2010 notice of proposed rulemaking (NPRM), the 2013 supplemental notice of proposed rulemaking (SNPRM), and all comments received may be viewed online through the Federal eRulemaking portal at *http://www.regulations.gov*. The Web site is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: *https://www.federalregister.gov*.

Background

I. Need for Tunnel Inspection Standards

The majority of road tunnels in the United States were constructed during two distinct periods of highway system expansion. A significant number of these tunnels were constructed in the 1930s and 1940s as part of public works programs associated with recovery from the Great Depression. Another significant number were constructed for the developing Interstate Highway System in the 1950s and 1960s. As a result, most of these structures have exceeded their designed service lives and need to be routinely inspected to ensure continued safe and efficient operation.

The structural, geotechnical, and functional components and systems that make up tunnels deteriorate and corrode due to the harsh environment in which these structures are operated. As a result, routine and thorough inspection of these elements is necessary to collect the data needed to maintain safe tunnel operation and to prevent structural, geotechnical, and functional failures. As our Nation's tunnels continue to age, an accurate and thorough assessment of each tunnel's condition is critical to avoid a decline in service and maintain a safe, functional, and reliable highway system.

In addition to ensuring safety, it is also necessary to collect data on the condition and operation of our Nation's tunnels for owners to make informed investment decisions as part of a systematic, integrated approach to transportation asset management. Without such an approach, ensuring an accountable and sustainable practice of maintenance, preservation, rehabilitation, or replacement across an inventory of tunnels is a significant challenge. Data-driven asset management provides tunnel owners with a proven framework for long-term accountability and accomplishment.[2] The data collected must be robust enough to support investment decisions within a State and consistent enough to identify national trends in performance and link Federal transportation expenditures to programmatic results.

Timely and reliable tunnel inspection is vital to uncovering safety problems and preventing failures. When corrosion or leakage occurs, electrical or mechanical systems malfunction, or concrete cracking and spalling signs appear, they may be symptomatic of larger problems. The importance of tunnel inspection was demonstrated in the summer of 2007 in the I–70 Hanging Lake tunnel in Colorado when a ceiling and roof inspection uncovered a crack in the roof that compromised the structural integrity of the tunnel. This discovery prompted the closure of the tunnel for several months for needed repairs. The repairs prevented a potential catastrophic tunnel failure and loss of life. That failure could have resulted in a longer period of repairs, injuries, and death.

Unfortunately, loss of life was not avoided in Oregon in 1999. In January of that year, a portion of the lining of the Sunset Tunnel located near Manning (west of Portland) collapsed, killing an Oregon DOT employee. At the time of the collapse, the lining was being inspected after a heavy rain to ensure its safety in response to a report by a concerned traveler. The extent of deterioration in the lining had not been identified and regularly documented in previous inspections of the tunnel, which occurred variably. As a result, the lining had deteriorated to the point that the safety inspection after the rain event was sufficient to trigger the collapse. Following the accident, Oregon DOT reviewed their tunnel inspection program and identified a need to define what a tunnel is and establish criteria, procedures, and professional qualifications for tunnel inspection.

Inadequate tunnel inspection was again linked to a loss of life in Massachusetts in 2006. In July of that year, a portion of the suspended ceiling collapsed onto the roadway in the I–90 Central Artery Tunnel in Boston, killing a motorist. It also resulted in closure of this portion of the tunnel for 6 months while repairs were made, causing significant traffic delays and productivity losses. The National Transportation Safety Board (NTSB) stated in its accident investigation report that, ''had the Massachusetts Turnpike Authority, at regular intervals between November 2003 and July 2006, inspected the area above the suspended ceilings in the D Street portal tunnels, the anchor creep that led to this accident would likely have been detected, and action could have been taken that would have prevented this accident.'' [3] Among its recommendations, NTSB suggested that FHWA seek legislative authority to establish a mandatory tunnel inspection program similar to the National Bridge Inspection Standards (NBIS) that would identify critical inspection elements and specify an appropriate inspection frequency. Additionally, the DOT Inspector General (IG), in testimony before Congress in October 2007, highlighted the need for a tunnel inspection and reporting system to ensure the safety of the Nation's tunnels, stating that FHWA ''should develop and implement a system to ensure that States inspect and report on tunnel conditions.'' The IG went on to state that FHWA should establish rigorous inspection standards.[4]

More recently, inspection of ceiling panels in the westbound I–264 Downtown Tunnel in Portsmouth, Virginia, prevented a catastrophic failure. The Virginia DOT routinely performs an in-depth inspection of this tunnel at approximate intervals of 5 to 7 years. During an inspection in 2009,

[2] On February 20, 2015 at 80 FR 9231, FHWA issued an NPRM to implement the MAP–21 Asset Management provisions (23 U.S.C. 119(e)). Please see that NPRM for more information on the establishment of State asset management plans.

[3] ''Ceiling Collapse in the Interstate 90 Connector Tunnel Boston, Massachusetts July 10, 2006,'' Highway Accident Report, NTSB/HAR–07/02, July 10, 2006. An electronic format version is available at: *http://www.ntsb.gov/doclib/reports/2007/HAR0702.pdf.*

[4] The U.S. Department of Transportation, Office of the Inspector General, ''Challenges Facing the U.S. Department of Transportation, Fiscal Year 2008,'' October 2007, CC–2008–007. An electronic format version is available at: *http://www.oig.dot.gov/sites/dot/files/pdfdocs/Statement6_DOTAcitivies101507_508version.pdf.*

Virginia DOT personnel found aggressive corrosion of embedded bolts used to support the ceiling panels over the roadway. Upon further evaluation, it was determined that the ceiling panels needed to be removed to ensure the safety of the traveling public. The tunnel was closed for 6 consecutive weekends to perform this maintenance activity. If there had not been a timely inspection, the corrosion would have worsened and there would likely have been a collapse that could have caused death, injuries, or property damage, and complete closure of the tunnel for an extended period of time, resulting in significant productivity losses.

Most recently, on December 2, 2012, the suspended ceiling in Japan's Sasago Tunnel collapsed onto the roadway below and crushed several cars, resulting in the deaths of nine motorists. Early reports in the media citing Japanese officials indicated that the collapse was likely the result of the failure of the anchor bolts connecting the suspended ceiling to the tunnel roof. According to the Central Japan Expressway Company, which is responsible for the operation of the tunnel, those connections had not been thoroughly inspected due to issues with access.[5]

The FHWA estimates that tunnels represent nearly 100 miles—approximately 517,000 linear feet—of Interstates, State routes, and local routes. Tunnels such as the Central Artery Tunnel in Massachusetts, the Lincoln Tunnel in New York, and the Fort McHenry and the Baltimore Harbor Tunnels in Maryland are a vital part of the national transportation infrastructure. These tunnels accommodate huge volumes of daily traffic, contributing to the Nation's mobility. For example, according to the Port Authority of New York and New Jersey, the Lincoln Tunnel carries approximately 120,000 vehicles per day, making it the busiest vehicular tunnel in the world. The Fort McHenry Tunnel handles a daily traffic volume of more than 115,000 vehicles. Any disruption of traffic in these or other highly traveled tunnels would result in a significant loss of productivity and have severe financial impacts on a large region of the country.

On October 29, 2012, flooding caused by Hurricane Sandy led to the closure of many of the vehicular, transit, and rail tunnels in the New York City metropolitan area. Although it is difficult to quantify the total economic impact of these tunnel closures, Amtrak reported an operational loss of approximately $60 million due to the closures of four of its tunnels in the region.[6] These closings, although the result of an extreme event and not a structural or functional safety issue, demonstrate the value of the continued operation of tunnels. Because of their importance to local, regional, and national economies and to our national defense, it is imperative that tunnels are properly inspected to ensure the continued safe passage of the traveling public and commercial goods and services.

Of particular concern is the possibility of a fire emergency in one of our Nation's tunnels. Numerous domestic and international incidents demonstrate that tunnel fires often result in a large number of fatalities. In April 1982, seven people lost their lives in the Caldecott tunnel, which carries State Route 24 between Oakland and Orinda, California, when a truck carrying flammable liquid crashed and subsequently collided with other vehicles. In October 2001, 11 people were killed when a fire erupted in the Gotthard tunnel in Switzerland following a head-on collision. In 2000, 162 people were killed when a fire started in the Kaprun train tunnel in Austria. In 1999, 39 people died when a truck caught fire in the Mont Blanc tunnel on the French-Italian border. Tests of 26 tunnels in 13 European countries in 2010 by the European Tunnel Assessment Programme indicated a number of inadequacies related to fire safety, including missing hydrants, no barriers to close the tunnel, inadequate lighting, and insufficient escape route signs.[7] National inspection standards are needed to ensure lights, signs, barriers, and tunnel walls are inspected and fire suppression systems are maintained in safe and operable condition. Such safety features are of critical importance in the event of a fire emergency.

Timely inspections of highway tunnels not only enhance the safe passage of the traveling public, they also contribute to the efficient movement of goods and people and to millions of dollars in fuel savings. For example, the Eisenhower/Johnson Memorial Tunnels, located west of Denver on I–70, facilitate the movement of people and goods from the eastern slope to the western slope of the Rocky Mountains. The Colorado DOT estimates that the public saves 9.1 miles by traveling through these tunnels instead of over U.S. Highway 6, Loveland Pass. In 2000, approximately 28,000 vehicles traveled through the tunnels per day, which is equal to 10.3 million vehicles per year.[8] Accordingly, FHWA estimates that by traveling through the Eisenhower/Johnson Memorial Tunnels, the public saved approximately 90.7 million miles of travel and millions of dollars in associated fuel costs in 2000. These tunnels help to expedite the transport of goods and people, prevent congestion along alternative routes, and save users money and fuel. If these tunnels were closed due to a collapse or other safety hazard, the economic effects would be considerable.

While the above examples do not constitute a comprehensive list of issues resulting from lack of inspections, they do demonstrate why routine and thorough tunnel inspection is vital to uncovering safety problems and preventing catastrophic failure of key tunnel components.

II. Research Related to Tunnel Inspections

In addition to the focus Congress has given to tunnel inspection, the NTSB, State DOTs, the IG, FHWA, and others have conducted extensive research related to tunnel design, construction, rehabilitation, and inspection. The following partial list of those activities and projects related to tunnel safety all underscore the need to develop consistent and reliable inspection standards.

A. *Underground Transportation Systems in Europe: Safety, Operations, and Emergency Response.*[9] In 2005, FHWA, the American Association of State Highway and Transportation Officials (AASHTO), and the National Cooperative Highway Research Program (NCHRP), sponsored a study of equipment, systems, and procedures used in the operation and management of tunnels in 9 European countries (Austria, Denmark, France, Germany, Italy, Norway, the Netherlands, Sweden, and Switzerland). One objective of this scan was to identify best practices, specialized technologies, and standards used in monitoring and inspecting the structural elements and operating

[5] *http://abcnews.go.com/blogs/headlines/2012/12/japan-orders-immediate-inspections-after-deadly-tunnel-collapse/.*

[6] *http://www.amtrak.com/ccurl/920/456/Amtrak-Requests-.pdf.*

[7] *http://www.independent.co.uk/news/world/europe/new-tunnel-rules-to-be-introduced-after-high-death-toll-7566220.html.*

[8] See *http://www.coloradodot.info/travel/eisenhower-tunnel/eisenhower-tunnel-interesting-facts.html.*

[9] Federal Highway Administration, ''Underground Transportation Systems in Europe: Safety, Operations, and Emergency Response,'' Office of International Programs, FHWA–PL–06–016, June 2006. An electronic format version is available at: *http://international.fhwa.dot.gov/uts/uts.pdf.*

equipment of roadway tunnels to ensure optimal performance and minimize downtime for maintenance or rehabilitation. As a result of the study, the international team recommended that the United States implement a risk-management approach to tunnel inspection and maintenance. In regard to current practices, the report states that ''only limited national guidelines, standards, or specifications are available for tunnel design, construction, safety inspection, traffic and incident management, maintenance, security, and protection against natural or manmade disasters.'' The report also notes that only ''through knowledge of the systems and the structure gained from intelligent monitoring and analysis of the collected data, the owner can use a risk-based approach to schedule the time and frequency of inspections and establish priorities.''

B. *NCHRP Project 20–07/Task 261, Best Practices for Implementing Quality Control and Quality Assurance for Tunnel Inspection.*[10] In response to NTSB's preliminary safety recommendations resulting from the I–90 Central Artery Tunnel partial ceiling collapse investigation in Boston, FHWA and AASHTO initiated this NCHRP research project. The objective of the project was to develop guidelines for owners to implement quality control and quality assurance practices for tunnel inspection, operational safety and emergency response systems testing, and inventory procedures to improve the safety of highway tunnels. During the course of the project, the researchers found that tunnel owners in the United States inspect their structures at variable intervals ranging from 1 week to 6 years. The report states that ''[s]ince there is currently no consistency in the tunnel inspection techniques used by the various tunnel owners, implementing NTIS and developing a tunnel inspector training program on applying those standards will be vital to ensuring a consistent tunnel inspection program for all tunnels across the nation.''

C. *Best Practices for Roadway Tunnel Design, Construction, Maintenance, Inspection, and Operations.*[11] This domestic scanning tour was conducted during August and September 2009, and done in partnership with FHWA, AASHTO, and NCHRP to determine if a need existed for national tunnel inspection standards and an NTI. The scan focused on the inventory criteria used by highway tunnel owners; highway tunnel design and construction standards used by State DOTs and other tunnel owners; maintenance and inspection practices; operations, including safety, as related to emergency response capability; and specialized tunnel technologies. The scan team found that the most effective tunnel inspection programs were developed from similar bridge inspection programs. It was determined that tunnel owners often use bridge inspectors to inspect their tunnels because bridges and tunnels are designed and constructed with similar materials and methods, exposed to similar environments, and can be reliably inspected with similar technologies. As a result, the scan team recommended that the development of a tunnel inspection program be as similar as possible to the current bridge inspection program to further capitalize on the success of the standards for bridge inspection established through the NBIS.

D. *2003 Informal FHWA Survey.* In 2003, FHWA conducted an informal survey to collect information about the tunnel inventory, maintenance practices, inspection practices, and tunnel management practices of each State. Of the 45 highway tunnel owners surveyed, 40 responses were received. The survey results suggest that there are approximately 350 highway tunnels (bores) in the Nation and they are currently inspected by their owners at intervals ranging from 1 day to 10 years.[12] The average inspection interval for the 37 responses that included data on this measure was a little over 24 months (2.05 years).

E. *Highway and Rail Transit Tunnel Inspection Manual (HRTTIM).* Recognizing that tunnel owners are not required to inspect tunnels routinely and inspection methods vary among entities that inspect tunnels, FHWA and the Federal Transit Administration developed the HRTTIM for the inspection of tunnels in 2003. These guidelines, updated in 2005,[13] outline recommended procedures and practices for the inspection, documentation, and priority classification of deficiencies for various elements that comprise a tunnel.

III. NTIS

Recognizing that the safety and security of our Nation's tunnels are of paramount importance and pursuant to the legislative mandate in MAP–21, FHWA developed the NTIS. The FHWA modeled the NTIS after the existing NBIS, located at 23 CFR part 650, subpart C. The more than 40-year history of the NBIS has enabled the States to identify and manage deterioration and the emergence of previously unknown problems in their bridge inventory; evaluate those structures properly; and make the repairs needed to mitigate the escalating cost of repairing or replacing older bridges. Similar needs and concerns exist for the owners of aging highway tunnels. The NBIS provided a starting point for designing a national tunnel inspection program. The FHWA has therefore modeled the NTIS after the NBIS, and will make appropriate changes in the NTIS as it gains more experience with tunnel inspections and safety problems. The NTIS will be added under subpart E of 23 CFR part 650—Bridges, Structures, and Hydraulics.

The NTIS require the proper safety inspection and evaluation of all tunnels. The NTIS are needed to ensure that all structural, mechanical, electrical, hydraulic, and ventilation systems and other major elements of our Nation's tunnels are inspected and tested on a regular basis. The NTIS will also enhance the safety of our Nation's highway tunnels by making tunnel inspections consistent across the Nation.

The NTIS will create a national inventory of tunnels that will result in a more accurate assessment and provide the public with a more transparent view of the number and condition of the Nation's tunnels. Tunnel information will be made available to the public in the same way as bridge data contained in the National Bridge Inventory (NBI). The tunnel inventory data will also be available in the annual report to Congress required by MAP–21. The tunnel inventory data will allow FHWA to track and identify any patterns of tunnel deficiencies and facilitate repairs

[10] National Cooperative Highway Research Program, ''Best Practices for Implementing Quality Control and Quality Assurance for Tunnel Inspection,'' Prepared for the AASHTO Technical Committee for Tunnels (T–20), NCHRP Project 20–07, Task 261 Final Report, October 2009. An electronic format version is available at: *http://onlinepubs.trb.org/onlinepubs/nchrp/docs/NCHRP20–07(261)_FR.pdf.*

[11] National Cooperative Highway Research Program, ''Best Practices for Roadway Tunnel Design, Construction, Maintenance, Inspection, and Operations,'' Prepared for the AASHTO Technical Committee for Tunnels (T–20), NCHRP Project 20–68A Scan 09–05 Final Report, April 2011. An electronic format version is available at: *http://onlinepubs.trb.org/onlinepubs/nchrp/docs/NCHRP20-68A_09-05.pdf.*

[12] The definition of a highway tunnel used in the 2003 survey pertained to a single ''bore'' or constructed shape, but did not pertain to a given tunnel name (*i.e.* a tunnel such as the Holland tunnel in New York actually consists of two tunnels, one in each direction).

[13] The Federal Highway Administration/Federal Transit Administration ''Highway and Rail Transit Tunnel Inspection Manual,'' 2005 edition, is available in electronic format at: *http://www.fhwa.dot.gov/bridge/tunnel/management/.*

by States to ensure the safety of the public. Tunnel owners will also be able to integrate tunnel inventory data into an asset management program for maintenance and repairs of their tunnels. The data collection requirements in the NTIS are consistent with the performance-based approach to carrying out the Federal-aid highway program established by Congress in MAP–21. These requirements will fulfill the congressional directive to establish a data-driven, risk-based approach for the maintenance, replacement, and rehabilitation of highway tunnels. Such an approach will help to ensure the efficient and effective use of Federal resources.

The NTIS will ensure that tunnels are inspected by qualified personnel by creating a certification program for tunnel inspectors and a comprehensive training course.

IV. Summary of Significant Changes Made in the Final Rule

The final rule was revised in response to comments received on the SNPRM (78 FR 46118). The following paragraphs summarize the most significant of those changes. Editorial or slight changes in language for consistency are not addressed in this section.

In § 650.505, a definition for *end-of-course assessment* was added. This definition was needed to clarify the qualification requirements for Program Managers and Team Leaders in § 650.509.

Section 650.507 was retitled *Tunnel Inspection Organization Responsibilities.* Since the provisions of this section deal primarily with the responsibilities of a tunnel inspection organization rather than the structure and mechanisms of that organization, the title was amended to better reflect the content.

Language was added to § 650.507(e)(2) to explicitly state that the Tunnel Inspection Organization is responsible for managing critical findings. The MAP–21 assigns this responsibility and the language in this section was added to emphasize that requirement (23 U.S.C. 144(h)(2)(D) and 144(h)(3)(B)).

Section 650.507(e)(4) was added to respond to comments received on § 650.509 *Qualifications of Personnel.* This new paragraph was added to ensure that adequately qualified personnel inspect complex tunnels or tunnels with distinctive features or functions.

In § 650.509, the qualifications for Program Manager and Team Leader have been significantly altered in response to comments received on the SNPRM. The majority of the commenters requested relief from the requirement that Program Managers and Team Leaders must have a P.E. license in addition to experience and training requirements. With only minor differences, the general qualifications for Program Managers and Team Leaders now closely mirror those for the same positions under the NBIS. Under the final rule, a P.E. license is only required for Team Leaders if an FHWA-approved process determines that the qualification is necessary to adequately and appropriately inspect a tunnel that is complex or has distinctive features or functions. The FHWA eliminated the training and national certification requirements for inspectors other than Program Managers and Team Leaders. Instead, the appropriate training for those inspectors is left to the discretion of the responsible States, Federal agencies, and tribal governments.

In § 650.511, the format of the *Inspection Date* was altered in response to comments. Some owners believe that the four-digit year should be captured in the NTI records. The FHWA concurs and the required format is now MM/DD/YYYY.

In § 650.513, in response to several comments, the requirement to conduct a load rating within 1 month of the completion of an inspection was extended to 3 months, and the requirement to post a tunnel within 48 hours of the determination of need was extended to 30 days. If an inspection determined that deterioration had significantly changed the capacity of an element, it is expected that a load rating would be conducted earlier than 3 months in order to ensure the safety of the tunnel. Likewise, if an inspection determined that the posting load was significantly below the legal load as to be a safety issue, it is expected that posting would occur earlier than 30 days. These are examples of critical findings that are required to be addressed under this rule.

A number of non-substantive changes were made to the regulatory text for clarity and formatting purposes.

Regulatory History

The FHWA issued an ANPRM on November 18, 2008, (73 FR 68365) to solicit public comments regarding 14 categories of information related to tunnel inspections to help FHWA develop the NTIS. The FHWA reviewed and analyzed the comments received in response to the ANPRM and published an NPRM on July 22, 2010 (75 FR 42643). In the NPRM, FHWA proposed establishing the NTIS based in part on the comments received in response to the ANPRM. The FHWA published an SNPRM on July 30, 2013, (78 FR 46118) in order to update NTIS for the comments received on the NPRM and incorporate the requirements mandated in MAP–21. The FHWA received comments on the SNPRM from 26 commenters, including: 16 State DOTs (Alabama, Alaska, California, Florida, Michigan, Missouri, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Virginia, and Washington); 1 engineering consulting firm (Architecture, Engineering, Consulting, Operations, and Maintenance Technology Corporation (AECOM)); 4 organizations (AASHTO, American Council of Engineering Companies (ACEC), National Society of Professional Engineers (NSPE), and Professional Engineers in California Government (PECG)); 2 local authorities (the Maryland Transportation Authority (MdTA) and Metropolitan Transportation Authority Bridges and Tunnels of New York City (MTABT); 2 private citizens (William Wright and John Williams); and 1 anonymous commenter. This final rule addresses the comments received on the SNPRM and establishes the NTIS.

Section-by-Section Analysis

650.501 Purpose

The California DOT commented that a regulation focused on in-service inspection will not prevent another occurrence of the Massachusetts ''Big Dig'' failure.

The FHWA Response: With regard to the ''Big Dig'' failure, the NTSB investigation found that ''had the Massachusetts Turnpike Authority, at regular intervals between November 2003 and July 2006, inspected the area above the suspended ceilings in the D Street portal tunnels, the anchor creep that led to this accident would likely have been detected, and action could have been taken that would have prevented this accident.'' [14] The FHWA concurs with NTSB that timely tunnel routine (in-service) inspections are key to preventing tunnel failures such as the Big Dig failure.

The Missouri DOT commented that although it seems logical to make the NTIS similar to the NBIS, tunnels are unique structures and should be treated differently from bridges.

The FHWA Response: The FHWA did use the NBIS as a starting point in developing the NTIS. The NBIS have proven successful in ensuring the safety

[14] NTSB, Ceiling Collapse in the Interstate 90 Connector Tunnel 103 (2007), *http://www.ntsb.gov/doclib/reports/2007/HAR0702.pdf.*

of the Nation's bridges for several decades. However, FHWA recognizes the difference between tunnels and bridges and portions of the NTIS depart from the companion provisions of the NBIS where necessary.

650.503 Applicability

The Alaska Department of Transportation and Public Facilities commented that owners should decide whether a structure will be defined as a tunnel, culvert, or bridge.

The FHWA Response: Where a structure could be defined as either a bridge or a tunnel, as in the case of a ''tunnel'' that is used to support a roadway, this regulation gives the structure's owner the discretion to determine how it will be classified (tunnel, culvert, or bridge). Under such a scenario the structure may be classified as either a tunnel or a bridge, but not both. Structures classified as bridges would be subject to the NBIS, while those structures classified as tunnels would be subject to the NTIS. Bridge-length culverts are classified as bridges and are also subject to the NBIS. When a structure functions solely as a tunnel, FHWA expects that it will be defined as a tunnel.

650.505 Definitions

American Association of State Highway and Transportation Officials (AASHTO) Manual for Bridge Evaluation. The FHWA changed this definition so that it's consistent with the incorporation be reference section. This change allows the FHWA to require the current version of the document to be utilized.

Complex tunnel. The AASHTO and the Ohio, Pennsylvania, and New York DOTs commented that the definition of ''complex tunnel'' is too vague and that a clearer definition is needed. They suggest adding additional features like geometrics, structural criteria, and/or inclusion of functional systems to better define a ''complex tunnel.'' The Missouri DOT suggested that there is no need to define ''complex tunnel'' since all tunnels are complex by their nature and will require an individual approach for inspection. The Oregon DOT suggested that the definition include tunnels with multiple traffic levels, multiple traffic directions, on/off ramps, and ventilation systems that have automated controls or fire suppression systems.

The FHWA response: The FHWA believes the modified version of the AASHTO T–20 definition is adequate to capture the structures targeted by this regulation without overcomplicating the determination of what is or is not a tunnel.[15] The current definition clearly states that a structure shall be inspected and reported only once under either the NBIS or the NTIS, but not both. The FHWA believes that including categories for tunnels, or additional detailed language on functional systems or type of construction, would narrow what is intended to be a fairly broad definition. Also, the definition for complex tunnel addresses advanced or unique structural elements or functional systems.

Critical findings. The Texas DOT suggested that FHWA define ''critical findings'' for tunnels in order to ensure national consistency. Ohio DOT suggested considering a condition coding of '2' or less as the definition of a ''critical finding.''

The FHWA response: The FHWA believes it is not possible to create an all-inclusive list of issues that could exist in tunnels and that adding additional language would limit the definition of a ''critical finding.'' Tunnels will be inspected using an element-level methodology included in the Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual and, as a result, will not generate condition codes.

End-of-course assessment. As outlined in the below discussion, FHWA has significantly altered the qualification requirements for Program Managers and Team Leaders in response to comments. As a result, it became necessary to include a definition for ''end-of-course assessment'' as this phrase is now used in the determination of the qualifications for a Program Manager and Team Leader. The term ''end-of-course assessment'' means a comprehensive examination given to students after the completion of a training course.

Inspection Date. Washington State DOT questioned whether the official Inspection Date is the first day or last day of the inspection if the inspection lasts for more than 1 day. Oregon DOT and AASHTO noted that some States record the Inspection Date as the date the inspection was completed.

The FHWA response: Irrespective of the duration of the inspection, the ''Inspection Date'' is the date, established by the Program Manager, on which the inspection begins.

Load rating. The Ohio DOT suggested that under the definition for ''load rating,'' ''there are non-vehicular loads the tunnel should account for *i.e.* rock impact, suspended systems.'' The AASHTO expressed concern that the definition does not include the evaluation of ''tunnel ceiling hangers or conduit attachments for dead load of the ceiling itself and for live load produced by trucks pushing air thru the tunnels that creates a compression force on the hangers.''

The FHWA response: The current definition of ''load rating'' in 23 CFR 650.305 is ''the determination of the live load carrying capacity of a bridge using bridge plans and supplemented by information gathered from a field inspection.'' The current definition in the AASHTO Manual for Bridge Evaluation is ''the determination of the live-load carrying capacity of an existing bridge.'' As the proposed definition is consistent with 23 CFR 650.305 and the AASHTO Manual, FHWA declines the changes suggested by AASHTO and Ohio DOT. In addition, the commenters' suggested changes would effectively incorporate structural evaluation, which is separate from load rating. Structural evaluation can be required by the owner at any time and should occur automatically if damage or deterioration with the potential to affect performance is detected through an inspection.

Routine permit load. Ohio DOT suggested that the definition for ''routine permit load'' should also include ''geometrics taking into consideration the limited size, curvature, and traffic control associated with permitted vehicles through tunnels.''

The FHWA response: The FHWA believes the definition in this rule is consistent with the definition used in the NBIS and is commonly accepted and understood within the bridge and tunnel community. Routine permit loads need to be defined for the purposes of this rule because they are used to conduct load ratings. While factors like geometrics and traffic control are important considerations for evaluating safe passage of vehicles in tunnels, for the purposes of defining routine permit load, they are unnecessary.

Tunnel. California and Ohio DOTs suggested that the definition of ''tunnel'' include such physical parameters as linear length, length to width, forced ventilation to limit carbon monoxide buildup, fire suppression systems, structures bored or mined through undisturbed material, emergency egress, and depth of cover. They suggested that the definition needs to be explicit to ensure public entities are able to consistently distinguish the difference between a tunnel, bridge, and culvert. The South Dakota DOT questioned

[15] ''AASHTO T–20'' refers to the American Association of State Highway and Transportation Officials Highway Subcommittee on Bridges and Structures, Technical Committee T–20 Tunnels.

whether FHWA intends for the tunnel inventory to include ''short/small hard rock unlined tunnels that have no man made structural components.'' Tennessee DOT suggested that the definition ensures a structure is exempt from the tunnel inspection program only if it is being inspected under the NBIS as a full bridge record, as opposed to only an underpass record. They also suggested that FHWA include a minimum length in the definition. Tennessee DOT explained that ''the length should be selected such that it is large enough to exclude normal underpass structures but will include any structure that is long enough to require the special attributes (lighting, ventilation, etc.) of true tunnels.'' They recommended a length of 50 meters. Florida DOT interpreted the proposed definition of ''tunnel'' to say that if a tunnel is inspected and inventoried as part of their bridge inspection program, then they don't have to include that tunnel in a tunnel inspection program.

The FHWA response: The FHWA believes the modified version of the AASHTO T–20 definition is adequate to capture the structures targeted with this proposed regulation without overly complicating the determination of what constitutes a tunnel. Consistent with the majority of the comments received on the ANPRM and the NPRM, this definition does not include a minimum length. The FHWA believes that including categories for tunnels, or additional detailed language on functional systems or type of construction, would narrow what is intended to be a broad definition. Also, the definition for ''complex tunnel'' addresses advanced or unique structural elements or functional systems. Finally, if a State DOT classifies a structure as a tunnel, it will need to be inspected and inventoried under NTIS. If a structure serves a dual purpose and is already being inspected and inventoried under NBIS, it will be the State DOT's decision to reclassify the structure as a tunnel.

Washington State DOT noted that the ''tunnel'' definition ''does not make reference to load carrying element. In fact it states ''bridges'' are covered separately under the NBI.'' The Washington State DOT suggested that FHWA modify the definition to clarify what the load rating requirements are referring to, and whether the load ratings for traffic carrying elements will be reported under NTIS or NBIS.

The FHWA Response: Within the NTIS regulations, the definition of load rating includes the phrase ''the determination of the vehicular live load carrying capacity within or above the tunnel.'' As the commenter notes, these structures do not include bridges or culverts. Therefore these elements will be reported to the NTI.

Tunnel inspection experience. The Washington State DOT noted that ''tunnel inspection experience'' should include experience in similar fields such as bridge inspection. The Ohio DOT suggested that the definition for tunnel inspection experience is too restrictive and will encourage entities to code potential tunnels as bridges.

The FHWA response: The FHWA added language in the SNPRM to clarify the criteria to be used in evaluating years of experience under § 650.509(a), including: The relevance of the individual's actual experience, exposure to problems or deficiencies common in the types of tunnels inspected by the individual, complexity of tunnels inspected relative to the individual's skills and knowledge, and the individual's understanding of data collection needs and requirements. Under the NTIS, tunnel inspection experience is only one of the requirements used to evaluate the eligibility of a Program Manager or Team Leader.

Oregon DOT and AASHTO noted that owner agencies have very few tunnels in comparison to bridges, making it unlikely that tunnel inspection will be a full time job in most agencies. They raised their concern that, as proposed, the experience requirement would cause inspection outsourcing. To address this, they suggested modifying the definition of ''tunnel inspection experience'' to make participation in a single tunnel inspection per calendar year sufficient.

The FHWA response: The FHWA believes that flexibility is built into the regulation in that it only requires the individual to actively participate in the performance of tunnel inspections in accordance with the NTIS, in either a field inspection, supervisory, or management role. It is expected that the Program Manager use his or her judgment in the evaluation of whether a Team Leader has reasonable experience in any given year to satisfy that year's experience criteria.

Tunnel-specific inspection procedures. Virginia DOT commented that ''written documentation should not be required for damage or special inspections.'' Oregon DOT and AASHTO expressed concern that if this requirement is not limited, FHWA could impose requirements for maintenance, drainage, operational, damage, or special inspections that would greatly restrict an owner's ability to manage and operate their tunnels.

The FHWA response: The FHWA agrees that it would be difficult to write specific procedures for any damage incident that could occur in a tunnel or special inspection that would be necessary for tunnel components. However, general guidance should be included in each structure inspection procedure to address how the inspectors should inspect and document a damage or special inspection of deficient tunnel components.

650.507 Tunnel Inspection Organization Responsibilities

The PECG commented that they ''firmly believe that the inspection process is inherently governmental'' and that the regulation should ''clearly state that a State is required to use their own professional staff to perform tunnel inspection functions unless the State lacks its own current or obtainable professional staff with the qualifications and capacity to perform the inspections.''

The FHWA Response: The final rule includes the qualification requirements for personnel who will manage, plan, and conduct tunnel inspections. The FHWA is not in a position to determine the most efficient and effective way for an owner to identify the personnel needed to meet those qualifications. Therefore, owners will need to make individual decisions based on the best use of their program resources.

Michigan DOT questioned whether this final rule would apply to privately or locally owned tunnels and, if so, whether the State program manager be responsible for inventory and inspection according to NTIS.

The FHWA Response: The MAP–21 legislation mandates that the NTIS apply to all highway tunnels. Therefore, if a privately or locally owned tunnel not owned by a Federal agency or tribal government services a public roadway, then it is subject to this final rule and the State DOT is ultimately responsible for the inspection and inventory of that tunnel.

Ohio DOT noted that State law does not give the Ohio DOT the authority to inspect, or cause to be inspected, locally owned tunnels. The AASHTO and Oregon DOT commented that some State laws do not allow the State DOT to conduct these inspections unless there is an executed agreement with the local owner.

The FHWA Response: This requirement is similar to the long standing requirement for the inspection of bridges under the NBIS. Under 23 U.S.C. 302, a State DOT is required to have adequate powers to fulfill its duties. If the current legal or regulatory

authority does not exist within a State to carry out this responsibility, the State DOT should seek that authority through the appropriate legislative process.

New York State DOT commented that many large tunnels are locally owned and suggested that FHWA deal directly with those owners instead of with the State highway agencies. New York State DOT also commented that requiring a State that owns a small number of small tunnels to establish a Tunnel Inspection Organization is a ''waste of resources, ineffective, and unnecessary.'' Ohio and Missouri DOTs also commented that States with a small number of tunnels should not be required to have a Program Manager or establish a Tunnel Inspection Organization, respectively.

The FHWA Response: Under 23 U.S.C. 302, FHWA's primary relationship in a State is with the State DOT. The State DOT maintains the primary relationship with the local owners within its borders. As such, the State DOT is in the best position to manage the inspection and inventory of locally owned tunnels. For States that have a small number of tunnels and cannot easily incorporate a tunnel inspection organization into their bridge inspection organization, it might be more effective for the State DOT to contract out many of the elements of a Tunnel Inspection Organization to another party. Although the delegation of some functions is permitted under this final rule, the State DOT retains all of the responsibilities detailed in the regulation.

Florida, Missouri, Texas, Michigan, New York State, and Virginia DOTs and AECOM questioned whether it was realistic, feasible, or necessary for a State DOT to maintain a registry of nationally certified tunnel inspectors. Several suggested that FHWA or another nationally recognized organization assume the responsibility. Virginia DOT also commented that the registry should include an inspector's current organizational information.

The FHWA Response: FHWA believes it is important for each State DOT to maintain a State-specific registry of certified inspectors who perform or have performed inspections on their tunnels. There are a number of reasons that each State should maintain this registry. The registry can be used to communicate with inspectors who work in that State to announce such things as anticipated work, training requirements, and training opportunities. State-specific requirements for inspectors can be incorporated and data quality is more easily maintained at the State level. Also, information affecting the good standing of any inspector would be local. With regard to the registry containing an inspector's organizational information, FHWA intended the requirement for the registry to contain an inspector's contact and organizational information.

Washington DOT questioned whether the requirement that the nationally certified tunnel inspector registry include a method to positively identify each inspector means that the registry should include photo identification.

The FHWA Response: FHWA did not intend to imply that a photograph was required for positive identification of an inspector. The FHWA also does not intend to dictate what method is used by a State DOT in fulfilling this requirement. However, a unique numbering system that positively ties an individual to a certification record would satisfy this requirement.

New York State DOT commented that clarification was needed regarding the collection of information that may affect the good standing of an inspector. They note that maintaining this information may also subject the State DOT to unnecessary legal exposure.

The FHWA Response: It is the intent of FHWA to ensure that all inspectors meet the requirements of national certification and that they have not previously demonstrated behavior that could call into question whether the inspector could be trusted to adequately perform all assigned inspection activities. The level of detail needed in the information collected to challenge or negate an inspector's good standing is left to the judgment of the State DOT.

The AASHTO and Oregon DOT commented that some States may have specific requirements for tunnel inspectors that are more restrictive or robust than national standards, and it would be an unnecessary burden to maintain two separate lists of inspectors—one for those meeting State requirements and one for those meeting national requirements.

The FHWA Response: It is not the intent of FHWA to require States to maintain a Federal-specific registry of certified tunnel inspectors. As long as the registry used by the State DOT fulfills the requirements of this regulation, it may also be used to maintain State specific information about each inspector.

650.509 Qualifications of Personnel

California, Texas, South Dakota, Michigan, Missouri, and Pennsylvania DOTs commented that requiring the Program Manager to have 10 years of tunnel inspection experience, be a P.E., and be a nationally certified tunnel inspector is excessive and cautioned that many States do not have staff that meet these requirements. Texas DOT recommended requiring 5 years of tunnel inspection experience in combination with a P.E. license. The MdTA supported the requirement that a Program Manager have a P.E. license. Florida DOT also supported the requirement for Program Managers to have a P.E. license but thought 10 years of inspection experience was excessive and preferred a requirement for 1 or 2 years of inspection experience. Ohio, Alaska, and New York State DOTs and AASHTO requested that consideration be given to add an experience component to allow non-P.Es. to perform the Program Manager role, similar to the NBIS. Another consideration offered by South Dakota DOT was that qualification requirements for a Program Manager be risk-based, depending on the complexity of an owner's tunnels. The MTABT commented that in addition to the P.E. license, 10 years of tunnel or bridge inspection experience, and comprehensive training, the Program Manager should have extensive experience in tunnel design and tunnel construction.

The FHWA Response: The FHWA has reconsidered the requirement that a Program Manager be a P.E. Recognizing the success that the NBIS has had using Program Managers qualified by experience in lieu of a P.E., the qualifications for a Program Manager in NTIS are now similar to those in the NBIS. A Program Manager shall, at a minimum, be a registered Professional Engineer or have 10 years of tunnel or bridge inspection experience, be a nationally certified tunnel inspector, and be able to determine the minimum qualifications for a Team Leader.

Alabama, Alaska, California, Missouri, New York State, North Carolina, and Pennsylvania DOTs and AASHTO commented that the proposed P.E. requirement for Team Leaders, in addition to tunnel inspection experience and inspector certification, is too restrictive and that the requirements for Team Leaders should mirror those of the NBIS. The MdTA agreed that the Team Leader should be required to have a P.E. Several States commented that the P.E. requirement would preclude in-house inspectors who have gained knowledge and experience from performing tunnel inspections or are seasoned bridge inspectors from filling these positions.

The FHWA Response: The FHWA has reconsidered the P.E. license requirement proposed for Team Leaders. Recognizing the success that the NBIS has had using Team Leaders qualified

by experience in lieu of a P.E. license, the qualifications for a Team Leader in NTIS are now similar to those in NBIS. However, FHWA added an additional requirement that requires a Program Manager to determine when a Team Leader who is leading the inspection of a complex tunnel or a tunnel with distinctive features or functions must have a P.E. license.

Washington State DOT commented that the proposed rule should require a minimal level of prior inspection experience to become a lead inspector.

The FHWA Response: The FHWA agrees that Team Leaders should have prior inspection experience and has added the requirement to the final rule. Team Leaders are now required to have either a P.E. license and at least 6 months of inspection experience, 5 years of inspection experience, or a combination of education, certification with 2 years of inspection experience.

The MdTA commented that any mechanical or electrical engineers supporting a tunnel inspection should only need their P.E. license and any discipline-specific certifications, and should not be required to be nationally certified tunnel inspectors. The MdTA commented further that the discipline-specific staff supporting an inspection should just know how to perform their job (InterNational Electrical Testing Association testing for example) and should not be required to be familiar with tunnel inspection in general. Similarly, Missouri DOT noted that inspectors of functional systems should not be required to be nationally certified tunnel inspectors.

The FHWA Response: The FHWA agrees with the comments and has limited the requirement for national certification as a tunnel inspector to the Program Manager and Team Leader.

Washington State DOT questioned whether a Team Leader for unlined tunnels will need a P.E. license in the field of geotechnical engineering.

The FHWA Response: The FHWA does not believe it necessary to identify the discipline of a P.E. license since license holders are ethically bound to practice engineering only in their area of expertise. However, under the provisions of the final rule, the Program Manager will determine whether a Team Leader mush have a P.E. license and any additional requirement of that license in accordance with the FHWA-approved process developed by the Tunnel Inspection Organization. The definition for Professional Engineer in section 650.505 of the rule emphasizes that a P.E. is limited to practicing within their area of expertise. Further, FHWA believes it is the responsibility of the Team Leader to assemble a team of inspectors with appropriate expertise and experience to inspect the various elements, components, and systems that comprise the tunnel.

The ACEC expressed support for requiring both Program Managers and Team Leaders to have a P.E. license.

The FHWA Response: The FHWA has reconsidered the requirement that a Program Manager and a Team Leader must be a P.E. Recognizing the success that the NBIS has had using Program Managers and Team Leaders qualified by experience in lieu of a P.E., the qualifications for a Program Manager and a Team Leader in NTIS are now similar to those in the NBIS. However, FHWA added an additional requirement that requires a Program Manager to determine when a Team Leader who is leading the inspection of a complex tunnel or a tunnel with distinctive features or functions must have a P.E. license.

Missouri, Oregon, and Washington State DOTs and NSPE suggested that the requirement that the Program Manager be a nationally certified tunnel inspector is excessive.

The FHWA response: The FHWA believes that due to the difference in the complexity of the structures that are being inspected under the NTIS, and the need for a general understanding of the functional systems included in the design of these structures, this requirement is appropriate for Program Managers.

Washington State DOT and MTABT stated that the experience listed in § 650.509(a)(1) is not clear or relevant.

The FHWA response: The FHWA believes that §§ 650.509(a)(1), (2), and (3) are all measures that may be used in evaluating the Program Manager's 10 years of experience requirement. Section 650.509(a)(1) addresses an individual's field experience in leading an inspection team (bridge or tunnel). This is just one skill set that a Program Manager should possess to understand the challenges associated with the tunnel inspection program.

Oregon DOT and AASHTO suggested that any tunnel inspection experience gained in a given year should be counted as credit for that year.

The FHWA response: The relevance of an individual's actual experience, including the extent to which the individual's experience on at least one tunnel inspection per calendar year has enabled the individual to develop the skills needed to properly lead a tunnel safety inspection, will be determined by the Program Manager.

The AASHTO commented that § 650.509(a)(1) will increase its members' costs because some States will lack qualified inspectors and may be forced to hire consultants to do inspections. The AASHTO further indicated that States ''would like to have the ability to perform interim inspections of special focus areas with bridge inspectors that have taken the tunnel inspector training.''

The FHWA response: The FHWA believes that the minimum criteria established in § 650.509(a) are necessary to ensure that tunnel inspectors are qualified to inspect tunnels.

California DOT questioned why experienced bridge inspectors who have not completed the certification training are not qualified to inspect tunnels under the direction of a Team Leader. North Carolina and Oregon DOTs and AASHTO suggested that the Program Manager should be able to establish State-specific qualifications for inspectors of functional systems.

The FHWA Response: The FHWA has reconsidered the requirement that all tunnel inspectors need to be nationally certified. Under the final rule, only the Program Manager and Team Leaders are required to be nationally certified tunnel inspectors. However, FHWA believes it is the responsibility of the Team Leader to assemble a team of inspectors with appropriate expertise and experience to inspect the various elements, components, and systems that comprise the tunnel.

Pennsylvania DOT and AECOM suggested that FHWA consider addressing qualifications for inspectors of functional systems. Pennsylvania DOT suggested more flexibility in those qualifications. South Dakota DOT suggested that inspectors of unlined tunnels should have a geotechnical background.

The FHWA Response: The FHWA believes it is the responsibility of the Team Leader to assemble a team of inspectors with appropriate expertise and experience to inspect the various elements, components, and systems that comprise the tunnel.

California DOT noted that the development of the specialized training and procedures by FHWA to improve inspections would benefit States, but is concerned about deadlines because no training program currently is in place.

The FHWA Response: The FHWA agrees that training for tunnel inspection is a critical part of the NTIS program, and we are actively working with National Highway Institute (NHI) to complete the development of this training. It is the intent of FHWA that the required training will be available shortly after the final rule is published,

which should provide sufficient time for all deadlines to be met.

California DOT noted that there is no current national certification program.

The FHWA Response: The FHWA added the requirements for nationally certified tunnel inspectors in the SNPRM as a result of the requirements of MAP–21. The FHWA is developing training and expects that the training required to become a nationally certified tunnel inspector will be available soon after the effective date of this final rule.

Oregon DOT commented that States should be able to establish inspector qualifications and maintain their own certification lists.

The FHWA Response: Because of the variability and complexity of the structures that are being inspected under the NTIS, FHWA believes that minimum national standards for inspectors will bring national consistency to tunnel inspections, evaluations, and data collection/submission. However, State DOTs may require additional qualifications for tunnel inspectors in their State. Any State maintained certification list or registry of inspectors that meet the minimum requirements of this final rule can serve as the State's registry of nationally certified tunnel inspectors.

The MTABT commented that ''the development and initiation of National Tunnel Inspector certification programs should be administered by individual States, similar to the Bridge Inspector certification and in advance of the effective date of this rule.''

The FHWA Response: The FHWA has approved alternate bridge inspection training courses used to meet the NBIS comprehensive training requirements; however, most States use the FHWA-developed training. Similarly, under the NTIS, FHWA will permit States to use FHWA-approved training in order for inspectors to meet the qualifications for national certification. Also, FHWA agrees that States should maintain a registry of nationally certified tunnel inspectors that work in their State.

Washington State DOT asked whether the training to be a ''nationally certified tunnel inspector'' will be ''specific to each discipline (structural, mechanical, electrical).''

The FHWA Response: The FHWA intends for the proposed tunnel inspection training course to be comprehensive in nature. This training course will cover the content of the TOMIE Manual and the Specifications for the NTI. The FHWA believes that adequate guidance is provided in these manuals to inspect and code the conditions of tunnel elements.

Florida DOT asked how long a State Highway Agency will have after a new Program Manager is designated for this individual to take the required comprehensive course.

The FHWA Response: The FHWA is currently developing a comprehensive tunnel inspection training course. We believe that it will be available for all owners to ensure that all programmatic requirements can be met and the initial inspections completed within 24 months from the effective date of this final rule. The FHWA expects future Program Managers to meet the requirements of NTIS before they are designated as the Program Manager.

California DOT questioned why refresher training for tunnels must be FHWA-approved and why refresher training is required every 48 months for tunnel inspectors. California DOT noted that there is no similar refresher training requirement in NBIS and suggested that NTIS be consistent. Similarly, New York State DOT suggests removing 48-month refresher training requirement to be consistent with NBIS for bridge inspections. Virginia DOT requested that the refresher training requirement interval be no less than 60 months. California DOT also asked how various disciplines (structural, mechanical, and electrical) will recertify.

The FHWA Response: The final rule has been revised to extend the interval for required refresher training to 60 months. Also, only Program Managers and Team Leaders are required to attend refresher training. The purpose of refresher training is to improve the quality of tunnel inspections, introduce new techniques, and maintain the consistency of the tunnel inspection program once every 60 months. The required refresher training will be comprehensive and will cover all disciplines. The FHWA currently requires its approval for bridge inspection training and bridge inspection refresher training.

The ACEC expressed support for the requirement that inspectors complete a comprehensive training course and periodic ''refresher'' courses in order to be certified, as provided in § 650.509(e).

The FHWA Response: The FHWA acknowledges the comment.

650.511 Inspection Interval

Alaska DOT commented that the initial inspection requirement for existing tunnels should be extended to 3 years from the effective date of this final rule if the existing tunnels are not currently inspected at a shorter interval. The AECOM commented that it will be a challenge for tunnel owners to meet the requirements of NTIS in 24 months and suggested that FHWA consider a phased approach.

The FHWA Response: The FHWA appreciates the challenge that implementation of this final rule will pose for tunnel owners. However, the 24-month requirement for both the initial and routine inspections was supported by comments on the NPRM received from State DOTs, AASHTO, and others. In addition, tunnels are constructed with similar materials and methods and face similar deterioration mechanisms as bridges, and the 24-month inspection interval required for bridges under NBIS has proven very successful. As a result of the significant support for this interval of inspection and the success of past practice in the bridge industry, FHWA elects to keep the initial inspection requirement at 24 months.

Alaska DOT also commented that the requirement for an initial inspection should be waived if an existing tunnel is already regularly inspected and that FHWA should permit the Program Manager to waive the requirement for a routine inspection when a tunnel is regularly inspected in a more rigorous manner.

The FHWA Response: The FHWA will not waive the requirement for an initial inspection. The initial inspection is intended to provide the baseline of inventory and condition information needed to fulfill the requirements of NTIS. However, if a tunnel is already regularly inspected and the State DOT can document that the latest inspection was conducted in accordance with the minimum requirements of NTIS, FHWA will accept the inventory and condition data from that inspection as the initial inspection. This information will establish the Inspection Date for the tunnel and then compel the next routine inspection at the appropriate interval.

The FHWA will not waive the requirement for a routine inspection of a tunnel that is regularly and rigorously inspected. However, if a tunnel is being regularly inspected in a more rigorous manner than required by NTIS, FHWA will recognize those inspections as meeting the definition of a routine inspection.

With regard to the requirement for initial inspection, Ohio DOT commented that 12 months is too short of a time period to enact such a comprehensive program that includes a new manual, training, possible contracts, and staffing components.

The FHWA Response: The time period proposed in the SNPRM and included in this final rule for conducting the initial inspection is 24 months from the effective date of the final rule.

Ohio DOT commented that the criteria used to support an extended routine inspection interval should be established before issuing the regulation to eliminate inconsistencies between FHWA Division Offices. Ohio DOT also commented that in addition to the factors listed in the SNPRM, the criteria should include access for emergency vehicles, traffic evacuation, and response to emergencies. Oregon and Virginia DOTs and AASHTO suggested removing the list of risk factors.

The FHWA Response: The FHWA has not attempted to produce an all-inclusive list of the criteria that need to be considered in order to justify an extended routine inspection interval. A general list of factors to be assessed is included in the final rule, but FHWA believes it is the responsibility of the State DOT to produce an appropriate evaluation that considers the risk associated with the particular circumstances of a tunnel in justifying an extended routine inspection interval. The FHWA has provided these general criteria to establish a minimum baseline and create consistency.

Washington State DOT commented that requiring an initial inspection for new tunnels before opening to traffic is ''overly restrictive and does not match [the] direction [of] the NBIS.'' Washington State DOT suggested requiring the inventory inspection within 90 days of a tunnel opening and the functional system inspection prior to the opening of the tunnel.

The FHWA Response: The FHWA believes that the thoroughness and efficiency of an initial tunnel inspection is increased when it is conducted prior to opening. In this scenario, FHWA thinks it likely that the initial inspection to fulfill the requirements of NTIS will be conducted concurrent with the final construction inspection. Because tunnels, unlike most bridges, typically contain many elements that are suspended or otherwise fixed over the travel lanes, FHWA wants the initial inspection of new tunnels to be conducted prior to opening the tunnel to ensure the safety of the traveling public.

Texas DOT suggested that the routine Inspection Date be reported in a month, day, and year (MM/DD/YYYY) format and that the whole 4-digit year be used.

The FHWA Response: The FHWA agrees with the suggestion and has revised the final rule to require the routine Inspection Date in a month, day, and year format with a 4-digit year.

The MTABT suggested an interval of 10 years between ''comprehensive inspections (in-depth inspections) for all structural and functional systems.'' The MTABT also commented that ''[r]outine [i]nspection intervals and intensity also be variable based on continuous routine maintenance and a full time presence of maintenance, operations, and engineering staff on-site.'' Alaska, Michigan, and Texas DOTs suggested that routine inspection intervals should be determined by States, by their Program Managers and Team Leaders, using a risk-based method. The Texas and Michigan DOTs suggested that routine inspection intervals should be determined by States using a risk-based method. The Alaska and Oregon DOTs commented that the frequency and type of inspection should be established by the owner and not regulated by Federal agencies.

The FHWA Response: The FHWA believes that the similarities between bridge and tunnel construction materials and associated deterioration mechanisms, design methodologies, and inspection technologies and protocols, along with the long-standing success of the 24-month inspection interval under NBIS and the current inspection activities of many tunnel owners, support the establishment of a 24-month routine inspection interval under NTIS. The FHWA also believes that there is flexibility in the final rule to accommodate both extended routine inspection intervals after consideration of appropriate factors and more rigorous inspection procedures based on the needs of a particular tunnel.

Washington State DOT stated that they currently inspect some tunnels on a 48-month interval and asked whether they will have to inspect them on a 24-month interval or provide FHWA a written request justifying the extended routine inspection interval as a result of the final rule.

The FHWA Response: For tunnels currently inspected on a 48-month interval, the tunnel owner will be required to either reduce the inspection interval to 24-months, or receive approval from FHWA for the extended inspection interval. The FHWA's approval will be based on submission of a written justification that considers the appropriate criteria provided in the final rule.

Washington State DOT commented that tunnel lining type should affect inspection interval and recommended that unlined tunnels and some types of lined tunnels should not be permitted for consideration of the extended inspection interval.

The FHWA Response: The FHWA expects that all appropriate risk factors need to be assessed when justifying an extended routine inspection interval. The tunnel owner is the best judge of the comprehensive list of criteria to be reviewed for a particular tunnel. The type and condition of the tunnel lining, although not explicitly stated in the regulation, should be considered as part of the assessment. The general criteria listed in the final rule include tunnel complexity, geotechnical conditions, and known deficiencies which should prompt a consideration of the type and condition of the tunnel lining.

Texas DOT suggested that there should be no maximum tolerance for early inspections.

The FHWA Response: Under the final rule, tunnel owners are allowed to begin an inspection 2 months before or after the Inspection Date to maintain that date in NTI. Inspections started prior to the 2-month tolerance given to the Inspection Date would require the Program Manager to modify the routine Inspection Date for a tunnel in order to maintain the regular 24-month interval. The FHWA believes that the need to modify this date should be minimized in order to avoid confusion in the data and history of inspection. However, the flexibility does exist for the Program Manager to modify the date if it is in the best interest of the tunnel owner, or traveling public to have a routine inspection started prior to the 2-month tolerance.

650.513 Inspection Procedures

California DOT commented that the manual incorporated by reference is still a draft.

The FHWA Response: The FHWA released the TOMIE Manual as a draft because we were seeking comment on the contents from State DOTs and others. The FHWA will issue a final version of the TOMIE Manual with this final rule.

Ohio DOT asked whether element-level inspections will be required or if NBIS condition rating inspections will be permitted.

The FHWA Response: The TOMIE Manual and the Specifications for the NTI, both incorporated by reference in this final rule, require element-level inspections and include condition state language.

Virginia DOT suggested that it is not necessary to have the Team Leader at the tunnel at all times during inspection, especially for components in which the Team Leader is not necessarily involved, as long as reporting procedures are in place for priority/critical findings.

The FHWA Response: The FHWA believes that while the Team Leader may not be able to add considerable technical expertise during a functional

system inspection, there are many quality control checks on data, documentation, safety, procedural checks, etc., that would be expected of the Team Leader while an inspection is being performed.

The MTABT suggested adding a requirement to the tunnel inspection manual for periodic settlement and sounding surveys for subaqueous tunnels. They further suggested that this testing would be valuable because any significant change in the amount of cover over a tunnel may change the stresses imposed on the tunnel linings. The MTABT also commented that the scope of inspections could be variable, excluding, for example, systems under rehabilitation, newly in-service, or recently tested.

The FHWA Response: The FHWA believes it is the responsibility of the Team Leader to assemble a team of inspectors with appropriate expertise and experience to inspect the various elements, components, and systems that comprise the tunnel. The FHWA also believes that the scope of inspections will vary over time, based on the needs of a particular tunnel, and that the Team Leader, working with the Program Manager, will identify those needs and the appropriate level of inspection rigor.

Ohio DOT suggested that the requirement to prepare and document tunnel-specific inspection procedures for each tunnel is ''overkill.'' They recommended that FHWA limit this requirement to only complex tunnels or clarify that the requirement will not result in unnecessary inspection manuals.

The FHWA Response: The FHWA expects that less detailed procedures will be developed for less complex tunnels.

Pennsylvania DOT requested clearer guidance on data and inventory reporting requirements for functional (non-structural) systems and inspection procedures.

The FHWA Response: The FHWA has developed the content of the TOMIE Manual and the Specifications for the National Tunnel Inventory to provide adequate guidance to inspect and code the conditions of these functional systems.

South Dakota DOT recommended different tunnel classifications with corresponding requirements based on risk and complexity.

The FHWA Response: The FHWA recognizes that there are differing types of tunnel construction. The FHWA believes it is the Program Manager's responsibility to establish a team of suitable inspectors to properly inspect a tunnel based on the risks associated with that tunnel.

The AASHTO suggested that written inspection procedures should be required only for the structural portion of the routine and in-depth inspections, but not for damage or special inspections.

The FHWA Response: The FHWA acknowledges that it would be difficult to write specific procedures for every damage incident that could occur in a tunnel or special inspection that would be necessary for tunnel components. General guidance should be included in each structure inspection procedure to address how the inspectors would inspect and document a damage or special inspection of deficient tunnel components.

Missouri DOT suggested that the NTIS regulations are too specific and complicated. They recommended that States write a tunnel-specific manual to cover all the components within a tunnel, qualifications needed for inspectors, inspection frequency for all components, load ratings, etc. They suggested that the contents of this manual would ultimately need to be agreed upon by FHWA and the State.

The FHWA Response: The FHWA modeled the complexity and level of detail of the NTIS after the NBIS. Under NTIS, States are free to develop tunnel-specific procedures and manuals as long as they comply with the program requirements of the regulation. The FHWA believes that as long as any tunnel-specific procedures meet the requirements of NTIS, they will ensure national consistency in tunnel inspection practices.

Alabama, Oregon, and Pennsylvania DOTs and AASHTO suggested that flexibility is needed to allow maintenance and operations personnel meeting the NTIS qualifications to either participate in, or have oversight of, the tunnel inspection process.

The FHWA Response: The FHWA believes that it is necessary to have independent inspectors performing inspections of all aspects of the tunnel to ensure that an unbiased examination is conducted. This minimizes the possibility of a compromised review.

California DOT asked why FHWA allows only 1 month between the Inspection Date and when the load rating is required and whether FHWA will allow assigned load ratings for tunnels.

The FHWA Response: In response to comments, FHWA has extended the requirement for a load rating to 3 months after the completion of an inspection. Assigned load ratings will be permitted for the live load carrying elements in tunnels as long as the criteria supporting an assigned load rating detailed in the 2nd Edition of the AASHTO Manual for Bridge Evaluation (incorporated by reference in section 650.517) are satisfied. An assigned load rating would typically be made by the load rating engineer of the entity responsible for load rating a tunnel. However, a Program Manager, Team Leader, or other qualified engineer could also make the assigned rating as long as they met the requirements of the 2nd Edition of the AASHTO Manual for Bridge Evaluation as indicated previously.

Washington State DOT questioned whether there was a need to load rate tunnel elements that do not carry live load. Washington State DOT also requested that the elements of a tunnel that do carry live load be defined.

The FHWA Response: The proposed definition for load rating in this rule is consistent with 23 CFR 650.305 and the AASHTO Manual for Bridge Evaluation. The intent is that only elements of a tunnel that carry live load will require a load rating. The FHWA believes it would be difficult to prepare an exhaustive list of the elements that carry live load in tunnels due to the complexity and variety that exists in tunnel construction. The Program Manager working with the Team Leader should identify live load carrying elements of each tunnel and document those in the tunnel records.

Missouri, Texas, Virginia, and Washington State DOTs commented that the proposed 48-hour timeframe to take action and post a structure is too short. These States indicated that sign fabrication and erection will take longer than 48 hours and recommended making the posting requirement consistent with NBIS, or following State policy or law. Missouri DOT recommended a more realistic expectation of 30 days.

The FHWA Response: In response to the comments, FHWA has reconsidered the posting timeframe requirement and has revised the NTIS regulations to require posting within 30 days.

New York State, Ohio, Oregon, Texas, and Virginia DOTs and AASHTO suggested that it is unreasonable to require that a load rating evaluation be conducted as soon as practical, but not later than 1 month after the completion of the inspection. The New York State and Texas DOTs recommended a 3-month or 90-day requirement.

The FHWA Response: In response to the comments, FHWA has reconsidered the 1-month requirement and has revised the final rule to include a 3-

month requirement to load rate a tunnel after the completion of an inspection.

Ohio DOT noted that ''some tunnels do not carry vehicles (above), but deterioration could still lower the load carrying capacity to the point of failure.'' Ohio DOT suggested eliminating the load-rating requirement or rewording it to ''consider dead load or falling rock onto liners etc.''

The FHWA Response: The FHWA expects that only elements of a tunnel that carry live load will be load rated. The deterioration described by Ohio DOT should be documented appropriately and, if necessary, a structural evaluation conducted to ensure the tunnel can remain safely open.

In § 650.513(h), Virginia DOT recommended changing, ''must also include diagrams . . .'' to ''. . . will also include diagrams,'' since all the information may not be required for all tunnels.

The FHWA Response: The FHWA agrees with the comment and has revised the language in the final rule to clarify that the tunnel data listed in § 650.513(h) is not required for every tunnel.

Virginia DOT recommends modifying the documentation requirement in § 650.513(h) by deleting part of the last sentence, ''as well as the national . . . for the inspection,'' and adding, ''In each inspection report, names of the Team Leader and inspectors and functional area inspected shall be identified.''

The FHWA Response: The FHWA will only require the identification in the NTI of the Team Leader or Team Leaders responsible, in whole or in part, for a tunnel inspection. Others that were a part of, or support, an investigation will be identified in the inspection documentation.

Oregon DOT and AASHTO recommended that electronic files be made equal to ''written documentation'' in the requirements for inspection documentation.

The FHWA Response: The FHWA agrees with the comment and has revised the language in the final rule.

Ohio DOT asked if FHWA will take the lead in quality assurance, as it did in the 23 Metrics for NBIS.

The FHWA Response: The FHWA intends to develop an oversight process, similar to the 23 Metrics for NBIS, to monitor a State DOT's compliance with NTIS.

California, Florida, Michigan, New York State, and Texas DOTs commented that the proposed requirement to notify FHWA of a critical finding within 24 hours of its discovery is too restrictive, and that regular updates on the resolution of critical findings and the annual summary reporting of the resolution of critical findings are excessive.

The FHWA Response: Due to the critical nature of these conditions, FHWA does not believe that these requirements are excessive. The intent of these requirements is to create a reporting mechanism to FHWA of the most extreme and critical structural, component, system deteriorations, or failures that could be a threat to the traveling public's safety. Further, this portion of the final rule seeks to ensure that severe conditions are addressed in a timely and appropriate manner through oversight and partnership with FHWA, which was specifically required in MAP–21. The regulation does not require a formal report or a developed resolution, but simply notification of the local FHWA Division Office. The FHWA believes this can easily be accomplished through a telephone conversation or an email message.

California DOT expressed concern that providing FHWA tunnel data on demand will create chaos by asking owners to answer questions on multiple sets of ever-changing data.

The FHWA Response: The FHWA expects that requests for data will be similar to those currently being made in support of the National Bridge Inspection Program. However, circumstances may arise when interim data sets will be needed to address an unforeseen challenge or situation.

Ohio DOT asked if FHWA will supply standard reporting formats.

The FHWA Response: The FHWA-approved reporting formats are included in the NTIS docket and available on the FHWA Web site at *http://www.fhwa.dot.gov/bridge/inspection/tunnel/*.

Oregon DOT commented that the use of a system similar to the NBIS metrics to provide oversight will not adequately target the needs of a tunnel inspection program and ''instead have the unintended consequence of overly burdening owners into tasks not directly related to safety and effective management into time consuming data reporting.''

The FHWA Response: The FHWA disagrees with the comment from Oregon DOT. Across the Nation, the NBIS' 23 Metrics process has helped focus owners and FHWA on gaps in compliance and issues that could potentially develop into safety concerns. The common understanding of the issues developed by assessment of the 23 Metrics will continue to strengthen the partnership between State DOTs and FHWA in addressing those challenges.

Washington State DOT commented that the final rule should include the AASHTO Manual for Bridge Evaluation as an incorporated reference.

The FHWA Response: The AASHTO Manual for Bridge Evaluation has been added to § 650.517 and is now incorporated by reference for subpart E.

Michigan and Oregon DOTs and AASHTO suggested FHWA use a number system similar to the current NBIS number (0–9) to identify critical findings.

The FHWA Response: The NBIS does not include a number system to identify critical findings. The FHWA has used the NBIS definition of critical findings at all stages of this rulemaking. The definition is broad enough to appropriately define critical findings without overlooking unforeseen circumstances that may arise to a similar level of urgency.

California DOT notes that the proposed tunnel inspection program will not address accidents that result in fires.

The FHWA Response: The FHWA believes that the tunnel inspection program will aid in recovery from these accidents by ensuring that functional systems are regularly inspected and evaluated to help minimize the impact on the traveling public during a fire event in a tunnel.

650.515 Inventory

California and Texas DOTs expressed concern about the requirement to provide FHWA preliminary inventory data within 120 days of the effective date of the rule. California DOT believes that the time period to provide data on the tunnel inventory is not sufficient to identify all tunnels owned by local agencies. Texas DOT believes the timeframe will not allow them to adequately train inspectors to collect the data.

The FHWA Response: The FHWA understands the concern with completing the preliminary tunnel inventory within 120 days of the effective date of this rule as required in § 650.515(a). The NPRM included a proposed requirement of 30 days for submitting preliminary inventory data. That proposal generated 3 comments, one in support of the 30 days, one suggesting 90 days, and one suggesting it was an unrealistic requirement. All other commenters to the NPRM were silent on this proposed requirement. As a result, FHWA extended the proposed timeframe to 120 days in the SNPRM. This new 120 timeframe generated comments from California DOT and Texas DOT, with all other commenters silent on the requirement. While FHWA

understands California DOT's concern, FHWA believes it is a reasonable timeframe based on the limited number of tunnels expected to be reported for each jurisdiction. Also, with regard to the comment from Texas DOT, FHWA expects the data reported to be compiled from existing records and will not require tunnel inspectors to be deployed to collect data.

Florida DOT requested that FHWA provide the appropriate format for inventory data submission. Washington State DOT and AASHTO asked where the required inventory and condition data is defined.

The FHWA Response: The Specifications for the NTI is the document that is intended to supplement the NTIS and provide the specifications for coding data to be submitted to the NTI. The TOMIE Manual is the document that provides guidance to tunnel owners on operations, maintenance, inspection and evaluation practices. Drafts of both of these documents were made available with the SNPRM for review and comment. Both documents have been incorporated by reference in § 650.517.

Washington State DOT expressed concern that the established time lines for reporting data should be consistent with the NBIS to reduce confusion.

The FHWA Response: Where appropriate, FHWA established the timing of reporting activities under NTIS in a manner that will prevent confusion between NBIS and NTIS program requirements.

The MdTA noted that tunnels are very complex and do not fit the mold of a bridge inspection program because their conditions are constantly changing. The MdTA commented further that the information collected for the NTI should be kept to a very high level.

The FHWA Response: The FHWA believes that the data defined in the Specifications for the National Tunnel Inventory and the TOMIE Manual is at a level appropriate for adequate national oversight and decisionmaking.

Pennsylvania DOT and AASHTO suggested that an extended compliance deadline of at least 3 years should be considered.

The FHWA Response: The FHWA agrees that establishing a system for collecting and reporting tunnel inspection and inventory data will be a challenge for tunnel owners who have not instituted an inspection program on their own. In recognition of this, FHWA has extended the initial inspection requirement to 24 months from the effective date of this final rule. The FHWA believes that, based on responses to the 2003 survey and comments received throughout the NTIS rulemaking process, 24 months is a reasonable timeframe.

650.517 Incorporation by Reference

The MTABT commented that the TOMIE Manual and the Specifications for the National Tunnel Inventory should be finalized after several cycles of technical reviews and field inspections are completed.

The FHWA Response: The FHWA believes it is necessary to have finalized versions of the TOMIE Manual and the Specifications for the National Tunnel Inventory in place with the final rule so that all tunnel owners will have the best knowledge of the national program requirements prior to the establishment of their State programs. The FHWA intends to make appropriate changes to these documents and the NTIS as we gather more experience with tunnel inspections and safety issues.

William White commented that there is not a national standard for exit signs. He suggested that a requirement that exit doors be green in color and that the use of ''the running figure'' exit sign be included in the final rule.

The FHWA Response: Use of the running figure exit sign and exit door identification are addressed in the TOMIE Manual, which is incorporated by reference in this final rule.

South Dakota DOT asked whether there will be further information added to the TOMIE Manual or another reference to better cover the inspection requirements for small/short hard rock tunnels.

The FHWA Response: The FHWA believes the TOMIE Manual provides adequate guidance to inspect small/short hard rock tunnels. Owners of these types of tunnels will be required to develop tunnel-specific inspection procedures that adequately address safety concerns in addition to the guidance given in the TOMIE Manual.

The ACEC expressed support for replacing the HRTTIM and its 0–9 ratings classification with the TOMIE Manual.

The FHWA Response: The FHWA agrees with the comment and believes that the element level inspection procedure and condition state rating system of the TOMIE Manual will better serve the purposes of ensuring safety and adequate asset management.

The Washington DOT suggested incorporating the AASHTO *Movable Bridge Inspection, Evaluation and Maintenance Manual* by reference for functional system inspection criteria and protocol.

The FHWA Response: The FHWA declines the suggestion to include the AASHTO *Movable Bridge Inspection, Evaluation and Maintenance Manual* as an incorporated reference. The FHWA believes the TOMIE Manual will sufficiently provide the guidance needed for the inspection of functional systems. However, in the absence of guidance elsewhere from FHWA, FHWA does encourage owners to use the AASHTO manual when it can provide valuable advice to the development of inspection criteria and protocols.

650.519 Additional Materials

The FHWA removed § 650.519 which recommended additional materials that States should consult when establishing their tunnel inspection programs. The FHWA feels that this material would be more appropriate for inclusion in a supplementary guidance document to accompany this final rule.

General Comments on the Regulation

California DOT commented that many of the requirements of this proposed rule exceed those listed in the NBIS. California DOT also noted that FHWA used the term ''data'' as an impetus for performing tunnel inspections to maintain safe operations and to prevent structural, geotechnical, and functional system failures. Finally, California DOT questioned whether a management system to collect data is needed for owners to make informed investment decisions when the NTIS will cover less than 60 structures in California.

The FHWA Response: Some of the provisions of the final rule exceed similar provisions in the current NBIS. In some instances this is due to the complexity of tunnels compared to bridges. In other instances, the differences result from FHWA's years of experience in implementing the NBIS. The collection of inspection data through a comprehensive and consistent methodology has ensured the successful operation of bridges under NBIS. The NTIS looks to duplicate that success. Finally, although FHWA believes it is prudent to manage every public investment as effectively as possible, the regulation does not require any State to have a management system in place for the inspection data, only that it collect and maintain that data and submit it to FHWA regularly or as requested.

Tennessee DOT suggested that tunnel inspections are needed to ensure the safety of the motoring public and recommended an allowance of their Federal-aid safety funds be used to implement this NTIS program. An anonymous commenter also suggested that a dedicated source of funding be made available to the States to cover the

cost of inspection of their tunnel inventory.

The FHWA Response: Under MAP–21, the inspection of tunnels on the NHS and the training of tunnel inspectors are eligible activities under the National Highway Performance Program. (23 U.S.C. 119(d)(2)(D) and (E)). In addition, the inspection of tunnels, regardless of the highway system or functional classification they are on, and the training of tunnel inspectors are eligible activities under the Surface Transportation Program. (23 U.S.C. 133(b)(4)).

The MdTA and Pennsylvania DOT expressed concern with security if the data collected by FHWA is made publicly available.

The FHWA Response: The FHWA agrees with the comment that the security of our Nation's tunnels is of the utmost importance. However, FHWA believes that the data being gathered for the NTI will be general enough as not to pose any security concern.

John Williams recommended that the final rule include a requirement that all immersed tube tunnels must have a Fixed Fire Fighting System (FFFS).

The FHWA Response: The FFFS is generally considered a best practice and although FHWA promotes it for new construction and rehabilitation if the existing structure can accommodate the demands of the technology, including design criteria as part of this regulation is not pragmatic. Design criteria generally advance as systems mature and new technologies are developed. Mandating criteria in regulation could impede maturation and discourage development of improved techniques.

Pennsylvania DOT requested FHWA flexibility in the implementation of NTIS.

The FHWA Response: The NTIS was first proposed in 2008. The FHWA has encouraged owners to continue to follow the progress of the rulemaking and prepare for implementation. However, FHWA understands the challenges that the implementation of NTIS poses for many tunnel owners. The FHWA is committed to working with its partners in the State DOTs to bring them into compliance with the regulation in a reasonable and appropriate manner.

Incorporation by Reference

In § 650.517, FHWA incorporates by reference a number of items. First, FHWA incorporates the ''Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual,'' 2015 edition, U.S. Department of Transportation, FHWA–HIF–15–005. The TOMIE Manual provides guidance to tunnel owners on operations, maintenance, inspection and evaluation practices. The TOMIE Manual is available at no charge on the FHWA Web site at: *http://www.fhwa.dot.gov/bridge/tunnel/*. Incorporation by reference of the TOMIE Manual is approved for §§ 650.505, 650.511(a), 650.513(a), and 650.513(h).

The FHWA also incorporates by reference the ''Specifications for National Tunnel Inventory,'' 2015 edition, U.S. Department of Transportation, FHWA–HIF–15–006. The Specifications for the NTI supplements the NTIS and provides the specifications for coding data to be submitted to the National Tunnel Inventory. The Specifications is available at no charge on the FHWA Web site at: *http://www.fhwa.dot.gov/bridge/inspection/tunnel/*. Incorporation by reference of the Specifications is approved for §§ 650.515(a) and 650.515(b).

Lastly, FHWA incorporates Sections 6 and 8 of the American Association of State Highway and Transportation Officials ''Manual of Bridge Evaluation'', with 2011, 2013, 2014 and 2015 interim revisions. The Manual was developed to assist bridge owners by establishing inspection procedures and evaluation practices that meet the National Bridge Inspection Standards. The manual is divided into eight Sections, with each Section representing a distinct phase of an overall bridge inspection and evaluation program. The Manual is available for purchase from the American Association of State Highway and Transportation Officials, Suite 249, 444 N. Capitol Street NW., Washington, DC 20001. It may also be ordered via the AASHTO bookstore located at the following Web site: *https://bookstore.transportation.org*. The FHWA believes that the entities affected by this regulation, namely tunnel owners, already own a copy of this AASHTO Manual. Incorporation by reference of the Manual is approved for §§ 650.505 and 650.513(a).

A copy of all of the incorporated documents outlined above will be on file and available for inspection at the National Archives and Records Administration. These documents will also be available for viewing at the Department of Transportation Library.

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

The FHWA has determined that this final rule constitutes a significant regulatory action within the meaning of Executive Order 12866 and DOT regulatory policies and procedures. This action complies with Executive Orders 12866 and 13563 to improve regulation. This action is considered significant because of widespread public interest in the safety of highway tunnels. It is not economically significant within the meaning of Executive Order 12866.

Having received relatively few comments from the ANPRM regarding costs and being mindful of the potential cost implications of the proposed rule, FHWA renewed its request for information regarding estimated or actual costs associated with tunnel inspections, particularly the typical inspection costs per linear foot of tunnel. In addition, FHWA requested comments regarding the anticipated increased costs the proposed NTIS would impose on tunnel owners. Only Washington State DOT commented on the cost of tunnel inspections in response to the NPRM. Washington State DOT stated that the budget for the recently completed mechanical and electrical inspection of the MLK Lid and Mount Baker Ridge Tunnel was $409,500 for the consultants alone. Washington State DOT was negotiating a scope of work and cost estimate for similar inspections of the Mercer Island Tunnel and the Convention Center. While FHWA appreciates such information, it is unclear what the scope of the work and inspection for this particular tunnel would be. Without further information on the length of the tunnel, the complexity of the design, and the number and type of functional systems, it is difficult to determine if the numbers provided by Washington State DOT fall within the anticipated cost range outlined below.

In the SNPRM, FHWA again requested comments on the potential costs and benefits of the proposed NTIS. The comments received and our responses are summarized below.

California DOT commented that there is no basis to conclude that the effects of the final rule on tunnel inspection cost are expected to be modest. They note that each State will have to invest significant resources to establish a tunnel inspection program. California DOT commented further that NTIS is duplicative of NBIS and will require additional program costs, including inspection software development and training, creation and support of a database for tunnels, a quality control and quality assurance program, compliance reviews, reporting, and corrective plans for tunnels.

The FHWA Response: The FHWA's basis for its cost-effectiveness statement is that a large majority of the tunnel

owners that responded to our 2003 survey reported that they are already inspecting tunnels at the 24-month interval required by the NTIS, collecting data in a data management program, and have an oversight program in place. The FHWA does believe there will be additional startup costs for implementation of NTIS, but those costs will be modest relative to the costs already incurred. Also, because NBIS does not include a requirement to inspect tunnels, does not provide procedures for inspecting tunnels, and does not identify the qualifications needed for tunnel inspectors, FHWA disagrees that the NTIS would be duplicative of the NBIS.

Virginia DOT commented that FHWA's conclusions regarding reported costs of inspections are based on a very low inspector hourly rate and recommended using $32.50 per hour. Virginia DOT further commented that it believes the cost of inspecting a tunnel is more than the proposed upper limit of $75.00/linear foot.

The FHWA Response: The FHWA appreciates the cost information and has increased the estimated hourly labor cost to $32 per hour. In addition, the upper limit of the range of inspection costs has been increased to $106 per linear foot.

Oregon DOT indicated that the cost to inspect one 2-lane tunnel each of the last 5 years was $50,000 and that if inspections are required every 2 years then Oregon DOT's costs will increase fivefold.

The FHWA Response: Oregon DOT responded to the 2003 FHWA survey that they were performing tunnel inspections at a 24-month interval. Unless that has significantly changed, it is unclear why costs would increase fivefold due to the implementation of NTIS.

The AASHTO submitted the following cost information: ''In Pennsylvania, the 3500-foot, four-lane Ft. Pitt Tunnel was inspected in 2006. The consultant used 1550 man-hours for a cost of $270,000 or $77.11 per LF [linear foot]. The four-lane Squirrel Hill Tunnel in Pennsylvania was inspected 2 years ago in 2330 man-hours for $300,000 or $71 per LF. The Massachusetts Department of Transportation estimates a typical tunnel inspection costs approximately $30.64 per LF of tunnel (Ted Williams Tunnel). Also in Massachusetts, inspection of the complex Tip O'Neill Tunnel (I–93 NB) is estimated at $106.23 per LF of tunnel. AASHTO further indicated that these costs and estimates do not include the cost of traffic control or police services.''

The FHWA Response: The FHWA is very appreciative for the cost information and has increased the upper end of the range of inspection costs to accommodate this new data. The range of inspection costs is now estimated to be from $5 to $106 per linear foot.

The MTABT commented that the FHWA's conclusions regarding reported costs of inspection are underestimated and based on limited survey data. They recommended ''a more pragmatic approach such as increasing the inspection interval and/or reducing inspection intensity.''

The FHWA Response: Based on comments received on the SNPRM, FHWA has increased the upper end of the range of inspection costs. In addition, the estimated hourly labor cost was increased to $32 per hour.

Current Cost of Tunnel Inspections

The FHWA lacks sufficient data on current tunnel inspection practices to accurately estimate the costs that will be incurred by tunnel owners as a result of the standards established in this final rule. The lack of knowledge concerning current tunnel inspection practices makes it difficult to accurately specify a baseline for this economic analysis. The below cost estimates are based on the limited data that was received from an informal 2003 survey of tunnel owners and the small number of comments that contained cost information. The 2003 survey was designed to collect information about the tunnel inventory, maintenance practices, inspection practices, and tunnel management practices of each State.[16] Of the 45 highway tunnel owners surveyed, 40 responses were received. Five of the tunnel owners surveyed did not respond. The survey results suggest that there are approximately 350 highway tunnels (bores) in the Nation and they are currently inspected by their owners at intervals ranging from 1 day to 10 years. These tunnels represent nearly 100 miles—running the distance of approximately 517,000 linear feet—of Interstate, State, and local routes. Tunnel inspection costs can vary greatly from tunnel to tunnel. The average inspection interval for the 37 responses that included data on this measure was a little over 24 months (2.05 years). Comments to the ANPRM, NPRM, and SNPRM suggested that current inspection costs range from $5 to $106 per linear foot depending on the complexity of the tunnel. Assuming that each highway tunnel includes 4 lanes, FHWA estimates that the total current inspection cost for all tunnel owners could range between $10,340,000 (4 lanes × 517,000 × $5) and $219,208,000 (4 lanes × 517,000 × $106), or $29,542 ($10,340,000/350) and $626,309 ($219,208,000/350) per tunnel bore. These figures reflect current inspection costs and do not include the additional costs anticipated with this rulemaking.

Costs Effects of the NTIS

Based on data from the 2003 survey, and subsequent communications the agency had with the 2 tunnel owners, only (MTABT and Virginia DOT), that together own 15 tunnel bores, would be required to increase inspection frequency as a result of this action.[17] These 2 tunnel owners have inspection intervals that are longer than the proposed 24 months and would therefore experience an increase in costs. Using the estimated inspection cost range for a single tunnel bore above ($29,542 to $626,309), we can estimate the total aggregate cost increase for the 2 tunnel owners.

Owner A currently inspects 4 tunnel bores at a 10-year interval. We estimate the current annual inspection costs for Owner A are between $2,954.2 ($29,542/10) and $62,630.9 ($626,309/10) per tunnel bore. Under the rule, we estimate the annual inspection costs for Owner A will be between $14,771 ($29,542/2) and $313,155 ($626,309/2) per tunnel bore. As a result, Owner A would see an estimated annual cost increase of between $11,817 ($14,771 − $2,954.2) and $250,524 ($313,155 − $62,630.9) per tunnel bore. For all 4 tunnel bores we estimate the current annual inspection costs are between $11,817 (4 × $2,954.2) and $250,524 (4 × $62,630.9). Under the rule, we estimate the annual inspection costs for all 4 tunnel bores will be between $59,084 (4 × $14,771) and $1,252,620 (4 × $313,155). As a result, Owner A would see an estimated total cost increase of between $47,267 ($59,084 − $11,817) and $1,002,096 ($1,252,620 − $250,524).

Owner B currently inspects 11 tunnel bores at a 7-year interval. We estimate the current annual inspection costs for Owner B are between $4,220.3 ($29,542/7) and $89,473 ($626,309/7) per tunnel bore. Under the proposed rule, we estimate the annual inspection costs for Owner B will be between $14,771 ($29,542/2) and $313,155 ($626,309/2)

[16] A copy of the FHWA's 2003 Survey is available on the docket.

[17] In July 2012, Virginia DOT entered into a 58-year concession with Elizabeth River Crossings for the Downtown and Midtown tunnels in southern Virginia. The concession agreement requires Elizabeth River Crossings to meet or exceed Virginia DOT's standards for tunnel inspections, including frequency.

per tunnel bore. As a result, Owner B would see an estimated annual cost increase of between $10,551 ($14,771 − $4,220) and $223,682 ($313,155 − $89,473) per tunnel bore. For all 11 tunnel bores we estimate the current annual inspection costs are between $46,423 (11 × $4,220.3) and $984,203 (11 × $89,473). Under the rule, we estimate the annual inspection costs for all 11 tunnel bores will be between $162,481 (11 × $14,771) and $3,444,705 (11 × $313,155). As a result, Owner B would see an estimated total cost increase of between $116,058 ($162,481 − $46,420) and $2,460,502 ($3,444,705 − $984,203).

Based on the above analysis, FHWA estimates the current aggregate annual cost of tunnel inspections for the 2 affected tunnel owners is between $58,240 ($11,817 + $46,423) and $1,234,727 ($250,524 + $984,203). Under the inspection interval required by the rule, we estimate the aggregate annual cost will be between $221,565 (59,084 + $162,481) and $4,697,325 ($1,252,620 + $3,444,705). As a result, FHWA estimates the aggregate annual cost increase of inspections for the 2 affected tunnel owners will be between $163,325 ($221,565 − $58,240) and $3,462,598 ($4,697,325 − $1,234,727). The discounted costs over 20 years (at 7 percent) are between $1.73 million and $36.683 million.

The FHWA notes that each tunnel owner must collect and submit inventory data information for all tunnels subject to this rule within 120 days of the effective date and when requested by FHWA. The total estimated cost to collect, manage, and report preliminary inventory data is $89,856 (2,808 hours × $32/hour = $89,856). This is a one-time cost for the two affected tunnel owners. As a result, FHWA estimates the total aggregate first year cost increase of inspections for the 2 affected tunnel owners will be between $253,181 ($163,325 + $89,856) and $3,552,454 ($3,462,598 + $89,856). Over 20 years the discounted total would be between $1.82 million and $36.773 million.

The FHWA expects that the overall increase in costs of inspecting tunnels would be modest, as the vast majority of tunnel owners already inspect at the 24-month interval proposed by the NTIS. However, FHWA does not have sufficient information regarding the cost increase from other provisions of the final rule, such as fixing critical defects and closing tunnels and roads in order to conduct the inspections. The FHWA recognizes that the 2003 survey does not represent the full universe of tunnel owners and tunnels, but believes that it is comprehensive enough to draw preliminary conclusions on the cost effects of this final rule. The FHWA also assumes that any increase in the cost per inspection resulting from the final rule would not cause the cost per inspection to exceed the upper end of the range of inspection costs in the analysis.

In addition to the costs associated with more frequent inspections, FHWA expects that tunnel owners may experience a modest increase in costs as a result of the training requirements contained in the final rule. Based on the training of bridge inspectors under the NBIS, we estimate that the cost to train a tunnel inspector will be approximately $3,000 over a 10-year period (1 basic class and 2 refresher classes).

Benefits Resulting From the NTIS

Upon implementation, FHWA expects that this final rule would result in some significant benefits that are not easily quantifiable, but nonetheless deserve mention in this analysis. Timely and reliable tunnel inspection is likely to uncover safety problems and prevent failures. The structural, geotechnical, and functional components and systems that make up tunnels deteriorate and corrode due to the harsh environment in which these structures are operated. As a result, routine and thorough inspection of these elements is necessary to collect the data needed to maintain safe tunnel operation and to prevent structural, geotechnical, and functional failures. As our Nation's tunnels continue to age, an accurate and thorough assessment of each tunnel's condition is critical to avoid a decline in service and maintain a safe, functional, and reliable highway system. The agency is taking this action to respond to the statutory directive in MAP–21 and because it believes that ensuring timely and reliable inspections of highway tunnels will result in substantial benefits by enhancing the safety of the traveling public and protecting investments in key infrastructure. We believe that repairs or changes resulting from the inspections could lead to substantial economic savings.

Currently, State DOTs differ from State to State in the way they inspect their tunnels. The methods are inconsistent and these differences hinder accurate analysis of tunnel conditions at the national level. This final rule would establish uniform inspection practices. The final rule will also yield greater accountability because the mandated reporting would increase visibility and transparency by providing the public with a more transparent view of the number and condition of the nation's tunnels. These benefits resulting from the final rule (*i.e.,* uniformity and greater accountability) would lead to improved tunnel conditions.

This final rule will also allow for more informed decisionmaking on tunnel condition-related project, program, and policy choices. The tunnel inventory data will allow FHWA to track and identify any patterns of tunnel deficiencies and facilitate repairs by States to ensure the safety of the public. Tunnel owners will also be able to integrate tunnel inventory data into an asset management program for maintenance and repairs of their tunnels. The data collection requirements in the NTIS are consistent with the performance-based approach to carrying out the Federal-aid highway program established by Congress in MAP–21. These requirements will fulfill the congressional directive to establish a data-driven, risk-based approach for the maintenance, replacement, and rehabilitation of highway tunnels. Such an approach will help to ensure the efficient and effective use of Federal resources.

The NTIS could protect investments in key infrastructure, as early detection of problems in tunnels could increase the longevity of these assets and avoid more costly rehabilitation and repair actions. It is generally accepted in the transportation structures community that inspection and maintenance are effective forms of avoiding substantial future costs. For example, a 2005 University of Minnesota study examined the benefits of pavement preservation and preventative maintenance and found that pavement preservation had many benefits, the most important of which is preserving a pavement's structural integrity and realizing a substantial maintenance cost-savings over the life of the pavement. The study found that it is much less expensive to repair a pavement when distresses are just beginning to appear. More specifically, the study concluded that, at a minimum, the costs of maintaining a runway were half those of not maintaining a runway when measured over the life of the asset.[18] However, the study's conclusions only considered the direct costs of

[18] ''Pavement preservation: protecting your airport's biggest investment,'' AirTAP Briefings, Airport Technical Assistance Program of the Center for Transportation Studies at the University of Minnesota, summer 2005. An electronic version is located at: *http://www.airtap.umn.edu/publications/briefings/2005/Briefings-2005-Summer.pdf*

maintenance and construction and not the indirect costs associated with the mobility of the traveling public, goods, services, and freight. As tunnels provide mobility, which is vital to local, regional, and national economies, and to our national defense, it is imperative that these facilities are properly inspected and maintained to avoid the direct costs of rehabilitation and the indirect costs to users.

The above description of tunnel inspection benefits were summarized from the limited benefit data submitted by tunnel owners in response to the NPRM and compiled by FHWA.

Summary

The FHWA does not have sufficient information to estimate total costs and benefits of this final rule (*e.g.* any change in how a state inspects a tunnel). However, the FHWA's preliminary estimates regarding the inspection portion (excludes training) of the rulemaking are between $1.82 million and $36.773 million over 20 years (discounted at 7 percent).

Regulatory Flexibility Act

As required by the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), FHWA has evaluated the effects of this final rule on small entities and anticipates that this action will not have a significant economic impact on a substantial number of small entities. Because the regulations are primarily intended for States and Federal agencies, FHWA has determined that the action will not have a significant economic impact on a substantial number of small entities. States and Federal agencies are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, the Regulatory Flexibility Act does not apply, and FHWA certifies that the action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The FHWA has determined that this final rule will not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). The NTIS is needed to ensure safety for the users of the Nation's tunnels and to help protect Federal infrastructure investment. As discussed above, FHWA finds that this regulatory action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $143,100,000 or more in any one year (2 U.S.C. 1532). Additionally, the definition of ''Federal mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

The FHWA has analyzed this final rule in accordance with the principles and criteria contained in Executive Order 13132. The FHWA has determined that a federalism summary impact statement is not required because this regulation is required by statute and will not preempt any State law.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program. Local entities should refer to the Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction, for further information.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. This action contains a collection of information requirement under the PRA. This information collection requirement has been previously submitted to OMB for approval, pursuant to the provisions of the PRA. The requirement has been approved through May 31, 2017; OMB Control No. 2125–0640.

The MAP–21 requires the Secretary to inventory all tunnels on public roads, on and off Federal-aid highways, including tribally owned and federally owned tunnels. In addition, each State, Federal agency, and tribal government is required to report to the Secretary on: the results of tunnel inspections and notation of any action taken pursuant to the findings of the inspections, and current inventory data for all highway tunnels reflecting the findings of the most recent tunnel inspection. In order to be responsive to the requirements of MAP–21 and in accordance with this final rule, FHWA will collect data to establish an NTI and require the submission of data on the results of tunnel inspections. A description of the collection requirements, the respondents, and an estimate of the annual reporting burden are set forth below.

National Tunnel Inventory Collection

The FHWA will collect data to establish an NTI. Initially a subset of the Inventory Items defined in the Specifications of the National Tunnel Inventory will be collected. This information will be reported to FHWA on the Preliminary Tunnel Inventory Data Form which is available on the FHWA Web site at: *http://www.fhwa.dot.gov/bridge/inspection/tunnel/*.

The following is the data that will be collected under the NTI on the Preliminary Tunnel Inventory Data Form:

(1) Identification Items: Tunnel number, tunnel name, State code, county code, place code, highway agency district, route number, route direction, route type, facility carried, linear referencing system (LRS) inventory route number, LRS mile point, tunnel portal's latitude, tunnel portal's longitude, border tunnel State or county code, border tunnel financial responsibility, border tunnel number, and border tunnel inspection responsibility.

(2) Age and Service Items: Year built, year rehabilitated, total number of lanes, average daily traffic, average daily truck traffic, year of average daily traffic, detour length, and service in tunnel.

(3) Classification Items: Owner, operator, direction of traffic, toll, NHS designation, STRAHNET designation, and functional classification.

(4) Geometric Data Items: Tunnel length, minimum clearance over tunnel roadway, roadway curb-to-curb width, and left curb and right curb widths.

(5) Structure Type and Material Items: Number of bores, tunnel shape, portal shape, ground conditions, and complexity.

The anticipated respondents include the 50 States, the District of Columbia, Puerto Rico, and any Federal agencies and tribal governments that own tunnels. The estimated burden on the States to collect, manage, and report this data is estimated to be 8 hours per tunnel for a total estimate of 2,808 hours for all 350 estimated tunnels in the Nation. This represents an average of 54 hours per respondent and so it is estimated that the burden will total 2,808 hours per year (52 responses × 54.00 hours per respondent = 2,808 hours).

Annual Inspection Reporting

In addition to the preliminary inventory information described above, tunnel owners are required to report to

the Secretary on the results of tunnel inspections and notations of any action taken pursuant to the findings of the inspections. For all inspections, tunnel owners will be required to enter the appropriate inspection data into the State DOT, Federal agency, or tribal government inventory within 3 months of the completion of the inspection. The number of responses per year is based on the total of 350 tunnels in the U.S., with approximately half inspected each year, based on the standard 24-month inspection interval. The annual responses are estimated at 175 for routine inspections. With the average time of 40 hours to collect, manage, and report routine inspection data, and an additional 2,080 hours to follow up on critical findings, it is estimated that the burden hours will total 9,080 hours per year (7,000 hours (175 responses × 40.00 hours per response) + 2,080 hours (for follow-up on critical findings) = 9,080 burden hours).

Estimated Total Annual Burden Hours

The FHWA estimates that the collection of information contained in this final rule will result in approximately 11,888 total annual burden hours (2,808 hours (preliminary inventory collection) + 9,080 (annual inspections) = 11,888 (total annual burden hours)). Since the majority of States are already inspecting their tunnels, they are likely to have much of the data needed to satisfy the preliminary inventory data collection burden. Likewise, since many States are already collecting and storing inspection data, they are likely to have much of the data needed to satisfy the routine inspection burden. As a result, FHWA expects that the additional burden on the States to report this data will be minimal.

A notice seeking public comments on the collection of information included in this final rule was published in the **Federal Register** on June 14, 2010, at 75 FR 33659. The FHWA received comments from four commenters, including one organization (AASHTO) and three State DOTs (New York, Oregon, and Virginia). These comments were addressed in the SNPRM.

In the SNPRM, FHWA renewed its request for comments on the collection of information. No additional comments on the information collection were received.

National Environmental Policy Act

The Department has analyzed this action for the purpose of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), and has determined that this action would not have a significant effect on the quality of the environment and qualifies for the categorical exclusion at 23 CFR 771.117(c)(20).

Executive Order 12630 (Taking of Private Property)

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

Executive Order 12988 (Civil Justice Reform)

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

Executive Order 13045 (Protection of Children)

The FHWA has analyzed this action under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule does not concern an environmental risk to health or safety that may disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

The FHWA has conducted a preliminary analysis of this action under Executive Order 13175. The FHWA believes that this final rule will not have substantial direct effects on one or more Indian Tribes, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. To FHWA's knowledge, there are no tunnels that are owned, operated, or maintained by Indian tribal governments. In addition, no comments were received from Indian tribal governments in response to the SNPRM.

Executive Order 13211 (Energy Effects)

The FHWA has analyzed this final rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The FHWA has determined that the rule will not constitute a significant energy action under that order because, although it is considered a significant regulatory action under Executive Order 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Executive Order 12898 (Environmental Justice)

Executive Order 12898 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. The FHWA has determined that this rule does not raise any environmental justice issues.

Regulation Identifier Number

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 650

Bridges, Grant programs—transportation, Highways and roads, Incorporation by reference, Reporting and recordkeeping requirements.

Issued in Washington, DC, on July 2, 2015, under authority delegated in 49 CFR 1.85(a)(1):

Gregory G. Nadeau,

Acting Administrator, Federal Highway Administration.

In consideration of the foregoing, the FHWA amends title 23, Code of Federal Regulations, part 650, as set forth below:

PART 650—BRIDGES, STRUCTURES, AND HYDRAULICS

■ 1. The authority citation for part 650 is revised to read as follows:

Authority: 23 U.S.C. 119, 144, and 315.

■ 2. Add subpart E to read as follows:

Subpart E—National Tunnel Inspection Standards

Sec.

650.501 Purpose.
650.503 Applicability.
650.505 Definitions.
650.507 Tunnel inspection organization responsibilities.
650.509 Qualifications of personnel.
650.511 Inspection interval.
650.513 Inspection procedures.
650.515 Inventory.
650.517 Incorporation by reference.

Subpart E—National Tunnel Inspection Standards

§ 650.501 Purpose.

This subpart sets the national minimum standards for the proper

safety inspection and evaluation of all highway tunnels in accordance with 23 U.S.C. 144(h) and the requirements for preparing and maintaining an inventory in accordance with 23 U.S.C. 144(b).

§ 650.503 Applicability.

The National Tunnel Inspection Standards (NTIS) in this subpart apply to all structures defined as highway tunnels on all public roads, on and off Federal-aid highways, including tribally and federally owned tunnels.

§ 650.505 Definitions.

The following terms used in this subpart are defined as follows:

American Association of State Highway and Transportation Officials (AASHTO) Manual for Bridge Evaluation. The term ''AASHTO Manual for Bridge Evaluation'' means the ''Manual for Bridge Evaluation'', incorporated by reference in § 650.517.

At-grade roadway. The term ''at-grade roadway'' means paved or unpaved travel ways within the tunnel that carry vehicular traffic and are not suspended or supported by a structural system.

Bridge inspection experience. The term ''bridge inspection experience'' has the same meaning as in § 650.305.

Complex tunnel. The term ''complex tunnel'' means a tunnel characterized by advanced or unique structural elements or functional systems.

Comprehensive tunnel inspection training. The term ''comprehensive tunnel inspection training'' means the FHWA-approved training that covers all aspects of tunnel inspection and enables inspectors to relate conditions observed in a tunnel to established criteria.

Critical finding. The term ''critical finding'' has the same meaning as in § 650.305.

Damage inspection. The term ''damage inspection'' has the same meaning as in § 650.305.

End-of-course assessment. The term ''end-of-course assessment'' means a comprehensive examination given to students after the completion of a training course.

Federal-aid highway. The term ''Federal-aid highway'' has the same meaning as in 23 U.S.C. 101(a)(5).

Functional systems. The term ''functional systems'' means non-structural systems, such as electrical, mechanical, fire suppression, ventilation, lighting, communications, monitoring, drainage, traffic signals, emergency response (including egress, refuge room spacing, or carbon monoxide detection), or traffic safety components.

Hands-on inspection. The term ''hands-on inspection'' has the same meaning as in § 650.305.

Highway. The term ''highway'' has the same meaning as in 23 U.S.C. 101(a)(11).

In-depth inspection. The term ''in-depth inspection'' means a close-up inspection of one, several, or all tunnel structural elements or functional systems to identify any deficiencies not readily detectable using routine inspection procedures. In-depth inspections may occur more or less frequently than routine inspections, as outlined in the tunnel-specific inspection procedures.

Initial inspection. The term ''initial inspection'' means the first inspection of a tunnel to provide all inventory, appraisal, and other data necessary to determine the baseline condition of the structural elements and functional systems.

Inspection Date. The term ''Inspection Date'' means the date established by the Program Manager on which a regularly scheduled routine inspection begins for a tunnel.

Legal load. The terms ''legal load means the maximum legal load for each vehicle configuration permitted by law for the State in which the tunnel is located.

Load rating. The term ''load rating'' means the determination of the safe vehicular live load carrying capacity within or above the tunnel using structural plans, and information gathered from an inspection. The results of the load rating may include the need for load posting.

Operating rating. The term ''operating rating'' has the same meaning as in § 650.305.

Portal. The term ''portal'' means the entrance and exit of the tunnel exposed to the environment; portals may include bare rock, constructed tunnel entrance structures, or buildings.

Procedures. The term ''procedures'' means the written documentation of policies, methods, considerations, criteria, and other conditions that direct the actions of personnel so that a desired end result is achieved consistently.

Professional Engineer (P.E.). The term ''Professional Engineer (P.E.)'' means an individual who has fulfilled education and experience requirements and passed examinations that, under State licensure laws, permits the individual to offer engineering services within areas of expertise directly to the public.

Program Manager. The term ''Program Manager'' means the individual in charge of the inspection program who has been assigned or delegated the duties and responsibilities for tunnel inspection, reporting, and inventory. The Program Manager provides overall leadership and guidance to inspection Team Leaders and load raters.

Public road. The term ''public road'' has the same meaning as in 23 U.S.C. 101(a)(21).

Quality assurance (QA). The term ''quality assurance (QA)'' means the use of sampling and other measures to ensure the adequacy of quality control procedures in order to verify or measure the quality of the entire tunnel inspection and load rating program.

Quality control (QC). The term ''quality control (QC)'' means the procedures that are intended to maintain the quality of a tunnel inspection and load rating at or above a specified level.

Routine inspection. The term ''routine inspection'' means a regularly scheduled comprehensive inspection encompassing all tunnel structural elements and functional systems and consisting of observations and measurements needed to determine the physical and functional condition of the tunnel, to identify any changes from initial or previously recorded conditions, and to ensure that tunnel components continue to satisfy present service requirements.

Routine permit load. The term ''routine permit load'' means a vehicular load that has a gross weight, axle weight, or distance between axles not conforming with State laws for legally configured vehicles, and is authorized for unlimited trips over an extended period of time to move alongside other heavy vehicles on a regular basis.

Special inspection. The term ''special inspection'' means an inspection, scheduled at the discretion of the tunnel owner, used to monitor a particular known or suspected deficiency.

State transportation department (State DOT). The term ''State transportation department (State DOT)'' has the same meaning as in 23 U.S.C. 101(a)(28).

Team Leader. The term ''Team Leader'' means the on-site individual in charge of an inspection team responsible for planning, preparing, performing, and reporting on tunnel inspections.

Tunnel. The term ''tunnel'' means an enclosed roadway for motor vehicle traffic with vehicle access limited to portals, regardless of type of structure or method of construction, that requires, based on the owner's determination, special design considerations that may include lighting, ventilation, fire protection systems, and emergency egress capacity. The terms ''tunnel'' does not include bridges or culverts inspected under the National Bridge

Inspection Standards (subpart C of this part).

Tunnel inspection experience. The term ''tunnel inspection experience'' means active participation in the performance of tunnel inspections in accordance with the National Tunnel Inspection Standards, in either a field inspection, supervisory, or management role.

Tunnel inspection refresher training. The term ''tunnel inspection refresher training'' means an FHWA-approved training course that aims to improve the quality of tunnel inspections, introduce new techniques, and maintain the consistency of the tunnel inspection program.

Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual. The term ''Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual'' means the ''Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual'' (incorporated by reference, *see* § 650.517).

Tunnel-specific inspection procedures. The term ''tunnel-specific inspection procedures'' means the written documentation of the directions necessary to plan for, and conduct an inspection. Directions include coverage of inspection methods, frequency of each method, inspection equipment, access equipment, identification of tunnel elements, components and functional systems, traffic coordination, and specialized qualifications for inspecting personnel.

§ 650.507 Tunnel inspection organization responsibilities.

(a) Each State DOT shall inspect, or cause to be inspected, all highway tunnels located on public roads, on and off Federal-aid highways, that are fully or partially located within the State's boundaries, except for tunnels that are owned by Federal agencies or tribal governments.

(b) Each Federal agency shall inspect, or cause to be inspected, all highway tunnels located on public roads, on and off Federal-aid highways, that are fully or partially located within the respective agency's responsibility or jurisdiction.

(c) Each tribal government shall inspect, or cause to be inspected, all highway tunnels located on public roads, on and off Federal-aid highways, that are fully or partially located within the respective tribal government's responsibility or jurisdiction.

(d) Where a tunnel is jointly owned, all bordering States, Federal agencies, and tribal governments with ownership interests should determine through a joint formal written agreement the inspection responsibilities of each State, Federal agency, and tribal government.

(e) Each State that contains one or more tunnels subject to these regulations, or Federal agency or tribal government with a tunnel under its jurisdiction, shall include a tunnel inspection organization that is responsible for all of the following:

(1) Statewide, Federal agency-wide, or tribal government-wide tunnel inspection policies and procedures (both general and tunnel-specific), quality control and quality assurance procedures, and preparation and maintenance of a tunnel inventory.

(2) Tunnel inspections, written reports, load ratings, management of critical findings, and other requirements of these standards.

(3) Maintaining a registry of nationally certified tunnel inspectors that work in their State or for their Federal agency or tribal government that includes, at a minimum, a method to positively identify each inspector, documentation that the inspector's training requirements are up-to-date, the inspector's current contact information, and detailed information about any adverse action that may affect the good standing of the inspector.

(4) A process, developed under the direction of a Professional Engineer and approved by FHWA, to determine when an inspection Team Leader's qualifications must meet § 650.509(b)(4) in order to adequately and appropriately lead an inspection of a complex tunnel or a tunnel with distinctive features or functions. At a minimum, the process shall consider a tunnel's type of construction, functional systems, history of performance, and physical and operational conditions.

(f) A State DOT, Federal agency, or tribal government may delegate functions identified in paragraphs (e)(1), (2), and (3) of this section through a formal written agreement, but such delegation does not relieve the State DOT, Federal agency, or tribal government of any of its responsibilities under this subpart.

(g) The State DOT, Federal agency, or tribal government tunnel inspection organization shall have a Program Manager with the qualifications listed in § 650.509(a), who has been delegated responsibility for paragraphs (e)(1), (2), and (3) of this section.

§ 650.509 Qualifications of personnel.

(a) A Program Manager shall, at a minimum:

(1) Be a registered Professional Engineer, or have 10 years of tunnel or bridge inspection experience;

(2) Be a nationally certified tunnel inspector;

(3) Satisfy the requirements of paragraphs (a)(1) and (2) of this section by August 13, 2017; and

(4) Be able to determine when a Team Leader's qualifications must meet the requirements of paragraph (b)(1)(i) of this section in accordance with the FHWA approved process developed in accordance with § 650.507(e)(4).

(b) A Team Leader shall, at a minimum:

(1) Meet at least one of the four qualifications listed in paragraphs (b)(1)(i) through (iv) of this section:

(i) Be a registered professional engineer and have six months of tunnel or bridge inspection experience.

(ii) Have 5 years of tunnel or bridge inspection experience.

(iii) Have all of the following:

(A) A bachelor's degree in engineering or engineering technology from a college or university accredited or determined as substantially equivalent by the Accreditation Board for Engineering and Technology.

(B) Successfully passed the National Council of Examiners for Engineering and Surveying Fundamentals of Engineering examination.

(C) Two (2) years of tunnel or bridge inspection experience.

(iv) Have all of the following:

(A) An associate's degree in engineering or engineering technology from a college or university accredited or determined as substantially equivalent by the Accreditation Board for Engineering and Technology.

(B) Four years of tunnel or bridge inspection experience.

(2) Be a nationally certified tunnel inspector.

(3) Provide documentation supporting the satisfaction of paragraphs (b)(1) and (2) of this section to the Program Manager of each State DOT, Federal agency, or tribal government for which they are performing tunnel inspections.

(4) Be a registered Professional Engineer and have six months of tunnel or bridge inspection experience if the Program Manager determines through the approved process developed under § 650.507(e)(4) that the tunnel being inspected is complex or has distinctive features or functions that warrant this level of qualifications.

(c) Load ratings shall be performed by, or under the direct supervision of, a registered Professional Engineer.

(d) Each State DOT, Federal agency, and tribal government shall determine inspection personnel qualifications for damage, cursory, and special inspections.

(e) A nationally certified tunnel inspector shall:

(1) Complete an FHWA-approved comprehensive tunnel inspection training course and score 70 percent or greater on an end-of-course assessment;

(2) Complete a cumulative total of 18 hours of FHWA-approved tunnel inspection refresher training over each 60 month period; and

(3) Maintain documentation supporting the satisfaction of paragraphs (e)(1) and (2) of this section, and, upon request, provide documentation of their training status and current contact information to the Tunnel Inspection Organization of each State DOT, Federal agency, or tribal government for which they will be performing tunnel inspections.

(f) Acceptable tunnel inspection training includes the following:

(1) *National Highway Institute training.* NHI courses on comprehensive tunnel inspection training.

(2) *FHWA approval of alternate training.* A State DOT, Federal agency, or tribal government may submit to FHWA a training course as an alternative to the NHI course. The FHWA shall approve alternative course materials and end-of-course assessments for national consistency and certification purposes. The Program Manager shall review the approved alternative training course every 5 years to ensure the material is current. Updates to approved course materials and end-of-course assessments shall be resubmitted to FHWA for approval.

(g) In evaluating the tunnel inspection experience requirements under paragraphs (a) and (b) of this section, a combination of tunnel design, tunnel maintenance, tunnel construction, and tunnel inspection experience, with the predominant amount in tunnel inspection, is acceptable. Also, the following criteria should be considered:

(1) The relevance of the individual's actual experience, including the extent to which the experience has enabled the individual to develop the skills needed to properly lead a tunnel safety inspection.

(2) The individual's exposure to the problems or deficiencies common in the types of tunnels being inspected by the individual.

(3) The individual's understanding of the specific data collection needs and requirements.

§ 650.511 Inspection interval.

(a) *Initial inspection.* A State DOT, Federal agency, or tribal government tunnel inspection organization shall conduct, or cause to be conducted, an initial inspection for each tunnel described in § 650.503 as follows:

(1) For existing tunnels, conduct a routine inspection of each tunnel according to the inspection guidance provided in the Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual (incorporated by reference, *see* § 650.517) by August 13, 2017.

(2) For tunnels completed after these regulations take effect, the initial routine inspection shall be conducted after all construction is completed and prior to opening to traffic, according to the inspection guidance provided in the Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual (incorporated by reference, *see* § 650.517).

(b) *Routine inspections.* A State DOT, Federal agency, or tribal government tunnel inspection organization shall conduct, or cause to be conducted, routine inspections for each tunnel described in § 650.503 as follows:

(1) Establish for each tunnel the NTIS routine Inspection Date in a month and year (MM/DD/YYYY) format. This date should only be modified by the Program Manager in rare circumstances.

(2) Inspect each tunnel at regular 24-month intervals.

(3) For tunnels needing inspection more frequently than 24-month intervals, establish criteria to determine the level and frequency to which these tunnels are inspected, based on a risk analysis approach that considers such factors as tunnel age, traffic characteristics, geotechnical conditions, and known deficiencies.

(4) Certain tunnels may be inspected at regular intervals up to 48 months. Inspecting a tunnel at an increased interval may be appropriate when past inspection findings and analysis justifies the increased inspection interval. At a minimum, the following criteria shall be used to determine the level and frequency of inspection based on an assessed lower risk: Tunnel age, time from last major rehabilitation, tunnel complexity, traffic characteristics, geotechnical conditions, functional systems, and known deficiencies. A written request that justifies a regular routine inspection interval between 24 and 48 months shall be submitted to FHWA for review and comment prior to the extended interval being implemented.

(5) Inspect each tunnel in accordance with the established interval. The acceptable tolerance for inspection interval is within 2 months before or after the Inspection Date established in paragraph (b)(1) of this section in order to maintain that date. The actual month, day, and year of the inspection are to be reported in the National Tunnel Inventory.

(c) *Damage, in-depth, and special inspections.* The Program Manager shall establish criteria to determine the level and frequency of damage, in-depth, and special inspections. Damage, in-depth, and special inspections may use non-destructive testing or other methods not used during routine inspections at an interval established by the Program Manager. In-depth inspections should be scheduled for complex tunnels and for certain structural elements and functional systems when necessary to fully ascertain the condition of the element or system; hands-on inspection may be necessary at some locations.

§ 650.513 Inspection procedures.

Each State DOT, Federal agency, or tribal government tunnel inspection organization, to carry out its inspection responsibilities, shall perform or cause to be performed all of the following:

(a) Inspect tunnel structural elements and functional systems in accordance with the inspection guidance provided in the Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual (incorporated by reference, *see* § 650.517).

(b) Provide at least one Team Leader, who meets the minimum qualifications stated in § 650.509, at the tunnel at all times during each initial, routine, and in-depth inspection. The State DOT, Federal agency, or tribal government shall report the nationally certified tunnel inspector identification for each Team Leader that is wholly or partly responsible for a tunnel inspection must be reported to the National Tunnel Inventory.

(c) Prepare and document tunnel-specific inspection procedures for each tunnel inspected and inventoried that shall:

(1) Take into account the design assumptions and the tunnel complexity; and

(2) Identify the—

(i) Tunnel structural elements and functional systems to be inspected;

(ii) Methods of inspection to be used;

(iii) Frequency of inspection for each method; and

(iv) Inspection equipment, access equipment, and traffic coordination needed.

(d) Establish requirements for functional system testing, direct observation of critical system checks, and testing documentation.

(e) For complex tunnels, identify specialized inspection procedures and additional inspector training and experience required to inspect complex tunnels. Inspect complex tunnels

according to the specialized inspection procedures.

(f) Conduct tunnel inspections with qualified staff not associated with the operation or maintenance of the tunnel structure or functional systems.

(g) Rate each tunnel's safe vehicular load-carrying capacity in accordance with the Sections 6 or 8, AASHTO Manual for Bridge Evaluation (incorporated by reference, *see* § 650.517). A State DOT, Federal agency, or tribal government shall conduct a load rating evaluation as soon as practical, but not later than three months after the completion of the inspection, if a change in condition is identified. Post or restrict the highways in or over the tunnel in accordance with Section 6, AASHTO Manual for Bridge Evaluation (incorporated by reference, *see* § 650.517), or in accordance with State law, when the maximum unrestricted legal loads or State routine permit loads exceed those allowed under the operating rating or equivalent rating factor. Postings shall be made as soon as possible but not later than 30 days after a valid load rating determines a need for such posting. At-grade roadways in tunnels are exempt from load rating. A State DOT, Federal agency, or tribal government, shall maintain load rating calculations or input files with a summary of results as a part of the tunnel record.

(h) Prepare tunnel inspection documentation as described in the Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual (incorporated by reference, *see* § 650.517), and maintain written reports or electronic files on the results of tunnel inspections, together with notations of any action taken to address the findings of such inspections. Maintain relevant maintenance and inspection data to allow assessment of current tunnel condition. At a minimum, information collected will include data regarding basic tunnel information (*e.g.,* tunnel location, posted speed, inspection reports, repair recommendations, and repair and rehabilitation work completed), tunnel and roadway geometrics, interior tunnel structural features, portal structure features, and tunnel systems information. When available, tunnel data collected shall include diagrams, photos, condition of each structural and functional system component, notations of any action taken to address the findings of such inspections, and the national tunnel inspector certification registry identification for each Team Leader responsible in whole or in part for the inspection.

(i) Use systematic quality control and quality assurance procedures to maintain a high degree of accuracy and consistency in the inspection program. Include periodic field review of inspection teams, data quality checks, and independent review of inspection reports and computations.

(j) Establish a Statewide, Federal agency-wide, or tribal government-wide procedure to ensure that critical findings are addressed in a timely manner. Notify FHWA within 24 hours of any critical finding and the activities taken, underway, or planned to resolve or monitor the critical finding. Update FHWA regularly or as requested on the status of each critical finding until it is resolved. Annually provide a written report to FHWA with a summary of the current status of the resolutions for each critical finding identified within that year or unresolved from a previous year.

(k) Provide information at least annually, or more frequently upon request, in cooperation with any FHWA review of State DOT, Federal agency, or tribal government compliance with the NTIS. The FHWA will assess annually State DOT compliance using statistical assessments and well-defined measures based on the requirements of this subpart.

§ 650.515 Inventory.

(a) *Preliminary inventory.* Each State, Federal agency, or tribal government shall collect and submit the inventory data items described in the Specifications for the National Tunnel Inventory (incorporated by reference, *see* § 650.517) for all tunnels subject to the NTIS by December 11, 2015.

(b) *National Tunnel Inventory.* Each State, Federal agency, or tribal government shall prepare, maintain, and make available to FHWA upon request, an inventory of all highway tunnels subject to the NTIS that includes the preliminary inventory information submitted in paragraph (a) of this section, reflects the findings of the most recent tunnel inspection conducted, and is consistent and coordinated with the Specifications for the National Tunnel Inventory.

(c) *Data entry for inspections.* For all inspections, each State DOT, Federal agency, or tribal government shall enter the appropriate tunnel inspection data into its inventory within 3 months after the completion of the inspection.

(d) *Data entry for tunnel modifications and new tunnels.* For modifications to existing tunnels that alter previously recorded data and new tunnels, each State DOT, Federal agency, or tribal government shall enter the appropriate data into its inventory within 3 months after the completion of the work.

(e) *Data entry for tunnel load restriction and closure changes.* For changes in traffic load restriction or closure status, each State DOT, Federal agency, or tribal government shall enter the data into its inventory within 3 months after the change in status of the tunnel.

§ 650.517 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the FHWA must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at 1200 New Jersey Avenue SE., Washington, DC 20590. For questions regarding the availability of this material at FHWA, call the FHWA Regulations Officer, Office of the Chief Counsel, HCC–10, 202–366–0761. This material is also available for inspection 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/code_of_federal_regulations/ibr_locations.html.*

(b) American Association of State Highway and Transportation Officials (AASHTO), Suite 249, 444 N. Capitol Street NW., Washington, DC 20001, 800–231–3475, *https://bookstore.transportation.org.*

(1) ''The Manual of Bridge Evaluation,'' Section 6 ''Load Rating'' and Section 8 ''Nondestructive Load Testing,'' Second Edition, 2011, copyright 2011, incorporation by reference approved for §§ 650.505 and 650.513(a).

(2) 2011 Interim Revisions to ''The Manual of Bridge Evaluation,'' Section 6 ''Load Rating,'' Second Edition, 2010, copyright 2011, incorporation by reference approved for §§ 650.505 and 650.513(a).

(3) 2013 Interim Revisions to ''The Manual of Bridge Evaluation,'' Section 6 ''Load Rating,'' Second Edition, 2010, copyright 2013, incorporation by reference approved for §§ 650.505 and 650.513(a).

(4) 2014 Interim Revisions to ''The Manual of Bridge Evaluation,'' Section 6 ''Load Rating,'' Second Edition, 2010, copyright 2013, incorporation by reference approved for §§ 650.505 and 650.513(a).

(5) 2015 Interim Revisions to ''The Manual of Bridge Evaluation,'' Section 6

''Load Rating,'' Second Edition, 2010, copyright 2014, incorporation by reference approved for §§ 650.505 and 650.513(a).

(c) Office of Bridges and Structures, Federal Highway Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590.

(1) FHWA–HIF–15–005, ''Tunnel Operations, Maintenance, Inspection and Evaluation (TOMIE) Manual,'' 2015 edition, available in electronic format at *http://www.fhwa.dot.gov/bridge/inspection/tunnel/*. Incorporation by reference approved for §§ 650.505, 650.511(a), and 650.513(a) and (h).

(2) FHWA–HIF–15–006, ''Specifications for National Tunnel Inventory,'' 2015 edition, available in electronic format at *http://www.fhwa.dot.gov/bridge/inspection/tunnel/*. Incorporation by reference approved for § 650.515(a) and (b).

[FR Doc. 2015–16896 Filed 7–13–15; 8:45 am]

BILLING CODE 4910–22–P

FEDERAL REGISTER

Vol. 80 Tuesday,

No. 134 July 14, 2015

Part VI

Commodity Futures Trading Commission

17 CFR Part 23

Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants—Cross-Border Application of the Margin Requirements; Proposed Rule

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 23

RIN 3038–AC97

Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants—Cross-Border Application of the Margin Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: On October 3, 2014, the Commission published proposed regulations to implement section 4s(e) of the Commodity Exchange Act, as added by section 731 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). This provision requires the Commission to adopt initial and variation margin requirements for swap dealers (''SDs'') and major swap participants (''MSPs'') that do not have a Prudential Regulator (collectively, ''CSEs'' or ''Covered Swap Entities''). In the October 3, 2014 proposing release, the Commission also issued an Advance Notice of Proposed Rulemaking (''ANPR'') requesting public comment on the cross-border application of such margin requirements. In this release, the Commission is proposing a rule for the application of the Commission's margin requirements to cross-border transactions.

DATES: Comments must be received on or before September 14, 2015.

ADDRESSES: You may submit comments, identified by RIN 3038–AC97 and ''Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants—Cross-Border Application of the Margin Requirements'' by any of the following methods:

- *CFTC Web site: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the Web site.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail, above.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit your comments using only one of these methods.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that may be exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the established procedures in § 145.9 of the Commission's regulations, 17 CFR 145.9.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted, or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Laura B. Badian, Assistant General Counsel, 202–418–5969, *lbadian@cftc.gov*, or Paul Schlichting, Assistant General Counsel, 202–418–5884, *pschlichting@cftc.gov*, Office of the General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
A. Dodd-Frank Act and the Scope of This Rulemaking
B. Key Considerations in the Cross-Border Application of the Margin Regulations
C. Advance Notice of Proposed Rulemaking
1. Guidance Approach
2. Prudential Regulators' Approach
3. Entity-Level Approach
4. Comments on the Alternative Approaches Discussed in the ANPR
II. The Proposed Rule
A. Overview
1. Use of Hybrid, Firm-Wide Approach
B. Key Definitions
1. U.S. Person
2. Guarantees
3. Foreign Consolidated Subsidiaries
C. Applicability of Margin Requirements to Cross-Border Uncleared Swaps
1. Uncleared Swaps of U.S. CSEs or Non-U.S. CSEs Whose Obligations Under the Relevant Swap Are Guaranteed by a U.S. Person
2. Uncleared Swaps of Non-U.S. CSEs (Including Foreign Consolidated Subsidiaries) Whose Obligations Under the Relevant Swap Are Not Guaranteed by a U.S. Person
3. Exclusion for Uncleared Swaps of Non-U.S. CSEs Where Neither Counterparty's Obligations Under the Relevant Swap Are Guaranteed by a U.S. Person and Neither Counterparty Is a Foreign Consolidated Subsidiary Nor a U.S. Branch of a Non-U.S. CSE
4. U.S. Branches of Non-U.S. CSEs
D. Substituted Compliance
E. General Request for Comments
III. Related Matters
A. Regulatory Flexibility Act
B. Paperwork Reduction Act
C. Cost-Benefit Considerations
1. Introduction
2. Proposed Rule
a. U.S. Person
b. Availability of Substituted Compliance and Exclusion
i. Uncleared Swaps of U.S. CSEs or of Non-U.S. CSEs Whose Obligations Under the Relevant Swap Are Guaranteed by a U.S. Person
ii. Uncleared Swaps of Non-U.S. CSEs Whose Obligations Under the Relevant Swap Are Not Guaranteed by a U.S. Person
iii. Exclusion for Uncleared Swaps of Non-U.S. CSEs Where Neither Counterparty's Obligations Under the Relevant Swap Are Guaranteed by a U.S. Person and Neither Counterparty Is a Foreign Consolidated Subsidiary Nor a U.S. Branch of a Non-U.S. CSE
iv. Foreign Consolidated Subsidiaries
v. U.S. Branch of a Non-U.S. CSE
c. Alternatives
d. Comparability Determinations
3. Section 15(a) Factors
a. Protection of Market Participants and the Public
b. Efficiency, Competitiveness, and Financial Integrity
i. Efficiency
ii. Competitiveness
iii. Financial Integrity of Markets
c. Price Discovery
d. Sound Risk Management Practices
e. Other Public Interest Considerations
4. General Request for Comment

I. Background

A. Dodd-Frank Act and the Scope of This Rulemaking

In the fall of 2008, as massive losses spread throughout the financial system and many major financial institutions failed or narrowly escaped failure with government intervention, confidence in the financial system was replaced by panic, credit markets seized up, and trading in many markets grounded to a halt. The financial crisis revealed the vulnerability of the U.S. financial system to widespread systemic risk resulting from, among other things, excessive leverage, poor risk management practices at financial firms, and the lack of integrated supervisory oversight of financial institutions and

financial markets.[1] The financial crisis also highlighted the contagion risks of under-collateralized counterparty exposures in a highly interconnected financial system.[2]

In the wake of the financial crisis, Congress enacted the provisions of the Commodity Exchange Act (''CEA'') relating to swaps in Title VII of the Dodd-Frank Act,[3] which establishes a comprehensive new regulatory framework for swaps. One of the cornerstones of this regulatory framework is the reduction of systemic risk to the U.S. financial system through the establishment of margin requirements for uncleared swaps.[4]

Section 731 of the Dodd-Frank Act added a new section 4s, which directs the Commission to adopt rules establishing minimum initial and variation margin requirements for SDs and MSPs on all swaps that are not cleared by a registered derivatives clearing organization. Section 4s(e) further provides that the margin requirements must: (i) Help ensure the safety and soundness of the SD or MSP; and (ii) be appropriate for the risk associated with the uncleared swaps held as a SD or MSP.[5]

The Dodd-Frank Act also requires that the Prudential Regulators,[6] in consultation with the Commission and the Securities and Exchange Commission (''SEC''), adopt a joint margin rule. Accordingly, each SD and MSP for which there is a Prudential Regulator must meet margin requirements established by the applicable Prudential Regulator, and each SD and MSP for which there is no Prudential Regulator must comply with the Commission's margin requirements. Further, the Dodd-Frank Act requires that the Commission, the Prudential Regulators and the SEC, to the maximum extent practicable, establish and maintain comparable minimum capital and minimum initial and variation margin requirements, including the use of noncash collateral, for SDs and MSPs.[7]

In determining whether, and the extent to which, section 4s(e) should apply to a CSE's swap activities outside the United States, the Commission focused on the text and objectives of that provision together with the language of section 2(i) of the CEA.[8] As discussed further below, the primary reason for the margin requirement is to protect CSEs in the event of a counterparty default. That is, in the event of a default by a counterparty, margin protects the CSE by allowing it to absorb the losses using collateral provided by the defaulting entity and to continue to meet all of its obligations. In addition, margin functions as a risk management tool by limiting the amount of leverage that a CSE can incur. Specifically, by requiring a CSE to post margin to its counterparties, the margin requirements ensure that a CSE has adequate eligible collateral to enter into an uncleared swap.

Risk arising from uncleared swaps can potentially have a substantial adverse effect on any CSE—irrespective of its domicile or the domicile of its counterparties—and therefore the stability of the U.S. financial system because each CSE has a sufficient nexus to the U.S. financial system to require registration as a CSE. In light of the role of margin in ensuring the safety and soundness of CSEs and preserving the stability of the U.S. financial system, and consistent with section 2(i), section 4s(e)'s margin requirements extend to all CSEs on a cross-border basis.

Pursuant to its new section 4s(e) authority, on October 3, 2014, the Commission published reproposed regulations to implement initial and variation margin requirements on uncleared swaps (''Proposed Margin Rules'') for SDs and MSPs that do not have a Prudential Regulator (collectively, ''CSEs'' or ''Covered Swap Entities'').[9] In the same release, the Commission also published an ANPR requesting public comment on the cross-border application of such margin requirements. In this release, the Commission is proposing a rule for the application of the Commission's uncleared swap margin requirements to cross-border transactions (referred to herein as the ''Proposed Rule'').

B. Key Considerations in the Cross-Border Application of the Margin Regulations

The swaps market is global in nature. Swaps are routinely entered into between counterparties located in different jurisdictions. Dealers and other market participants conduct their swaps business through subsidiaries, affiliates, and branches dispersed across geographical boundaries. The global and highly interconnected nature of the swaps market heightens the potential that risks assumed by a firm overseas can be transmitted across national borders to cause or contribute to substantial losses to U.S. persons and threaten the stability of the entire U.S. financial system. Therefore, it is important that margin requirements for uncleared swaps apply on a cross-border basis in a manner that effectively addresses risks to U.S. persons and the U.S. financial system.

The Commission recognizes that non-U.S. CSEs and non-U.S. counterparties may be subject to comparable or different rules in their home jurisdictions. Conflicting and duplicative requirements between U.S. and foreign margin regimes could potentially lead to market inefficiencies

[1] *See* Financial Crisis Inquiry Commission, ''The Financial Crisis Inquiry Report: Final Report of the National Commission on the Causes of the Financial and Economic Crisis in the United States,'' Jan. 2011, at xviii–xxv, 307–8, 363–5, 386, *available at http://www.gpo.gov/fdsys/pkg/GPO-FCIC/pdf/GPO-FCIC.pdf.*

[2] *Id.* at xxiv–xxv, 49–51.

[3] Pub. L. 111–203, 124 Stat. 1376 (2010).

[4] The Financial Crisis Inquiry Commission stated in its report that the failure of American International Group, Inc. (''AIG'') was possible because the sweeping deregulation of over-the-counter derivatives (including credit default swaps) effectively eliminated federal and state regulation of these products, including capital and margin requirements that would have reduced the likelihood of AIG's failure. *Id.* at 352.

[5] Section 4s(e)(3)(A)(i) of the CEA, 7 U.S.C. 6s(e)(3)(A)(i).

[6] The term ''Prudential Regulator'' is defined in section 1a(39) of the CEA, as amended by section 721 of the Dodd-Frank Act. This definition includes the Board of Governors of the Federal Reserve System (''FRB''); the Office of the Comptroller of the Currency (''OCC''); the Federal Deposit Insurance Corporation (''FDIC''); the Farm Credit Administration; and the Federal Housing Finance Agency.

[7] *See* section 4s(e)(3)(D)(ii) of the CEA, 7 U.S.C. 6s(e)(3)(D)(ii), which was added by section 731 of the Dodd-Frank Act. The Prudential Regulators, the Commission, and the SEC are also required to consult periodically (but not less frequently than annually) on minimum capital requirements and minimum initial and variation margin requirements. *See* section 4s(e)(3)(D)(i) of the CEA, 7 U.S.C. 6s(e)(3)(D)(i).

[8] *See* 7 U.S.C. 2(i). Section 2(i) of the CEA states that the provisions of the Act relating to swaps that were enacted by the Wall Street Transparency and Accountability Act of 2010 (including any rule prescribed or regulation promulgated under that Act), shall not apply to activities outside the United States unless those activities—(1) have a direct and significant connection with activities in, or effect on, commerce of the United States; or (2) contravene such rules or regulations as the Commission may prescribe or promulgate as are necessary or appropriate to prevent the evasion of any provision of the Act [CEA] that was enacted by the Wall Street Transparency and Accountability Act of 2010.

[9] The Commission's Proposed Margin Rules are set forth in proposed rules §§ 23.150 through 23.159 of part 23 of the Commission's regulations, proposed as 17 CFR 23.150 through 23.159. *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 79 FR 59898 (Oct. 3, 2014). In September 2014, the Prudential Regulators published proposed regulations to implement initial and variation margin requirements for SDs and MSPs that have a Prudential Regulator. *See* Margin and Capital Requirements for Covered Swap Entities, 79 FR 53748 (Sept. 24, 2014), *available at http://www.gpo.gov/fdsys/pkg/FR-2014-09-24/pdf/2014-22001.pdf.* The Commission originally proposed margin rules for public comment in 2011. *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 76 FR 23732 (April 28, 2011).

and regulatory arbitrage, as well as competitive disparities that undermine the relative position of U.S. CSEs and their counterparties. Therefore, it is essential that a cross-border margin framework takes into account the global nature of the swaps market and the supervisory interests of foreign regulators with respect to entities and transactions covered by the Commission's margin regime.[10]

In granting the Commission new authorities under the Dodd-Frank Act, Congress also reaffirmed and called for coordination and cooperation among domestic and foreign regulators. Section 752(a) of the Dodd-Frank Act requires the Commission, the Prudential Regulators, and the SEC to consult and coordinate with foreign regulatory authorities on the ''establishment of consistent international standards'' with respect to the regulation of swaps.[11] In this regard, the Commission recognizes that efforts are underway by other domestic and foreign regulators to implement margin reform and that regulatory harmonization and coordination are indispensable to achieving a workable cross-border framework.

In developing a cross-border framework for margin regulations, the Commission aims to strike the proper balance among these sometimes competing considerations. To that end, the Commission has consulted and coordinated with the Prudential Regulators and foreign regulatory authorities. Commission staff worked closely with the staff of the Prudential Regulators, and the Proposed Rule is closely aligned with the cross-border proposal that was published by the Prudential Regulators in September 2014. In addition, Commission staff has participated in numerous bilateral and multilateral discussions with foreign regulatory authorities addressing national efforts to implement margin reform and the possibility of conflicts and overlaps between U.S. and foreign regulatory regimes. Recognizing that systemic risks arising from global and interconnected swaps market must be addressed through coordinated regulatory requirements for margin across international jurisdictions, the Commission has played an active role in encouraging international harmonization and coordination of margin requirements for uncleared swaps.

The Commission notes that its collaboration with the Basel Committee on Banking Supervision (''BCBS'') and the Board of the International Organization of Securities Commissions (''IOSCO'') as a member of the Working Group on Margining Requirements (''WGMR'') resulted in the issuance of a final margin policy framework for non-cleared, bilateral derivatives in September 2013 (referred to herein as the ''BCBS–IOSCO framework'').[12] Individual regulatory authorities across major jurisdictions (including the EU, Japan, and the United States) have since started to develop their own margin rules.[13] The Proposed Rule is consistent with the standards in the final BCBS–IOSCO framework, and we have been in continuous communication with regulators in the EU and Japan as we developed our cross-border margin proposal. Although at this time foreign jurisdictions do not yet have their margin regimes in place, the Commission has participated in ongoing, collaborative discussions with regulatory authorities in the EU and Japan regarding their cross-border approaches to the margin rules, including the anticipated scope of application of margin requirements in their jurisdiction to cross-border swaps, their plans for recognizing foreign margin regimes, and their anticipated timelines.

The Commission believes that its ongoing bilateral and multilateral discussions with foreign regulatory authorities in major jurisdictions (including the EU and Japan) are critical to fostering international cooperation and harmonization and in reducing conflicting and duplicative regulatory requirements. The Commission expects that these discussions will continue as it finalizes and then implements its framework for the application of margin requirements to cross-border transactions, and as other jurisdictions develop their own respective approaches.

C. Advance Notice of Proposed Rulemaking

The ANPR sought public comment on three potential alternative approaches to the cross-border application of its margin requirements: (1) A transaction-level approach that is consistent with the Commission's cross-border guidance (''Guidance Approach'');[14] (2) an

[10] In developing the proposed cross-border framework, the Commission is guided by principles of international comity, which counsels due regard for the important interests of foreign sovereigns. *See* Restatement (Third) of Foreign Relations Law of the United States (the ''Restatement''). The Restatement provides that even where a country has a basis for jurisdiction, it should not prescribe law with respect to a person or activity in another country when the exercise of such jurisdiction is unreasonable. *See* Restatement section 403(1). The reasonableness of such an exercise of jurisdiction, in turn, is to be determined by evaluating all relevant factors, including certain specifically enumerated factors where appropriate: (a) The link of the activity to the territory of the regulating state, *i.e.,* the extent to which the activity takes place within the territory, or has substantial, direct, and foreseeable effect upon or in the territory; (b) the connections, such as nationality, residence, or economic activity, between the regulating state and the persons principally responsible for the activity to be regulated, or between that state and those whom the regulation is designed to protect; (c) the character of the activity to be regulated, the importance of regulation to the regulating state, the extent to which other states regulate such activities, and the degree to which the desirability of such regulation is generally accepted; (d) the existence of justified expectations that might be protected or hurt by the regulation; (e) the importance of the regulation to the international political, legal, or economic system; (f) the extent to which the regulation is consistent with the traditions of the international system; (g) the extent to which another state may have an interest in regulating the activity; and (h) the likelihood of conflict with regulation by another state. *See* Restatement section 403(2).

Notably, the Restatement does not preclude concurrent regulation by multiple jurisdictions. However, where concurrent jurisdiction by two or more jurisdictions creates conflict, the Restatement recommends that each country evaluate its own interests in exercising jurisdiction and those of the other jurisdiction, and where possible, to consult with each other.

[11] 15 U.S.C. 8325(a) (added by section 752 of the Dodd-Frank Act). Also, before commencing any rulemaking or issuing an order regarding swaps, the Commission must consult and coordinate to the extent possible with the SEC and the Prudential Regulators for the purposes of assuring regulatory consistency and comparability, to the extent possible. *See* 15 U.S.C. 8302(a)(1) (added by section 712(a)(1) of the Dodd-Frank Act).

[12] *See* Margin Requirements for Non-centrally Cleared Derivatives (Sept. 2013), *available at http://www.bis.org/publ/bcbs261.pdf.*

[13] *See* European Banking Authority, European Securities and Markets Authority, and European Insurance and Occupational Pensions Authority, Consultation Paper on draft regulatory technical standards on risk-mitigation techniques for OTC-derivative contracts not cleared by a CCP under Article 11(15) of Regulation (EU) No 648/2012 (for the European Market Infrastructure Regulation) (April 14, 2014), *available at https://www.eba.europa.eu/documents/10180/655149/JC+CP+2014+03+%28CP+on+risk+mitigation+for+OTC+derivatives%29.pdf*, and Second Consultation Paper on draft regulatory technical standards on risk-mitigation techniques for OTC-derivative contracts not cleared by a CCP under Article 11(15) of Regulation (EU) No 648/2012 (for the European Market Infrastructure Regulation) (Jun. 10, 2015), *available at https://www.eba.europa.eu/documents/10180/1106136/JC-CP-2015-002+JC+CP+on+Risk+Management+Techniques+for+OTC+derivatives+.pdf*; Financial Services Agency of Japan, draft amendments to the ''Cabinet Office Ordinance on Financial Instruments Business'' and ''Comprehensive Guidelines for Supervision'' with regard to margin requirements for non-centrally cleared derivatives (July 3, 2014). Available in Japanese at *http://www.fsa.go.jp/news/26/syouken/20140703-3.html.*

[14] Interpretative Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (July 26, 2013) (''Guidance''). The Commission addressed, among other things, how the swap provisions in the Dodd-Frank Act (including the margin requirement for uncleared swaps) generally would apply on a cross-border basis. In this regard, the Commission stated that as a general policy matter it expected to apply the margin requirement as a transaction-level requirement.

approach that is consistent with the approach proposed by the Prudential Regulators (the ''Prudential Regulators' Approach''); [15] and (3) an entity-level approach described in the ANPR (''Entity-Level Approach''). To provide context for the discussion of the Proposed Rule, the three alternative approaches discussed in the ANPR are summarized below.

1. Guidance Approach

Under the first alternative discussed in the ANPR, the Commission's margin requirements would be applied on a transaction-level basis, consistent with its cross-border Guidance.[16] The Commission stated in the Guidance that it would generally treat its margin requirements for uncleared swaps as a transaction-level requirement. Consistent with the rationale stated in the Guidance, under this transaction-level approach, the Commission's Proposed Margin Rules would apply to a U.S. SD/MSP (other than a foreign branch of a U.S. bank that is a SD/MSP) for all of its uncleared swaps, regardless of whether its counterparty is a U.S. person,[17] without substituted compliance.

However, under this approach the margin requirements would apply to a non-U.S. SD/MSP (whether or not it is a ''guaranteed affiliate'' [18] or an ''affiliate conduit'' [19]) only with respect to its uncleared swaps with a U.S. person counterparty and a non-U.S. counterparty that is a guaranteed affiliate or an affiliate conduit; the margin requirements would not apply to uncleared swaps with a non-U.S. person counterparty that is not a guaranteed affiliate or an affiliate conduit. Where the non-U.S. counterparty is a guaranteed affiliate or an affiliate conduit, the Commission would allow substituted compliance (*i.e.,* the non-U.S. SD/MSP would be permitted to comply with the margin requirements of its home country's regulator if the Commission determines that such requirements are comparable to the Commission's margin requirements).[20]

2. Prudential Regulators' Approach

The second alternative discussed in the ANPR was the Prudential Regulators' Approach to cross-border application of the margin requirements.[21] Under the Prudential Regulators' proposal issued in September 2014 (the ''September proposal''), the Prudential Regulators would apply the margin requirements to all uncleared swaps of CSEs under their supervision with a limited exception.[22] Specifically, the Prudential Regulators would not apply their margin requirements to any foreign non-cleared swap of a foreign covered swap entity.[23] This exclusion would only be available where neither the non-U.S. SD/MSP's nor the non-U.S. counterparty's obligations under the relevant swap are guaranteed by a U.S. person and neither party is ''controlled'' by a U.S. person. Under the ''control'' test used in the September proposal, the term ''control'' of another company means: (1) Ownership, control, or power to vote 25 percent or more of a class of voting securities of the company, directly or indirectly or acting through one or more other persons; (2) ownership or control of 25 percent or more of the total equity of the company, directly or indirectly or acting through one or more other persons; or (3) control in any manner of the election of a majority of the directors or trustees of the company.

3. Entity-Level Approach

Under the third alternative discussed in the ANPR, margin requirements would be treated as an entity-level requirement. Under this Entity-Level Approach, the Commission would apply its proposed cross-border rules on margin on a firm-wide level—that is, to all uncleared swaps activities of a SD/MSP registered with the Commission, irrespective of whether the counterparty is a U.S. person, and with no possibility of exclusion. This approach takes into account that a non-U.S. SD/MSP entering into uncleared swaps faces counterparty credit risk regardless of where the swap is executed or whether the counterparty is a U.S. person.[24] That risk, if it leads to a default by the non-U.S. SD/MSP, could cause adverse consequences to its U.S. counterparties and the U.S. financial system. At the same time, in recognition of international comity, under this approach the Commission would consider, where appropriate, allowing CSEs to avail themselves of substituted compliance.

4. Comments on the Alternative Approaches Discussed in the ANPR

After publishing the ANPR, the Commission received comments that responded to the three alternative approaches.[25] There was no consensus

[15] *See* Margin and Capital Requirements for Covered Swap Entities, 79 FR 53748 (Sept. 24, 2014), *available at http://www.gpo.gov/fdsys/pkg/FR-2014-09-24/pdf/2014-22001.pdf.*

[16] *See* Interpretative Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (July 26, 2013).

[17] The scope of the term ''U.S. person'' as used in the Cross-Border Guidance Approach and the Entity-Level Approach would be the same as under the Guidance. *See* Guidance at 45316–45317 for a summary of the Commission's interpretation of the term ''U.S. person.''

[18] Under the Guidance, *id.* at 45318, the term ''guaranteed affiliate'' refers to a non-U.S. person that is an affiliate of a U.S. person and that is guaranteed by a U.S. person. The scope of the term ''guarantee'' under the Guidance Approach and the Entity-Level Approach would be the same as under note 267 of the Guidance and accompanying text.

[19] Under the approach discussed in the Guidance, *id.* at 45359, the factors that are relevant to the consideration of whether a person is an ''affiliate conduit'' include whether: (i) The non-U.S. person is majority-owned, directly or indirectly, by a U.S. person; (ii) the non-U.S. person controls, is controlled by, or is under common control with the U.S. person; (iii) the non-U.S. person, in the regular course of business, engages in swaps with non-U.S. third party(ies) for the purpose of hedging or mitigating risks faced by, or to take positions on behalf of, its U.S. affiliate(s), and enters into offsetting swaps or other arrangements with such U.S. affiliate(s) in order to transfer the risks and benefits of such swaps with third-party(ies) to its U.S. affiliates; and (iv) the financial results of the non-U.S. person are included in the consolidated financial statements of the U.S. person. Other facts and circumstances also may be relevant.

[20] Where the uncleared swap is between a non-U.S. SD/MSP (whether or not it is a guaranteed affiliate or an affiliate conduit) and a foreign branch of a U.S. bank that is a SD/MSP, substituted compliance would be available if certain conditions are met.

[21] *See* section 9 of the proposed rule on Margin and Capital Requirements for Covered Swap Entities, 12 CFR part 237 (Sept. 24, 2014) for a complete description of the proposed cross-border application of margin requirements to swaps by the Prudential Regulators, *available at http://www.gpo.gov/fdsys/pkg/FR-2014-09-24/pdf/2014-22001.pdf.*

[22] A summary of the Prudential Regulators' Approach to the cross-border application of their proposed margin requirements is included in the ANPR. *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 79 FR 59917(Oct. 3, 2014). For further information on the Prudential Regulators' Approach generally, *see* Margin and Capital Requirements for Covered Swap Entities, 79 FR 53748 (Sept. 24, 2014), *available at http://www.gpo.gov/fdsys/pkg/FR-2014-09-24/pdf/2014-22001.pdf.*

[23] The Prudential Regulators define a ''foreign covered swap entity'' as any covered swap entity that is *not* (i) an entity organized under U.S. or State law, including a U.S. branch, agency, or subsidiary of a foreign bank; (ii) a branch or office of an entity organized under U.S. or State law; or (iii) an entity controlled by an entity organized under U.S. or State law. Under the Prudential Regulators' proposal, a ''foreign non-cleared swap'' would include any non-cleared swap of a foreign covered swap entity to which neither the counterparty nor any guarantor (on either side) is (i) an entity organized under U.S. or State law, including a U.S. branch, agency, or subsidiary of a foreign bank; (ii) a branch or office of an entity organized under U.S. or State law; or (iii) a covered swap entity controlled by an entity organized under U.S. or State law.

[24] A summary of the Entity-Level Approach to the cross-border application of the Proposed Margin Rules is included in the ANPR. *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 79 FR 59917 (Oct. 3, 2014).

[25] Comment letters received in response to the ANPR may be found on the Commission's Web site *at http://comments.cftc.gov/PublicComments/CommentList.aspx?id=1528.*

among commenters on a preferable approach.

Several commenters supported the Guidance Approach, with modifications, on the basis that margin rules should not apply to swaps between a foreign swap dealer and a foreign, non-guaranteed counterparty.[26] Some of these commenters suggested modifications to the availability of substituted compliance in the approach described in the Guidance.[27] For example, one commenter suggested that the Commission should treat non-U.S. margin requirements that conform to the BCBS–IOSCO framework as ''essentially identical'' to the Commission's regime and therefore accessible to all SDs as a means of complying with the Commission's margin requirements.[28] Another commenter suggested that the Commission modify its approach to substituted compliance outlined in the Guidance to allow substituted compliance for trades between U.S. persons and non-U.S. persons at such parties' mutual agreement.[29] In addition, some commenters that supported the Guidance Approach expressed the view that it should include an emerging markets exception.[30] Still another commenter argued that the Commission's Guidance correctly classified margin as a transaction-level rather than an entity-level requirement because, as with the clearing requirement, it is practicable to separate out transactions which are subject to the margin requirements and transactions which are not. This commenter stated that it would be an odd result if the Commission were to determine that the reach of the clearing requirement was not as great as that of the margin requirement, given that both requirements are intended to address counterparty credit risk.[31]

In contrast, some commenters argued against adopting the Guidance Approach. One commenter argued that the Guidance Approach has become a significant driver of conflict between U.S. and European regulatory requirements, and is undermining the goal of a globally coordinated regulatory framework.[32] Another commenter argued that this approach provides an excessively broad exemption for ''non-guaranteed'' foreign affiliates of U.S. banks, and that it is completely inappropriate to apply such an exemption to a crucial prudential requirement such as derivatives margin, which could pose major risks to the financial system by encouraging a race to the bottom among jurisdictions concerning margin requirements.[33]

Other commenters generally supported the Entity-Level Approach, with modifications, on the basis that it captures all registrants' uncleared trades, regardless of the domicile of the registrant or the counterparty. These commenters generally favored this approach because, rather than exempting foreign to foreign transactions, it makes substituted compliance available for these transactions. One commenter stated that the Entity-Level Approach is the most appropriate choice because it provides market participants with more certainty in determining which jurisdiction's margin requirements apply. Further, this commenter stated that the Entity-Level Approach is consistent with how collateral is currently handled under a single master agreement and would mitigate legal uncertainty and operational errors that can arise if trades are subject to different margin requirements under the same master agreement.[34] Another commenter favored the Entity-Level Approach because it imposes prudential rules on all swaps activities of U.S.-headquartered firms, regardless of where the swap transaction is booked. This commenter stated that both the Prudential Regulators' Approach and the Guidance Approach provide a means for U.S. firms to escape U.S. oversight.[35]

Another commenter supported a cross-border approach that combines the Guidance Approach with certain enhancements found in the Entity-Level Approach. This commenter suggested that the Entity-Level Approach correctly subjects certain non-U.S. SDs and MSPs to U.S. regulations—at least with respect to variation margin and the collection of initial margin—where the Guidance Approach would permit substituted compliance to both parties in all respects. However, this commenter stated that the Entity-Level Approach also contains provisions that are significantly weaker than the Guidance Approach, such as making substituted compliance available to certain non-U.S. counterparties of U.S. SDs or MSPs. This commenter also expressed the view that the Guidance Approach correctly requires both counterparties to fully comply with U.S. rules in all transactions involving a U.S. SD or MSP.[36]

Commenters generally did not support the Prudential Regulators' Approach as their first choice, but two commenters thought it might be workable with modifications. The first commenter stated that if the Commission elects not to adopt the ''Entity-Level'' Approach, the Prudential Regulators' Approach might be workable, although this commenter had reservations about situations where different jurisdictions' regimes apply to the same transaction.[37] The other commenter argued that if its first choice, the Entity-Level Approach, is not adopted, the Prudential Regulators' Approach is greatly superior to the Guidance Approach, as it would apply margin requirements to foreign affiliates of U.S. banks that are classified as SDs or MSPs, regardless of whether such affiliates are nominally guaranteed. However, this commenter argued that the Prudential Regulators' Approach is flawed in that, like the Guidance Approach, it would exempt controlled foreign subsidiaries of U.S. banks that are not registered with the Commission as swaps entities.[38]

Two commenters specifically argued against the Prudential Regulators' Approach. One commenter contended that the Prudential Regulators' Approach provides limited clarity on how the ''control'' test should be applied, which means that foreign bank subsidiaries of U.S. banks cannot be certain whether they are subject to U.S. rules or foreign rules, and provides limited guidance as to how foreign covered swaps entities can determine whether a financial end-user counterparty is a U.S. entity or a foreign entity, in comparison to the clear ''U.S. person'' standard in the Guidance.[39] The other commenter is concerned with the Prudential Regulators' Approach as it relates to funds. This commenter stated that the Prudential Regulators' definition of ''foreign non-cleared swap'' effectively classifies funds organized outside of the United States, but with a U.S. principal place of business (*e.g.,* funds with a U.S.-based manager), as foreign entities. This

[26] *See* International Swaps and Derivatives Association, Inc. (''ISDA'') (Nov. 24, 2014), Managed Funds Association (''MFA'') (Dec. 2, 2014), and INTL FCStone Inc. (Dec. 3, 2014).

[27] *See* ISDA (Nov. 24, 2014) and MFA (Dec. 2, 2014).

[28] *See* ISDA (Nov. 24, 2014).

[29] *See* MFA (Dec. 2, 2014).

[30] *See* ISDA (Nov. 24, 2014) and American Bankers Association (Nov. 25, 2014).

[31] *See* INTL FCStone Inc. (Dec. 3, 2014).

[32] *See* Alternative Investment Management Association (''AIMA'') (Dec. 2, 2014).

[33] *See* Americans for Financial Reform (''AFR'') (Dec. 2, 2014).

[34] *See* Securities Industry and Financial Markets Association, Asset Management Group (Nov. 24, 2014).

[35] *See* Public Citizen (Dec. 2, 2014).

[36] *See* Better Markets, Inc. (Dec. 2, 2014).

[37] *See* AIMA (Dec. 2, 2014).

[38] *See* AFR (Dec. 2, 2014).

[39] *See* Committee on Capital Markets Regulation (Nov. 24, 2014).

commenter stated that if funds with a U.S.-based manager are not considered ''U.S. persons'' subject to U.S. derivatives regulation, even though they have a substantial U.S. nexus, they would likely be required to margin their covered swaps in accordance with the foreign margin rules to which their non-U.S. CSE counterparty is subject, which would give too much deference to the foreign regulatory regime.[40]

One commenter asserted that both the Prudential Regulators' Approach and the Guidance Approach would appropriately exclude swaps between foreign-headquartered swap entities that are not controlled or guaranteed by a U.S. person and a non-U.S. person that is not guaranteed by a U.S. person from the scope of the margin rules, noting that if U.S. rules require the foreign-headquartered swap entity to post margin, this would create the potential for conflicts or inconsistencies with its home country margin requirements.[41]

One commenter did not explicitly support any of the three approaches, noting that all of the proposals diverge in potentially significant ways from the final framework developed by BCBS and IOSCO and the OTC margin framework proposed in April 2014 by European supervisory agencies, and that none of the proposals embrace substituted compliance in a comprehensive manner that would address cross-border conflicts or inconsistencies that could arise. This commenter suggested that the Commission should use an outcomes-based approach that looks to whether giving full recognition to an equivalent foreign OTC margin framework as a whole would ensure an acceptable reduction of aggregate unmargined risk.[42]

II. The Proposed Rule

A. Overview

Based on, among other things, consideration of the comments to the ANPR and after close consultation with the Prudential Regulators, the Commission is proposing a rule for the application of the Commission's Proposed Margin Rules to cross-border transactions (as noted above, the proposed cross-border margin rule is referred to herein as the ''Proposed Rule''). As discussed above, a cross-border framework for margin necessarily involves consideration of significant, and sometimes competing, legal and policy considerations, including the impact on market efficiency and competition.[43] The Commission, in developing the Proposed Rule, aims to balance these considerations to effectively address the risk posed to the safety and soundness of CSEs, while creating a workable framework that reduces the potential for undue market disruptions and promotes global harmonization. The Commission also recognizes that there are other possible approaches to applying the margin rules in the cross-border context. Accordingly, the Commission invites public comment regarding all aspects of the Proposed Rule.

1. Use of Hybrid, Firm-Wide Approach

The Proposed Rule is a combination of the entity- and transaction-level approaches and is closely aligned with the Prudential Regulators' Approach. In general, under the Proposed Rule, margin requirements are designed to address the risks to a CSE, as an entity, associated with its uncleared swaps (entity-level); nevertheless, certain uncleared swaps would be eligible for substituted compliance or excluded from the Commission's margin rules based on the counterparties' nexus to the United States relative to other jurisdictions (transaction-level).

Although margin is calculated for individual transactions or positions, and therefore, could be applied on a transaction-level basis, the Commission believes that as a general matter margin requirements should apply on a firm-wide basis, irrespective of the domicile of the counterparties or where the trade is executed. The primary reason for collecting margin from counterparties is to protect an entity in the event of a counterparty default. That is, in the event of a default by a counterparty, margin protects the non-defaulting counterparty by allowing it to absorb the losses using collateral provided by the defaulting entity and to continue to meet all of its obligations. In addition, margin functions as a risk management tool by limiting the amount of leverage that a CSE can incur. Specifically, by requiring a CSE to post margin to its counterparties, the margin requirements ensure that a CSE has adequate eligible collateral to enter into an uncleared swap. In this way, margin serves as a first line of defense to protect a CSE as a whole from risk arising from uncleared swaps.

The source of counterparty credit risk to a CSE, however, is not confined to its uncleared swaps with U.S. counterparties. Risk arising from uncleared swaps involving non-U.S. counterparties can potentially have a substantial adverse effect on a CSE—including a non-U.S. CSE—and therefore the stability of the U.S. financial system because CSEs have a sufficient nexus to the U.S. financial system to require registration as a CSE. Given the function of margin, the Commission believes that margin should be treated as an entity-level requirement in the cross-border context, and thus not take into account the domicile of CSE counterparties or where the trade is executed.

The Commission also believes that treating margin as an entity-level requirement is consistent with the role of margin in a CSE's overall risk management program. Margin, by design, is complementary to capital.[44] That is, margin and capital requirements serve different but equally important risk mitigation functions that are best implemented at the entity-level. Unlike margin, capital is difficult to rapidly adjust in response to changing risk exposures; thus, capital can be viewed as a backstop, in the event that the margin is not enough to cover all of the losses that resulted from the counterparty default. Standing alone, either capital or margin may not be enough to prevent a CSE from failing, but together, they are designed to reduce the probability of default by the CSE and limit the amount of leverage that can be undertaken by CSEs (and other market participants), which ultimately mitigates the possibility of a systemic event.[45]

At the same time, the Commission recognizes that a CSE's uncleared swaps with a particular counterparty may implicate the supervisory interests of foreign regulators and it is important to calibrate the cross-border application of the margin requirements to mitigate, to the extent possible and consistent with the Commission's regulatory interests, the potential for conflicts or duplication with other jurisdictions. Therefore, the Proposed Rule, while applying margin

[40] *See* MFA (Dec. 2, 2014).

[41] *See* Institute of International Bankers (Nov. 24, 2014). This commenter also stated that these foreign swaps would have little effect on the U.S. financial system in the event of a default; further, under the Dodd-Frank Act, the risk to the United States of a default by the foreign-headquartered swap entity on its swaps with U.S. counterparties would already be mitigated by capital and margin collection requirements.

[42] *See* Securities Industry and Financial Markets Association (''SIFMA'') (Nov. 24, 2014).

[43] The Commission's consideration of the costs and benefits associated with the Proposed Rule is discussed in section III.C. below.

[44] *See* BCBS and IOSCO, Margin requirements for non-centrally cleared derivatives (Sept. 2013) at 3, *available at http://www.bis.org/publ/bcbs261.pdf.*

[45] Section 4s(e) of the CEA, 7 U.S.C. 6s(e), directs the Commission to adopt capital requirements for SDs and MSPs. The Commission proposed capital rules in 2011. *See* Capital Requirements for Swap Dealers and Major Swap Participants, Notice of proposed rulemaking, 76 FR 27802 (May 12, 2011).

requirements to a CSE as a whole, also permits a U.S. CSE or non-U.S. CSE to avail itself of substituted compliance (to the extent applicable under the Proposed Rule) by complying with the margin requirements of the relevant foreign jurisdiction in lieu of compliance with the Commission's margin requirements, provided that the Commission finds that such jurisdiction's margin requirements are comparable to the Commission's margin requirements, as further discussed in section II.D. below.

In addition, the Proposed Rule provides for a limited exclusion of uncleared swaps between non-U.S. CSEs and non-U.S. counterparties (the ''Exclusion'') in certain circumstances. The Commission recognizes that the supervisory interest of foreign regulators in certain uncleared swaps between non-U.S. CSEs and their non-U.S. counterparties may equal or exceed the supervisory interest of the United States. The Proposed Rule takes into account the interests of other jurisdictions and balances those interests with the supervisory interests of the United States in order to calibrate the application of margin rules to non-U.S. CSEs' swaps with non-U.S. counterparties. Accordingly, the Commission believes that it would be appropriate to not apply the Commission's margin rules to uncleared swaps meeting the criteria for the Exclusion, which is described in section II.C.3. below.

B. Key Definitions

The Proposed Rule uses certain key definitions to establish a proposed framework for the application of margin requirements in a cross-border context. Specifically, the Proposed Rule defines the terms ''U.S. person,'' ''guarantee,'' and ''Foreign Consolidated Subsidiary'' in order to identify those persons or transactions that, because of their substantial connection or impact on the U.S. market, raise or implicate greater supervisory interest relative to other CSEs, counterparties, and uncleared swaps that are subject to the Commission's margin rules. These definitions are discussed below.

1. U.S. Person

Generally speaking, the term ''U.S. person'' would be defined to include those individuals or entities whose activities have a significant nexus to the U.S. market by virtue of their organization or domicile in the United States or the depth of their connection to the U.S. market, even if domiciled or organized outside the United States. The proposed definition generally follows the traditional, territorial approach to defining a U.S. person, and the Commission believes that this definition provides an objective and clear basis for determining those individuals or entities that should be identified as a U.S. person.[46]

The Proposed Rule would define a ''U.S. person'' for purposes of the cross-border application of the margin rules to mean:

(1) Any natural person who is a resident of the United States (Proposed Rule § 23.160(a)(10)(i));

(2) Any estate of a decedent who was a resident of the United States at the time of death (Proposed Rule § 23.160(a)(10)(ii));

(3) Any corporation, partnership, limited liability company, business or other trust, association, joint-stock company, fund or any form of entity similar to any of the foregoing (other than an entity described in paragraph (a)(10)(iv) or (v) of proposed § 23.160) (a legal entity), in each case that is organized or incorporated under the laws of the United States or having its principal place of business in the United States, including any branch of the legal entity (Proposed Rule § 23.160(a)(10)(iii));

(4) Any pension plan for the employees, officers or principals of a legal entity described in paragraph (a)(10)(iii) of proposed § 23.160, unless the pension plan is primarily for foreign employees of such entity (Proposed Rule § 23.160(a)(10)(iv));

(5) Any trust governed by the laws of a state or other jurisdiction in the United States, if a court within the United States is able to exercise primary supervision over the administration of the trust (Proposed Rule § 23.160(a)(10)(v));

(6) Any legal entity (other than a limited liability company, limited liability partnership or similar entity where all of the owners of the entity have limited liability) owned by one or more persons described in paragraphs (a)(10)(i) through (a)(10)(v) of proposed § 23.160 who bear(s) unlimited responsibility for the obligations and liabilities of the legal entity, including any branch of the legal entity (Proposed Rule § 23.160(a)(10)(vi)); and

(7) Any individual account or joint account (discretionary or not) where the beneficial owner (or one of the beneficial owners in the case of a joint account) is a person described in paragraphs (a)(10)(i) through (a)(10)(vi) of proposed § 23.160 (Proposed Rule § 23.160(a)(10)(vii)).[47]

A non-U.S. person is defined to be any person that is not a U.S. person.[48]

The proposed definition is generally consistent with the definition of this term set forth in the Guidance, with certain exceptions discussed below.

Prongs (1), (2), (3), (4), (5), and (7) (Proposed Rule § 23.160(a)(10)(i), (ii), (iii), (iv), (v), and (vii)) identify certain persons as a ''U.S. person'' by virtue of their domicile or organization within the United States. The Commission has traditionally looked to where a legal entity is organized or incorporated (or in the case of a natural person, where he or she resides) to determine whether it

[46] In addition, the Commission notes that the proposed definition of ''U.S. person'' is similar to the definition of ''U.S. person'' used by the SEC in the context of cross-border security-based swaps. In the SEC's August 2014 release adopting rules and providing guidance regarding the application of Title VII of the Dodd-Frank Act to cross-border security-based swap activities and persons engaged in those activities, the SEC defined the term ''U.S. person'' in Rule 240.3a71–3(a)(4)(i) under the Securities Exchange Act of 1934 to mean, except as provided in paragraph (a)(4)(iii) of the rule, any person that is (1) A natural person resident in the United States (Rule 240.3a71–3(a)(4)(i)(A)); (2) A partnership, corporation, trust, investment vehicle, or other legal person organized, incorporated, or established under the laws of the United States or having its principal place of business in the United States (Rule 240.3a71–3(a)(4)(i)(B)); (3) An account (whether discretionary or non-discretionary) of a U.S. person (Rule 240.3a71–3(a)(4)(i)(C)); or (4) An estate of a decedent who was a resident of the United States at the time of death(Rule 240.3a71–3(a)(4)(i)(D)).

Paragraph (a)(4)(ii) of SEC Rule 240.3a71–3 also defines, for purposes of that section, ''principal place of business'' to mean the location from which the officers, partners, or managers of the legal person primarily direct, control, and coordinate the activities of the legal person. With respect to an externally managed investment vehicle, this location is the office from which the manager of the vehicle primarily directs, controls, and coordinates the investment activities of the vehicle.

Paragraph (a)(4)(iii) of SEC Rule 240.3a71–3 states that the term ''U.S. person'' does not include the International Monetary Fund, the International Bank for Reconstruction and Development, the Inter-American Development Bank, the Asian Development Bank, the African Development Bank, the United Nations, and their agencies and pension plans, and any other similar international organizations, their agencies and pension plans.

Paragraph (a)(4)(iv) of SEC Rule 240.3a71–3 states that a person shall not be required to consider its counterparty to a security-based swap to be a U.S. person if such person receives a representation from the counterparty that the counterparty does not satisfy the criteria set forth in paragraph (a)(4)(i) of that section, unless such person knows or has reason to know that the representation is not accurate; for the purposes of this final rule a person would have reason to know the representation is not accurate if a reasonable person should know, under all of the facts of which the person is aware, that it is not accurate.

See Application of ''Security-Based Swap Dealer'' and ''Major Security-Based Swap Participant'' Definitions to Cross-Border Security-Based Swap Activities; Final rule; interpretation (Republication), 79 FR 47371 (Aug. 12, 2014).

[47] *See* § 23.160(a)(10) of the Proposed Rule.

[48] *See* § 23.160(a)(5) of the Proposed Rule.

is a U.S. person.[49] In the Commission's view, these persons—by virtue of their decision to organize or locate in the United States and because they are likely to have significant financial and legal relationships in the United States—are appropriately included within the definition of ''U.S. person'' for purposes of the proposed cross-border margin framework.

Under prong (3) (Proposed Rule § 23.160(a)(10)(iii)), consistent with its traditional approach, the Commission proposes to define ''U.S. person'' also to include persons that are organized or incorporated outside the United States, but have their principal place of business in the United States. For purposes of this prong, the Commission proposes to interpret ''principal place of business'' to mean the location from which the officers, partners, or managers of the legal person primarily direct, control, and coordinate the activities of the legal person. This interpretation is consistent with the Supreme Court's decision in *Hertz Corp.* v. *Friend,* which described a corporation's principal place of business, for purposes of diversity jurisdiction, as the ''place where the corporation's high level officers direct, control, and coordinate the corporation's activities.'' [50]

The Commission is of the view that the application of the principal place of business concept to a fund may require consideration of additional factors beyond those applicable to operating companies. In the case of a fund, the Commission notes that the senior personnel that direct, control, and coordinate a fund's activities are generally not the persons who are named as directors or officers of the fund, but rather are persons who work for the fund's investment adviser or the fund's promoter. Therefore, consistent with the Guidance, the Commission generally would consider the principal place of business of a fund to be in the United States if the senior personnel responsible for either (1) the formation and promotion of the fund or (2) the implementation of the fund's investment strategy are located in the United States, depending on the facts and circumstances that are relevant to determining the center of direction, control and coordination of the fund.[51]

Prong (6) (Proposed Rule § 23.160(a)(10)(vi)) of the proposed definition of ''U.S. person'' would include certain legal entities owned by one or more U.S. person(s) and for which such person(s) bear unlimited responsibility for the obligations and liabilities of the legal entity. As noted above, the Guidance included a similar concept in the definition of the term ''U.S. person;'' however the definition contained in the Guidance would generally characterize a legal entity as a U.S. person if the entity were ''directly or indirectly majority-owned'' by one or more persons falling within the term ''U.S. person'' and such U.S. person(s) bears unlimited responsibility for the obligations and liabilities of the legal entity. Where a U.S. person serves as a financial backstop for all of a legal entity's obligations and liabilities, creditors and counterparties look to the U.S. person when assessing the risk in dealing with the entity, regardless of the amount of equity owned by the U.S. person. Under such circumstances, because the U.S. person has unlimited responsibility for all of the legal entity's obligations, the Commission believes that the legal entity should be deemed to be a U.S. person.

The Proposed Rule would not include the U.S. majority-ownership prong that was included in the Guidance (50% U.S. person ownership of a fund or other collective investment vehicle).[52] Some commenters have argued that a majority ownership test for funds should not be included on the basis that ownership alone is not indicative of whether the activities of a non-U.S. fund with a non-U.S.-based manager has a direct and significant effect on the U.S. financial system, and that it is difficult to determine the identity of the beneficial owner of a fund in certain fund structures (*e.g.,* fund-of-funds or master-feeder). Alternatively, an argument for retaining the majority-ownership test would be that many of these funds have large U.S. investors, who can be adversely impacted in the event of a counterparty default. On balance, the Commission believes the majority-ownership test should not be included in the definition of U.S. person for purposes of the margin rules. Non-U.S. funds with U.S. majority-ownership, even if treated as a non-U.S. person, would be excluded from the Commission's margin rules only in limited circumstances (namely, when these funds trade with a non-U.S. CSE that is not a consolidated subsidiary of a U.S. entity or a U.S. branch of a non-U.S. CSE). This, coupled with the implementation issues raised by commenters, persuades the Commission not to propose to define those funds that are majority-owned by U.S. persons (and that would otherwise not fall within the definition of a ''U.S. person''), as U.S. persons.

The proposed definition of ''U.S. person'' determines a legal person's status at the entity level and thus includes any foreign operations that are part of the U.S. legal person, regardless of their location. Consistent with this approach, the definition of ''U.S. person'' under the Proposed Rule would include a foreign branch of a U.S. person.

Under the proposed definition, the status of a legal person as a U.S. person would not affect whether a separately incorporated or organized legal person in the affiliated corporate group is a U.S. person. Therefore, an affiliate or a subsidiary of a U.S. person that is organized or incorporated in a non-U.S. jurisdiction would not be deemed a ''U.S. person'' solely by virtue of its relationship with a U.S. person.

The proposed ''U.S. person'' definition does not include the prefatory phrase ''includes, but is not limited to'' that was included in the Guidance. The Commission believes that this prefatory phrase should not be included in order to provide legal certainty regarding the application of U.S. margin requirements to cross-border swaps.

The Commission understands that the information necessary for a swap counterparty to accurately assess the status of its counterparties as U.S. persons may not be available, or may be available only through overly burdensome due diligence. For this reason, the Commission believes that a swap counterparty generally should be permitted to reasonably rely on its counterparty's written representation in determining whether the counterparty is within the definition of the term ''U.S. person.'' In this context, the Commission's policy is to interpret the ''reasonable'' standard to be satisfied

[49] *See, e.g.,* 17 CFR 4.7(a)(1)(iv) (defining ''Non-United States person'' for purposes of part 4 of the Commission regulations relating to commodity pool operators).

[50] *See Hertz Corp.* v. *Friend,* 559 U.S. 77, 80 (2010).

[51] *See* the Guidance, 78 FR 45309–45312, for guidance on application of the principal place of business test to funds and other collective investment vehicles in the context of cross-border swaps, including examples of how the Commission's approach could apply to a consideration of whether the ''principal place of business'' of a fund is in the United States in particular hypothetical situations. However, because of variations in the structure of collective investment vehicles as well as the factors that are relevant to the consideration of whether a collective investment vehicle has its principal place of business in the United States under the Guidance, these examples were included in the Guidance for illustrative purposes only.

[52] The Commission's definition of the term ''U.S. person'' as used in the Guidance included a prong (iv) which covered ''any commodity pool, pooled account, or collective investment vehicle (whether or not it is organized or incorporated in the United States) of which a majority ownership is held, directly or indirectly, by a U.S. person(s).''

when a party to a swap conducts reasonable due diligence on its counterparties, with what is reasonable in a particular situation to depend on the relevant facts and circumstances.[53]

Under the Proposed Rule, a ''non-U.S. person'' is any person that is not a ''U.S. person'' (as defined in the Proposed Rule).[54] References in this preamble to a ''U.S. counterparty'' are to a swap counterparty that is a ''U.S. person'' under the Proposed Rule, and references to a ''non-U.S. counterparty'' are to a swap counterparty that is a ''non-U.S. person'' under the Proposed Rule.[55]

Request for Comment. The Commission requests comment on all aspects of the proposed definition of ''U.S. person,'' including the following:

1. Does the proposed definition of ''U.S. person'' appropriately identify all individuals or entities that should be designated as U.S. persons? Is the proposed definition too narrow or broad? Why?

2. Should the definition of ''U.S. person'' include the U.S. majority-ownership prong for funds and other collective investment vehicles, as set forth in the Guidance? Please explain.

3. Should the definition of ''U.S. person'' include certain legal entities owned by one or more persons described in prongs (1), (2), (3), (4), or (5) (Proposed Rule § 23.160(a)(10)(i), (ii), (iii), (iv) or (v)) of the proposed U.S. person definition who bear(s) unlimited responsibility for the obligations and liabilities of the legal entity? Please explain.

4. Should the definition of ''U.S. person'' be identical to the definition of ''U.S. person'' that the SEC adopted in its August 2014 rulemaking? For example:

a. Should the definition of ''U.S. person'' exclude certain designated (and any similar) international organizations, their agencies and pension plans, with headquarters in the United States?

b. Should the Commission define the term ''principal place of business'' as the location from which the officers, partners, or managers of a legal person primarily direct, control, and coordinate the activities of the legal person, and specify that in the case of an externally managed investment vehicle, this location is the office from which the manager of the vehicle primarily directs, controls, and coordinates the investment activities of the vehicle?

c. Should the Commission delete prong (6) (Proposed Rule § 23.160(a)(10)(vi)) of the proposed definition of ''U.S. person'' which includes certain legal entities owned by one or more U.S. person(s) and for which such person(s) bear unlimited responsibility for the obligations and liabilities of the legal entity and instead treat such arrangements as recourse guarantees?

d. Should any other changes be made to the proposed definition of ''U.S. person'' to conform it to the definition adopted by the SEC?

2. Guarantees

Under the Proposed Rule, uncleared swaps of non-U.S. CSEs, where the non-U.S. CSE's obligations under the uncleared swap are guaranteed by a U.S. person, would be treated the same as uncleared swaps of a U.S. CSE. The Commission believes that this treatment is appropriate because the swap of a non-U.S. CSE whose obligations under the swap are guaranteed by a U.S. person is identical, in relevant respects, to a swap entered directly by a U.S. person. That is, by virtue of the guarantee, the U.S. guarantor is responsible for the swap it guarantees in a manner similar to a direct counterparty to the swap. The U.S. person guarantor effectively acts jointly with the non-U.S. person whose swap it guarantees to engage in swaps transactions. The counterparty, pursuant to the recourse guarantee, looks to both the direct non-U.S. counterparty and its U.S. guarantor in entering into the swap.

The Proposed Rule would define the term ''guarantee'' as an arrangement pursuant to which one party to a swap transaction with a non-U.S. counterparty has rights of recourse against a U.S. person guarantor (whether such guarantor is affiliated with the non-U.S. counterparty or is an unaffiliated third party) with respect to the non-U.S. counterparty's obligations under the relevant swap transaction. Under the Commission's proposal, a party to a swap transaction has rights of recourse against the U.S. person guarantor if the party has a conditional or unconditional legally enforceable right, in whole or in part, to receive payments from, or otherwise collect from, the U.S. person in connection with the non-U.S. person's obligations under the swap.[56] Accordingly, the term ''guarantee'' would apply whenever a party to the swap has a legally enforceable right of recourse against the U.S. guarantor of a non-U.S. counterparty's obligations under the relevant swap, regardless of whether such right of recourse is conditioned upon the non-U.S. counterparty's insolvency or failure to meet its obligations under the relevant swap, and regardless of whether the counterparty seeking to enforce the guarantee is required to make a demand for payment or performance from the non-U.S. counterparty before proceeding against the U.S. guarantor.

Under the Proposed Rule, the terms of the guarantee need not necessarily be included within the swap documentation or even otherwise reduced to writing (so long as legally enforceable rights are created under the laws of the relevant jurisdiction), provided that a swap counterparty has a conditional or unconditional legally enforceable right, in whole or in part, to receive payments from, or otherwise collect from, the U.S. person in connection with the non-U.S. person's obligations under the swap.[57]

Further, the Commission's proposed definition of guarantee would not be affected by whether the U.S. guarantor is an affiliate of the non-U.S. CSE because, in each case, the swap counterparty has a conditional or unconditional legally enforceable right, in whole or in part, to receive payments from, or otherwise collect from, the U.S. person in connection with the non-U.S. person's obligations under the swap.

The Commission notes that the definition of ''guarantee'' in the Proposed Rule is narrower in scope than the one used in the Guidance.[58] In proposing this definition, the Commission is cognizant that many other types of financial arrangements or support, other than a guarantee as defined in the Proposed Rule, may be provided by a U.S. person to a non-U.S. CSE (*e.g.,* keepwells and liquidity puts,

[53] The Commission notes that under the External Business Conduct Rules, a SD or MSP generally meets its due diligence obligations if it reasonably relies on counterparty representations, absent indications to the contrary. As in the case of the External Business Rules, the Commission believes that allowing for reasonable reliance on counterparty representations encourages objectivity and avoids subjective evaluations, which in turn facilitates a more consistent and foreseeable determination of whether a person is within the Commission's interpretation of the term ''U.S. person.''

[54] *See* § 23.160(a)(5) of the Proposed Rule.

[55] Under the Proposed Rule, a ''U.S. CSE'' is a CSE that is a U.S. person. The term ''U.S. CSE'' includes a foreign branch of a U.S. CSE. A ''non-U.S. CSE'' is any CSE that is not a U.S. person.

[56] *See* § 23.160(a)(2) of the Proposed Rule.

[57] Further, the definition of ''guarantee'' is intended to encompass any swap of a non-U.S. person where the counterparty to the swap has rights of recourse, regardless of the form of the arrangement, against at least one U.S. person (either individually or jointly or severally with others) for the non-U.S. person's obligations under the swap.

[58] In the Guidance, the Commission interpreted the term ''guarantee'' generally to include not only traditional guarantees of payment or performance of the related swaps, but also other formal arrangements that, in view of all the facts and circumstances, support the non-U.S. person's ability to pay or perform its swap obligations with respect to its swaps.

certain types of indemnity agreements, master trust agreements, liability or loss transfer or sharing agreements). The Commission understands that these other financial arrangements or support transfer risk directly back to the U.S. financial system, with possible significant adverse effects, in a manner similar to a guarantee with a direct recourse to a U.S. person. The Commission, however, believes that application of a narrower definition of guarantee for purposes of identifying those uncleared swaps that should be treated like uncleared swaps of a U.S. CSEs would reduce the potential for conflict with the non-U.S. CSE's home regulator. Moreover, the Commission believes that a non-U.S. CSE that has been provided with financial arrangements or support from a U.S. person that do not fall within the term ''guarantee'' as defined in the Proposed Rule in many cases is likely to meet the definition of a ''Foreign Consolidated Subsidiary'' and therefore, as discussed in the next section, would be subject to the Commission's margin requirements, with substituted compliance (but not the Exclusion) available. Therefore, the Commission believes that a narrow definition of guarantee would achieve a more workable framework for non-U.S. CSEs, without undermining protection of U.S. persons and U.S. financial system.

The Commission is aware that some non-U.S. CSEs removed guarantees in order to fall outside the scope of certain Dodd-Frank requirements. The proposed coverage of foreign subsidiaries of a U.S. person as a ''Foreign Consolidated Subsidiary,'' which is discussed in the next section, and whose swaps would not be eligible for the Exclusion under any circumstances (as discussed in section II.C.3. below), would address the concern that even without a guarantee, as defined under the Guidance or in the Proposed Rule, foreign subsidiaries of a U.S. person with a substantial nexus to the U.S. financial system are adequately covered by the margin requirements.

Request for Comment. The Commission seeks comment on all aspects of the proposed definition of ''guarantee,'' including the following:

1. Should the broader use of the term ''guarantee'' in the Guidance be used instead of the proposed definition, and if so, why? Would an alternative definition be more effective in light of the purpose of the margin requirements, and if so, why?

2. Is the Commission's assumption that a non-U.S. CSE is likely to meet the definition of a ''Foreign Consolidated Subsidiary'' when it has been provided with financial arrangements or support from a U.S. person that do not fall within the term ''guarantee'' (as defined in the Proposed Rule) correct? If not, why not?

3. Is it appropriate to distinguish, for purposes of the Proposed Rule, between those arrangements under which a party to the swap has a legally enforceable right of recourse against the U.S. guarantor and those arrangements where there is not direct recourse against a U.S. guarantor?

3. Foreign Consolidated Subsidiaries

The Proposed Rule uses the term ''Foreign Consolidated Subsidiary'' in order to identify swaps of those non-U.S. CSEs whose obligations under the relevant uncleared swap are not guaranteed by a U.S. person but that raise substantial supervisory concern in the United States, as a result of the possible negative impact on their U.S. parent entities and the U.S. financial system. Consolidated financial statements report the financial position, results of operations and statement of cash flows of a parent entity together with subsidiaries in which the parent entity has a controlling financial interest (which are required to be consolidated under U.S. generally accepted accounting principles (''GAAP'')). In the Commission's view, the fact that an entity is included in the consolidated financial statements of another is an indication of potential risk to the other entity that offers a clear and objective standard for the application of margin requirements.

Specifically, the Proposed Rule defines the term ''Foreign Consolidated Subsidiary'' as a non-U.S. CSE in which an ultimate parent entity [59] that is a U.S. person has a controlling interest, in accordance with U.S. GAAP, such that the U.S. ultimate parent entity includes the non-U.S. CSE's operating results, financial position and statement of cash flows in the U.S. ultimate parent entity's consolidated financial statements, in accordance with U.S. GAAP.

In the case of Foreign Consolidated Subsidiaries whose obligations under the relevant swap are not guaranteed by a U.S. person, substituted compliance would be broadly available under the Proposed Rule to the same extent as other non-U.S. CSEs whose obligations under the relevant swap are not guaranteed by a U.S. person, even though the financial position, operating results, and statement of cash flows of the Foreign Consolidated Subsidiary have a direct impact on the financial position, risk profile and market value of the consolidated group (which includes a U.S. parent entity); however, the Exclusion would not be available for swaps with a Foreign Consolidated Subsidiary because their swap activities have a direct impact on the financial position, risk profile, and market value of a U.S. parent entity that consolidates the Foreign Consolidated Subsidiary's financial statements and a potential spill-over effect on the U.S. financial system.[60]

The Commission believes that not extending the Exclusion to Foreign Consolidated Subsidiaries under the Proposed Rule would be appropriate because the U.S. parent entity that consolidates the Foreign Consolidated Subsidiary's financial statements may have an incentive to provide support to a Foreign Consolidated Subsidiary, or the Foreign Consolidated Subsidiary may pose financial risk to the U.S. parent entity. In addition, market participants (including counterparties) may have the expectation that the parent entity will provide support to the Foreign Consolidated Subsidiary although, whether the U.S. parent entity actually steps in to fulfill the obligations of the Foreign Consolidated Subsidiary would depend on a business judgment rather than a legal obligation.[61] Notably, although consolidation has a direct impact on the U.S. parent entity, the U.S. parent entity stands in a different legal position than a U.S. guarantor because, in the absence of a direct recourse guarantee, the U.S. parent entity has no legal obligation to pay or perform under the relevant swap if the Foreign Consolidated Subsidiary defaults on its swap obligations. Therefore, the Commission believes that, in the absence of a direct recourse

[59] Under the Proposed Rule, the term ''ultimate parent entity'' means the parent entity in a consolidated group in which none of the other entities in the consolidated group has a controlling interest, in accordance with U.S. GAAP.

[60] The Exclusion under the Proposed Rule is discussed in section II.C.3. below.

[61] For example, when General Electric announced on April 10, 2015 that it would guarantee repayment of approximately $210 billion of debt from GE Capital, the prices of some GE Capital bonds reportedly went up as much as 1.5% even though previously the parent company had provided other support but not an unconditional guarantee. According to an article in the Wall Street Journal, Russell Solomon, an analyst at Moody's Investors Service, stated: ''We've always assumed that GE would support GE Capital almost no matter what . . . But now this says they'll support it no matter what.'' Similarly, the article reports that Standard & Poor's Rating Services stated that General Electric's decision to back GE Capital debt ''strengthens our view of GE's support, by buttressing the parent's proven willingness and ability to support its subsidiary with a contractual obligation to do so.'' *See* Mike Cherney and Katy Burne, WSJ, Apr. 10, 2015, *available at http://www.wsj.com/articles/ges-move-alters-the-bond-market-1428707800.*

guarantee from a U.S. person, uncleared swaps with a Foreign Consolidated Subsidiary should not be treated the same as swaps with a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person.

The Commission considered proposing a ''control'' test similar to that proposed by the Prudential Regulators. The ''control test'' in the Prudential Regulators' proposal is based solely on an entity's ownership level and control of the election of the board,[62] which may or may not clearly identify, depending on the facts and circumstances, those non-U.S. CSEs that are likely to raise greater supervisory concerns than other non-U.S. CSEs (in each case whose obligations under the relevant swap are not guaranteed by a U.S. person). Therefore, the Commission is using a ''consolidation test'' rather than a ''control test'' in the proposed definition of a ''Foreign Consolidated Subsidiary'' in order to provide a clear, bright-line test for identifying those non-U.S. CSEs whose uncleared swaps are likely to raise greater supervisory concerns.

Request for Comment. The Commission seeks comment on all aspects of the Proposed Rule's definition of ''Foreign Consolidated Subsidiary,'' including:

1. Does the proposed definition of a ''Foreign Consolidated Subsidiary'' appropriately capture those non-U.S. CSEs that should not be eligible for the Exclusion? If not, please explain and provide an alternative(s).

2. The consolidation test in the definition of a ''Foreign Consolidated Subsidiary'' is intended to provide a clear, bright-line test for identifying those non-U.S. CSEs whose uncleared swaps are likely to raise greater supervisory concerns relative to other non-guaranteed non-U.S. CSEs. Should the proposed consolidation test be used in lieu of the control test proposed by the Prudential Regulators? Why or why not? Should the Commission use both a consolidation test and a control test? If so, please explain. Would any other tests or criteria be more appropriate? If so, please explain what tests or criteria should be used and why they are more appropriate.

3. Under the definition of Foreign Consolidated Subsidiary, the Commission is using U.S. GAAP as the standard for purposes of determining whether an entity consolidates another entity. In reviewing registration data of CSEs, the Commission believes that this definition balances the goals of the statute and the burdens placed on the industry; however, should the Commission also consider including in the definition of Foreign Consolidated Subsidiary, non-U.S. CSEs whose U.S. ultimate parent entity uses a different standard than U.S. GAAP in determining whether a parent entity must consolidate an entity for financial reporting purposes? If so, please explain why.

4. Should the Commission also include in the definition of ''Foreign Consolidated Subsidiary'' those non-U.S. CSEs whose U.S. ultimate parent entity is not required to prepare consolidated financial statements under any accounting standard or for any other reason (*e.g.,* the U.S. ultimate parent entity is not a public company under federal securities laws and is not required to prepare consolidated financial statements by private investors or debtholders as a condition to investing or financing), but which would consolidate the non-U.S. CSE if it were required to prepare consolidated financial statements in accordance with U.S. GAAP? If so, please explain why?

5. Under the definition of Foreign Consolidated Subsidiary, the Commission is only including non-U.S. CSEs whose financial statements are consolidated by an ultimate parent entity that is a U.S. person. Should the Commission also include immediate and intermediate parent entities of the non-U.S. CSE in the definition? If so, please explain why?

C. Applicability of Margin Requirements to Cross-Border Uncleared Swaps

The following section describes the application of the Commission's margin rules to cross-border swaps between CSEs and various types of counterparties, as well as when the Exclusion from the Commission's margin requirements would be applicable. Table A to this release (see below) illustrates how the Proposed Rule would apply to specific transactions between various types of counterparties, and should be read in conjunction with the rest of the preamble and the text of the Proposed Rule.

1. Uncleared Swaps of U.S. CSEs or Non-U.S. CSEs Whose Obligations Under the Relevant Swap Are Guaranteed by a U.S. Person

Under the Proposed Rule, the Commission's margin rules[63] would apply to all uncleared swaps of U.S. CSEs,[64] with no exclusions. By their nature, U.S. CSEs have a significant impact on the U.S. swaps market, and the Commission therefore has a strong interest in ensuring their viability. However, substituted compliance would be available with respect to initial margin posted to (but not collected from) any non-U.S. counterparty (including a non-U.S. CSE) whose obligations under the uncleared swap are not guaranteed by a U.S. person. The Commission proposes to provide substituted compliance in this situation (assuming that the non-U.S. counterparty is subject to comparable margin requirements in a foreign jurisdiction) because the swap counterparty is a non-U.S. person and where its swap obligations are not guaranteed by a U.S. person, the foreign regulator may have equal or greater interest in the collection of margin by the non-U.S. counterparty. However, substituted compliance would not apply to the collection of margin by the U.S. CSE from the non-U.S. counterparty, as the Commission has a significant regulatory interest in the collection of margin by the U.S. CSE, which protects the U.S. CSE and the U.S. financial system from counterparty credit risk.

The same treatment that applies to U.S. CSEs would also apply to a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person. The Commission believes that this result is appropriate because the economics of the transaction are no different from a trade entered directly by the U.S. guarantor, as discussed in section II.B.2. above. In addition, the Commission believes that treating uncleared swaps of these entities differently from those of U.S. CSEs would lead to unwarranted competitive distortions. That is, the non-U.S. CSE that enters into a swap with a direct recourse guarantee from a U.S. person would be positioned to benefit from more competitive pricing when dealing with non-U.S. counterparties (as compared to U.S. CSEs) to the extent

[62] Under the Prudential Regulators' proposal, the term ''control'' of another company means: (1) Ownership, control, or power to vote 25 percent or more of a class of voting securities of the company, directly or indirectly or acting through one or more other persons; (2) ownership or control of 25 percent or more of the total equity of the company, directly or indirectly or acting through one or more other persons; or (3) control in any manner of the election of a majority of the directors or trustees of the company.

[63] The Commission's Proposed Margin Rules are set forth in proposed §§ 23.150 through 23.159 of part 23 of the Commission's regulations, proposed as 17 CFR 23.150 through 23.159.

[64] Foreign branches of a U.S. CSE are treated as part of the related principal entity and hence an uncleared swap executed by or through a foreign branch would be treated as an uncleared swap of a U.S. CSE.

that either substituted compliance or the Exclusion would be available.

The Commission believes that requiring U.S. CSEs and non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person to comply with its margin requirements, with only limited substituted compliance for margin posted to (but not collected from) any non-U.S. counterparty (including a non-U.S. CSE) whose obligations under the uncleared swap are not guaranteed by a U.S. person, would help ensure their safety and soundness and support the stability of the U.S. financial markets, reducing the likelihood of another financial crisis affecting the U.S. economy.

Request for Comment. The Commission requests comments on all aspects of the proposed treatment of uncleared swaps of U.S. CSEs and/or non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person, including:

1. Is the Proposed Rule's treatment of U.S. CSEs and non-U.S. CSEs whose obligations under the swap are guaranteed by a U.S. person appropriate? If not, please explain. If a different treatment should apply to U.S. CSEs or non-U.S. CSEs whose obligations under the swap are guaranteed by a U.S. person, please describe the alternative treatment that should apply and explain why.

2. What are the competitive implications of the proposed treatment of uncleared swaps of non-U.S. CSEs whose obligations under the swap are guaranteed by a U.S. person?

3. Does the proposed treatment of non-U.S. CSEs whose obligations under the swap are guaranteed by a U.S. person appropriately take into account the supervisory interest of a non-U.S. CSE's home jurisdiction?

2. Uncleared Swaps of Non-U.S. CSEs (Including Foreign Consolidated Subsidiaries) Whose Obligations Under the Relevant Swap Are Not Guaranteed by a U.S. Person

Under the Proposed Rule, non-U.S. CSEs (including Foreign Consolidated Subsidiaries) whose obligations under the relevant uncleared swap are not guaranteed by a U.S. person may avail themselves of substituted compliance to a greater extent than if their obligations under the swap were guaranteed by a U.S. person. The Commission believes that this approach is appropriate since a non-U.S. CSE whose swap obligations are not guaranteed by a U.S. person (including a Foreign Consolidated Subsidiary), on balance, may implicate equal or greater supervisory concerns on the part of a foreign regulator relative to the supervisory interest of the Commission (in comparison to U.S. CSEs or non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person, because the Commission has a significant regulatory interest in uncleared swaps of these CSEs). Under the Proposed Rule, where the obligations of a non-U.S. CSE (including a Foreign Consolidated Subsidiary) under the relevant swap are not guaranteed by a U.S. person, substituted compliance would be available with respect to its uncleared swaps with any counterparty, except where the counterparty is a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person.[65]

Further, uncleared swaps entered into by Foreign Consolidated Subsidiaries would not be eligible for the Exclusion under the Proposed Rule. As described above, the financial position, operating results, and statement of cash flows of a Foreign Consolidated Subsidiary are incorporated into the financial statements of the U.S. ultimate parent entity and therefore, likely have a direct impact on the consolidated entity's financial position, risk profile, and market value. Under these circumstances, and given the importance of margin in mitigating counterparty credit risk, the Commission has greater supervisory concerns with respect to the uncleared swaps of a Foreign Consolidated Subsidiary than other non-U.S. CSEs. Therefore, the Commission believes that extending the Exclusion to a Foreign Consolidated Subsidiary would not further the goal of ensuring the safety and soundness of a CSE and the stability of U.S. financial markets. The Commission is also concerned that extending the Exclusion to Foreign Consolidated Subsidiaries would encourage a U.S. entity to use their non-U.S. subsidiaries to conduct their swap activities with non-U.S. counterparties, possibly bifurcating the U.S. entity's U.S. and non-U.S.-facing businesses, and potentially resulting in separate pools of liquidity.

Request for Comment. The Commission requests comments on all aspects of the proposed treatment of uncleared swaps of non-U.S. CSEs (including Foreign Consolidated Subsidiaries) whose obligations under the relevant swap are not guaranteed by a U.S. person, including:

1. The Proposed Rule makes substituted compliance more broadly available to a Foreign Consolidated Subsidiary whose obligations under the relevant swap are not guaranteed by a U.S. person than a non-U.S. CSE (including a Foreign Consolidated Subsidiary) whose obligations under the relevant swap are guaranteed by a U.S. person. Should Foreign Consolidated Subsidiaries be treated the same as non-U.S. CSEs that are guaranteed by a U.S. person and if not, what treatment is appropriate?

2. What are the competitive implications of the proposed treatment of Foreign Consolidated Subsidiaries (relative to other non-U.S. CSEs)? Does the proposed treatment appropriately take into account the supervisory interest of a non-U.S. CSE's home jurisdiction?

3. Exclusion for Uncleared Swaps of Non-U.S. CSEs Where Neither Counterparty's Obligations Under the Relevant Swap Are Guaranteed by a U.S. Person and Neither Counterparty Is a Foreign Consolidated Subsidiary Nor a U.S. Branch of a Non-U.S. CSE

Under the Proposed Rule, an uncleared swap entered into by a non-U.S. CSE with a non-U.S. person counterparty (including a non-U.S. CSE) would be excluded from the Commission's margin rules, provided that neither counterparty's obligations under the relevant swap are guaranteed by a U.S. person and neither counterparty is a Foreign Consolidated Subsidiary nor a U.S. branch of a non-U.S. CSE.[66]

As discussed above, the Commission believes that, given the importance of margin to the safety and soundness of a CSE, as a general matter, margin requirements should apply to the uncleared swaps of a CSE, without regard to the domicile of the counterparty or where the trade is executed. At the same time, the Commission believes that it is appropriate to make a limited exception to this principle of firm-wide application of margin requirements in the cross-border context, consistent with section 4s(e) of the CEA[67] and comity principles, so as to exclude a narrow class of uncleared swaps involving a

[65] With respect to uncleared swaps with a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person, substituted compliance would only be available for initial margin collected by the non-U.S. CSE whose obligations under the relevant swap are not guaranteed by a U.S. person, as discussed in section II.C.1.

[66] See § 23.160(b)(2)(ii) of the Proposed Rule.

[67] Section 4s(e)(3)(A) of the CEA, 7 U.S.C. 6s(e)(3)(A). The section calls for, among other things, that margin requirements ''be appropriate for the risks associated with the non-cleared swaps held as a swap dealer or major market participant.''

non-U.S. CSE and a non-U.S. counterparty.

The Commission notes that a non-U.S. CSE that can avail itself of the Exclusion would still be subject to the Commission's margin rules with respect to all uncleared swaps not meeting the criteria for the Exclusion, albeit with the possibility of substituted compliance. The non-US CSE would also be subject to the Commission's capital requirements, which, as proposed, would impose a capital charge for uncollateralized exposures.[68] Additionally, any excluded swaps would most likely be covered by the margin requirements of another jurisdiction that adheres to the BCBS–IOSCO framework.[69]

The Commission also recognizes that the supervisory interest of foreign regulators in the uncleared swaps of non-U.S. CSEs (and their non-U.S. counterparties) that are eligible for the Exclusion may equal or exceed the supervisory interest of the United States in such uncleared swaps. Both counterparties are domiciled outside the United States and likely would be subject to the supervision of a foreign regulator. As discussed above, the Commission believes that a workable cross-border framework must take into account the interests of other jurisdictions and balance those interests with the supervisory interests of the United States in order to calibrate the application of margin rules to non-U.S. CSEs' swaps with non-U.S. counterparties. Such an approach would help mitigate the potential for conflicts with other jurisdictions and ultimately promote global harmonization. For all of the foregoing reasons, the Commission believes that it would be appropriate to not apply the Commission's margin rules to uncleared swaps meeting the criteria for the Exclusion.

The Commission acknowledges that similar mitigating factors and comity considerations may apply to Foreign Consolidated Subsidiaries, but as discussed above, a Foreign Consolidated Subsidiary's financial position, operating results, and statement of cash flows are directly reflected in its U.S. Ultimate Parent entity's financial statements, which implicates greater supervisory concerns. Therefore, the Commission believes that it has a greater regulatory interest in Foreign Consolidated Subsidiaries than other non-U.S. CSEs (that are not guaranteed by a U.S. person), and that the uncleared swaps of Foreign Consolidated subsidiaries should not be excluded from the margin requirements.

Further, the Commission believes that the uncleared swaps of a U.S. branch of a non-U.S. CSE should not be excluded from the margin requirements for the reasons discussed in the next section.

Request for Comment. The Commission is requesting comments on all aspects of the proposed Exclusion, including:

1. In light of the mitigating factors cited above and the Commission's supervisory interest in the safety and soundness of all CSEs and the critical role that margin plays in helping ensure the safety and soundness of CSEs, is the proposed Exclusion appropriate, and if not, please explain why not? Is the scope of the Exclusion appropriate, or should it be broader or narrower, and if so, why?

2. Under the Proposed Rule, uncleared swaps with a Foreign Consolidated Subsidiary would not be eligible for the Exclusion from the Commission's margin requirements. Should Foreign Consolidated Subsidiaries be eligible for the Exclusion and if so, why?

4. U.S. Branches of Non-U.S. CSEs

The Proposed Rule treats uncleared swaps executed through or by a U.S. branch of a non-U.S. CSE the same as those swaps of a non-U.S. CSE, except that the Exclusion from the margin rules would not be available to a U.S. branch of a non-U.S. CSE.

Generally speaking, because the risks posed by uncleared swaps are borne by a CSE as a whole, it should not matter if the transaction is entered by or through a U.S. branch or office within the United States. Nevertheless, the Commission believes that extending the Exclusion (to the extent than the Exclusion might otherwise apply to the non-U.S. CSE, as discussed above) would not be appropriate in the case of uncleared swaps executed by or through a U.S. branch of a non-U.S. CSE.

The Commission notes that non-U.S. CSEs can conduct their swap dealing business within the United States utilizing a number of different legal structures, including a U.S. subsidiary or a U.S. branch or office. Excluding uncleared swaps conducted by or through U.S. branches of non-U.S. CSEs would give these non-U.S. CSEs an unfair advantage when dealing with non-U.S. clients relative to U.S. CSEs (including those CSEs that are subsidiaries of foreign entities). That is, a U.S. branch of a non-U.S. CSE that is permitted to operate outside of the Commission's margin requirements would be able to offer a more competitive price to non-U.S. clients than a U.S. CSE. The Commission believes that when a non-U.S. CSE is conducting its swap activities within the United States through a branch or office located in the United States, it should be subject to U.S. margin laws. However, the Commission also believes that, consistent with comity principles, substituted compliance should be available for uncleared swaps executed by or through a U.S. branch of a non-U.S. CSE whose obligations under the relevant swap are not guaranteed by a U.S. person with any counterparty (except where the counterparty is a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person).[70]

Request for Comment. The Commission seeks comment on the Proposed Rule's treatment of uncleared swaps conducted by or through a ''U.S. branch of a non-U.S. CSE.'' In particular, the Commission requests comment on the following questions:

1. How should the Commission determine whether a swap is executed through or by a U.S. branch of a non-U.S. CSE for purposes of applying the Commission's margin rules on a cross-border basis? Should the Commission base the determination of whether the swap activity is conducted at a U.S. branch of a non-U.S. CSE for purposes of applying the Commission's margin rules on a cross-border basis on the same analysis as is used in the Volcker rule?[71]

2. The Commission seeks comment on the proposed treatment of U.S. branches

[68] *See* Capital Requirements of Swap Dealers and Major Swap Participants, Notice of proposed rulemaking, 76 FR 27802 (May 12, 2011).

[69] The non-U.S. CSE that qualifies for the exclusion would be eligible for substituted compliance, with respect to all margin requirements, if its counterparty to the uncleared swap is a U.S. person that is not a CSE. If the uncleared swap is with a U.S. CSE, substituted compliance would only be available with respect to initial margin posed by the U.S. CSE counterparty.

[70] With respect to uncleared swaps with a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person, substituted compliance would only be available for initial margin collected by the U.S. branch of a non-U.S. CSE whose obligations under the relevant swap are not guaranteed by a U.S. person. *See* section II.C.1.

[71] Under the Volcker rule, personnel that arrange, negotiate, or execute a purchase or sale conducted under the exemption for trading activity of a foreign banking entity must be located outside of the United States. *See* Prohibitions and Restrictions on Proprietary Trading and Certain Interests in, and Relationships With, Hedge Funds and Private Equity Funds; Final Rule, 79 FR 5808 (Jan. 31, 2014). Thus, for example, personnel in the United States cannot solicit or sell to or arrange for trades conducted under this exemption. Personnel in the United States also cannot serve as decision makers in transactions conducted under this exemption. Personnel that engage in back-office functions, such as clearing and settlement of trades, would not be considered to arrange, negotiate, or execute a purchase or sale for purposes of this provision. *Id.* at 5927, n.1526.

of non-U.S. CSEs, including whether these branches should be eligible for the Exclusion in light of the policy objectives outlined above. If the Exclusion should be available, please explain why. The Commission also seeks comment regarding whether the scope of substituted compliance for U.S. branches of non-U.S. CSEs under the Proposed Rule is appropriate. If not, please explain why.

D. Substituted Compliance

As noted above, consistent with CEA section 2(i) and comity principles, the Commission would allow CSEs to comply with comparable margin requirements in a foreign jurisdiction under certain circumstances. In this release, we are proposing to establish a standard of review that will apply to Commission determinations regarding whether some or all of the relevant foreign jurisdiction's margin requirements are comparable to the Commission's corresponding margin requirements, as well as procedures for requests for comparability determinations, including eligibility requirements and submission requirements.

Specifically, the Commission would permit a U.S. CSE or a non-U.S. CSE, as applicable, to avail itself of substituted compliance (to the extent applicable under the Proposed Rule) by complying with the margin requirements of the relevant foreign jurisdiction in lieu of compliance with the Commission's margin requirements, provided that the Commission finds that such jurisdiction's margin requirements are comparable to the Commission's margin requirements. Failure to comply with the applicable foreign margin requirements could result in a violation of the Commission's margin requirements. Further, all CSEs, regardless of whether they rely on a comparability determination, would remain subject to the Commission's examination and enforcement authority.[72]

The Commission is proposing a comparability standard that is outcome-based with a focus on whether the margin requirements in the foreign jurisdiction achieve the same regulatory objectives as the CEA's margin requirements. Under this outcome-based approach, the Commission would not look to whether a foreign jurisdiction has implemented specific rules and regulations that are identical to rules and regulations adopted by the Commission. Rather, the Commission would evaluate whether a foreign jurisdiction has rules and regulations that achieve comparable outcomes. If it does, the Commission believes that a comparability determination may be appropriate, even if there may be differences in the specific elements of a particular regulatory provision.[73]

In evaluating whether a foreign jurisdiction's margin requirements are comparable to the Commission's margin requirements, the Commission would consider whether the foreign jurisdiction's margin rules are consistent with international standards.[74] That is, the Commission would determine, considering all relevant facts and circumstances, whether a foreign jurisdiction has adopted margin rules that adequately address the BCBS–IOSCO framework. The Commission believes that considering this factor is appropriate because BCBS and IOSCO established this framework to ensure globally harmonized margin rules for uncleared derivative transactions. Individual regulatory authorities across major jurisdictions (including the EU, Japan, and the United States) have started to develop their own margin rules consistent with the final BCBS–IOSCO framework for non-centrally cleared, bilateral derivatives.[75] If the foreign jurisdiction's margin rules are not consistent with international standards, then the Commission may not find the rules comparable. In providing information to the Commission for a determination, applicants should include, among other things, information describing any difference between the foreign jurisdiction's margin requirements and international standards.[76]

Under the proposal, once the Commission has determined that a foreign jurisdiction's margin requirements adhere to the BCBS–IOSCO framework, the Commission would evaluate the various elements of the foreign jurisdiction's margin requirements.[77] Because the Commission is not proposing to make a binary determination of comparability (*i.e.,* all or nothing), but instead would make comparability determinations on an element-by-element basis, it is possible that a foreign margin system would be comparable with respect to some, but not all, elements of the margin requirements. For instance, a foreign jurisdiction may impose variation margin requirements on a non-U.S. CSE's uncleared swaps with financial end-users that achieve outcomes comparable to the Commission's margin requirements, but the same foreign jurisdiction may not achieve comparable regulatory outcomes with respect to segregation and rehypothecation requirements. By assessing each of the relevant elements separately, the Commission would have the flexibility to determine, with respect to one element of the requirements, that the outcomes are comparable, but not another. The elements that the Commission would be analyzing, among others, would include, but not be limited to: (i) The transactions subject to the foreign jurisdiction's margin requirements; (ii) the entities subject to the foreign jurisdiction's margin requirements; (iii) the methodologies for calculating the amounts of initial and variation margin; (iv) the process and standards for approving models for calculating initial and variation margin models; (v) the timing and manner in which initial and variation margin must be collected and/or paid; (vi) any threshold levels or amounts; (vii) risk management controls for the calculation of initial and variation margin; (viii) eligible collateral for initial and variation margin; (ix) the requirements of custodial arrangements, including

[72] Under Commission regulations 23.203 and 23.606, all records required by the CEA and the Commission's regulations to be maintained by a registered swap dealer or MSP shall be maintained in accordance with Commission regulation 1.31 and shall be open for inspection by representatives of the Commission, the United States Department of Justice, or any applicable prudential regulator. The Commission believes that, before a non-U.S. CSE should be permitted to rely on substituted compliance, it should assure the Commission that it can provide the Commission with prompt access to books and records and submit to onsite inspection and examination. The Commission further expects that access to books and records and the ability to inspect and examine a non-U.S. CSE will be a condition to any comparability determination.

[73] As noted below, because the Commission would make comparability determinations on an element-by-element basis, it is possible that a foreign jurisdiction's margin requirements would be comparable with respect to some, but not all, elements of the margin requirements.

[74] Under the Proposed Rule, the term ''international standards'' means the margin policy framework for non-cleared, bilateral derivatives issued by the Basel Committee on Banking Supervision and the International Organization of Securities Commissions in September 2013, as subsequently updated, revised, or otherwise amended, or any other international standards, principles or guidance relating to margin requirements for non-cleared, bilateral derivatives that the Commission may in the future recognize, to the extent that they are consistent with United States law (including the margin requirements in the Commodity Exchange Act). *See* § 23.160(a)(3) of the Proposed Rule. For further information regarding the margin policy framework for non-cleared, bilateral derivatives issued by the Basel Committee on Banking Supervision and the International Organization of Securities in September 2013, *see* note 12, *supra.*

[75] *See* note 13, *supra.*

[76] *See* § 23.160(c)(2)(iii) of the Proposed Rule.

[77] *See* § 23.160(c)(2) of the Proposed Rule.

rehypothecation and the segregation of margin; (x) documentation requirements relating to margin; and (xi) the cross-border application of the foreign jurisdiction's margin regime.

Moreover, the Commission would expect that the applicant, at a minimum, describe how the foreign jurisdiction's margin requirements addresses each of the above-referenced elements, and identify the specific legal and regulatory provisions that correspond to each element (and, if necessary, whether the foreign jurisdiction's margin requirements do not address a particular element), and describe the objectives of the foreign jurisdiction's margin requirements. Further, the applicant would be required to furnish copies of the foreign jurisdiction's margin requirements (including an English translation of any foreign language document) and any other information or documentation that the Commission deems appropriate.

In addition, in paragraph (c)(3) of the Proposed Rule,[78] the Commission sets out its standard of review that would take into consideration all other relevant factors, including but not limited to, the scope and objectives of the foreign jurisdiction's margin requirement(s) for uncleared swaps; how the foreign jurisdiction's margin requirements compare to international standards; whether the foreign jurisdiction's margin requirements achieve comparable outcomes to the Commission's corresponding margin requirements; the ability of the relevant regulatory authority or authorities to supervise and enforce compliance with the foreign jurisdiction's margin requirements; and any other facts and circumstances the Commission deems relevant.[79]

The Proposed Rule provides that any CSE that is eligible for substituted compliance may apply, either individually or collectively. In addition, the Proposed Rule provides that a foreign regulatory authority that has direct supervisory authority over one or more covered swap entities and that is responsible for administering the relevant foreign jurisdiction's margin requirements may submit a request for a comparability determination with respect to some or all of the Commission's margin requirements. Persons requesting a comparability determination may want to coordinate their application with other market participants and their home regulators to simplify and streamline the process. Once a comparability determination is made for a jurisdiction, it will apply for all entities or transactions in that jurisdiction to the extent provided in the Proposed Rule and the determination, subject to any conditions specified by the Commission.

The Commission expects that the comparability determination process would require close consultation, cooperation, and coordination with other appropriate U.S. regulators and relevant foreign regulators. Further, the Commission expects that, in connection with a comparability determination, the foreign regulator(s) would enter into, or would have entered into, an appropriate memorandum of understanding (''MOU'') or similar arrangement with the Commission.

In issuing a Comparability Determination, the Commission may impose any terms and conditions it deems appropriate.[80] Further, the Proposed Rule would provide that the Commission may, on its own initiative, further condition, modify, suspend, terminate, or otherwise restrict a comparability determination in the Commission's discretion. This could result, for example, from a situation where, after the Commission issues a comparability determination, the basis of that determination ceases to be true. In this regard, the Commission would require an applicant to notify the Commission of any material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the relevant foreign jurisdiction's supervisory or regulatory regime) as the Commission's comparability determination may no longer be valid.[81]

Request for Comment. The Commission is seeking comments on all aspects of the proposed standard of review that will apply to Commission determinations regarding whether some or all of the relevant foreign jurisdiction's margin requirements are comparable to the Commission's corresponding margin requirements, as well as proposed procedures for requests for comparability determinations, including eligibility requirements and submission requirements. Among other things, commenters may wish to submit comments on the following questions:

1. Please provide comments on the appropriate standard of review for comparability determinations and the degree of comparability and comprehensiveness that should be applied to comparability determinations.

2. Are the proposed procedures, including eligibility requirements and submission requirements, for comparability determinations appropriate?

3. Many foreign jurisdictions are in the process of implementing margin reform. Should the Commission develop an interim process that takes into account a different implementation timeline? Please provide details and address competitive implications for U.S. CSEs and non-U.S. CSEs that are required to comply with the Commission's margin regulations.

4. In the Guidance, the Commission discussed ''a de minimis'' exemption with respect to transaction-level requirements for foreign branches of U.S. swap dealers located in ''emerging markets'' that, in the aggregate, constitute less than 5 percent of the firm's notional swaps.[82] The Proposed Rule does not contain an exemption for CSEs operating in ''emerging markets.'' Should the Commission develop an exemption for emerging markets? If so, what should be the eligibility criteria or conditions? For example, should the Commission provide an exemption where a non-U.S. CSE is operating in a jurisdiction that does not permit the related collateral to be held outside that jurisdiction and/or that lacks legal or operational infrastructure relating to proper segregation of initial margin? Should the Commission require the CSE to collect initial and variation margin from its counterparty in eligible emerging market jurisdictions, but only require the CSE to post variation margin? Should the Commission limit the type of eligible collateral that could be used in eligible emerging market jurisdictions? Which jurisdictions, if any, should qualify as ''emerging markets'' for purposes of the exemption? What should be the process for determining that the qualifying criteria are met? Please provide quantitative data, to the extent practical.

5. As some emerging market jurisdictions' laws may not support legally enforceable netting

[78] *See* § 23.160(c)(3) of the Proposed Rule.

[79] The submission should include a description of the ability of the relevant foreign regulatory authority or authorities to supervise and enforce compliance with the foreign jurisdiction's margin requirements, including the powers of the foreign regulatory authority or authorities to supervise, investigate, and discipline entities for compliance with the margin requirements and the ongoing efforts of the regulatory authority or authorities to detect, deter, and ensure compliance with the margin requirements. *See* § 23.160(c)(2)(iv) of the Proposed Rule.

[80] The violation of such terms and conditions may constitute a violation of the Commission's margin requirements and/or result in the modification or revocation of the comparability determination.

[81] The Commission expects to impose this obligation as one of the conditions to the issuance of a comparability determination.

[82] *See* the Guidance, 78 FR 45351.

arrangements, which would then, under the Proposed Margin Rules and under certain circumstances, require that a CSE and its counterparty post and collect gross margin, should the Commission, if it does not provide for an emerging markets exception, permit the CSE and its counterparty to collect/post variation margin on a net basis? If so, what conditions, if any, should the Commission place on this requirement to ensure that CSEs and the U.S. financial system are adequately protected?

6. Is the scope of substituted compliance under the Proposed Rule appropriate? Should additional or fewer transactions be eligible for substituted compliance, and if so, how should the Proposed Rule be modified?

E. General Request for Comments

In addition to the specific requests for comments included above, the Commission seeks comment on all aspects of the Proposed Rule. Commenters are encouraged to address, among other things, the scope and application of the Proposed Rule, costs and benefits of the Proposed Rule, alternatives to the Proposed Rule, practical implications for CSEs and other market participants and the market generally related to the Proposed Rule, whether the Proposed Rule sufficiently supports the statutory goals of ensuring the safety and soundness of the CSE and protecting the financial system against the risks associated with uncleared swaps, and whether the Proposed Rule sufficiently takes into account principles of international comity. In particular, the Commission requests comment on the following:

1. Does the Proposed Rule's approach to the cross-border application of margin requirements satisfy the Commission's statutory requirements, including the requirement to help ensure the safety and soundness of CSEs, and the requirement that the Commission, the Prudential Regulators, and the SEC, to the maximum extent practicable, establish and maintain comparable minimum initial and variation margin requirements?

2. Would it be more appropriate to apply the margin requirements at the entity-level, without any exclusion? If yes, please explain.

3. Would it be more appropriate to apply the margin requirements at a transaction-level? If yes, please explain.

4. Is the scope of the Proposed Rule appropriate, or should it be changed, and if so, how?

5. Would an alternative approach to the Proposed Rule better achieve the Commission's statutory requirements or otherwise be preferable or more appropriate? If yes, please explain.

6. Does the Commission's Proposed Rule strike the right balance between the Commission's supervisory interest in offsetting the risk to CSEs and the financial system arising from the use of uncleared swaps and international comity principles? If not, please explain.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'') requires that agencies consider whether the regulations they propose will have a significant economic impact on a substantial number of small entities.[83] The Commission previously has established certain definitions of ''small entities'' to be used in evaluating the impact of its regulations on small entities in accordance with the RFA.[84] The proposed regulation establishes a mechanism for CSEs [85] to satisfy margin requirements by complying with comparable margin requirements in the relevant foreign jurisdiction as described in paragraph (c) of the Proposed Rule,[86] but only to the extent that the Commission makes a determination that complying with the laws of such foreign jurisdiction is comparable to complying with the corresponding margin requirement(s) for which the determination is sought.

The Commission previously has determined that SDs and MSPs are not small entities for purposes of the RFA.[87] Thus, the Commission is of the view that there will not be any small entities directly impacted by this rule.

The Commission notes that under the Proposed Margin Rules, SDs and MSPs would only be required to collect and post margin on uncleared swaps when the counterparties to the uncleared swaps are either other SDs and MSPs or financial end users. As noted above, SDs and MSPs are not small entities for RFA purposes. Furthermore, any financial end users that may be indirectly [88] impacted by the Proposed Rule would be similar to eligible contract participants (''ECPs''), and, as such, they would not be small entities.[89] Further, to the extent that there are any foreign financial entities that would not be considered ECPs, the Commission expects that there would not be a substantial number of these entities significantly impacted by the Proposed Rule. As noted above, most foreign financial entities would likely be ECPs to the extent they would trade in uncleared swaps. The Commission expects that only a small number of foreign financial entities that are not ECPs, if any, would trade in uncleared swaps.

Accordingly, the Commission finds that there will not be a substantial number of small entities impacted by the Proposed Rule. Therefore, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the proposed regulations will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'') 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. This proposed rulemaking would result in the collection of information requirements within the meaning of the PRA, as discussed below. The proposed rulemaking contains collections of information for which the Commission has not previously received control numbers from the Office of Management and Budget (''OMB''). If adopted, responses to this collection of information would be required to obtain or retain benefits. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. The Commission has submitted to OMB an information collection request to obtain an OMB control number for the collections contained in this proposal.

Section 731 of the Dodd-Frank Act, amended the CEA,[90] to add, as section

[83] 5 U.S.C. 601 *et seq.*

[84] 47 FR 18618 (Apr. 30, 1982).

[85] Section 23.151 of the Proposed Margin Rules defines CSEs as a SD or MSP for which there is no prudential regulator.

[86] *See* § 23.160(c) of the Proposed Rule.

[87] *See* 77 FR 30596, 30701 (May 23, 2012).

[88] The RFA focuses on direct impact to small entities and not on indirect impacts on these businesses, which may be tenuous and difficult to discern. *See Mid-Tex Elec. Coop., Inc.* v. *FERC,* 773 F.2d 327, 340 (D.C. Cir. 1985); *Am. Trucking Assns.* v. *EPA,* 175 F.3d 1027, 1043 (D.C. Cir. 1985).

[89] As noted in paragraph (1)(xii) of the definition of ''financial end user'' in § 23.151 of the Proposed Margin Rules, a financial end-user includes a person that would be a financial entity described in paragraphs (1)(i)–(xi) of that definition, if it were organized under the laws of the United States or any State thereof. The Commission believes that this prong of the definition of financial end-user would capture the same type of U.S. financial end-users that are ECPs, but for them being foreign financial entities. Therefore, for purposes of the Commission's RFA analysis, these foreign financial end-users will be considered ECPs and therefore, like ECPs in the U.S., not small entities.

[90] 7 U.S.C. 1 *et seq.*

4s(e) thereof, provisions concerning the setting of initial and variation margin requirements for SDs and MSPs. Each SD and MSP for which there is a Prudential Regulator, as defined in section 1a(39) of the CEA, must meet margin requirements established by the applicable Prudential Regulator, and each CSE must comply with the Commission's regulations governing margin. With regard to the cross-border application of the swap provisions enacted by Title VII of the Dodd-Frank Act, section 2(i) of the CEA provides the Commission with express authority over activities outside the United States relating to swaps when certain conditions are met. Section 2(i) of the CEA provides that the provisions of the CEA relating to swaps enacted by Title VII of the Dodd-Frank Act (including Commission rules and regulations promulgated thereunder) shall not apply to activities outside the United States unless those activities (1) have a direct and significant connection with activities in, or effect on, commerce of the United States or (2) contravene such rules or regulations as the Commission may prescribe or promulgate as are necessary or appropriate to prevent the evasion of any provision of Title VII.[91] Because margin requirements are critical to ensuring the safety and soundness of a CSE and supporting the stability of the U.S. financial markets, the Commission believes that its margin rules should apply on a cross-border basis in a manner that effectively addresses risks to the registered CSE and the U.S. financial system.

As noted above, the Proposed Rule would establish margin requirements for uncleared swaps of CSEs on a firm-wide, entity-level basis (with substituted compliance available in certain circumstances), except as to a narrow class of uncleared swaps between a non-U.S. CSE and a non-U.S. counterparty that fall within the Exclusion. The Proposed Rule would establish a procedural framework in which the Commission would consider permitting compliance with comparable margin requirements in a foreign jurisdiction to substitute for compliance with the Commission's margin requirements in certain circumstances. The Commission would consider whether the requirements of such foreign jurisdiction with respect to margin of uncleared swaps are comparable to the Commission's margin requirements.

Specifically, the Proposed Rule would provide that a CSE who is eligible for substituted compliance may submit a request, individually or collectively, for a comparability determination.[92] Persons requesting a comparability determination may coordinate their application with other market participants and their home regulators to simplify and streamline the process. Once a comparability determination is made for a jurisdiction, it would apply for all entities or transactions in that jurisdiction to the extent provided in the determination, as approved by the Commission. In providing information to the Commission for a comparability determination, applicants must include, at a minimum, information describing any differences between the relevant foreign jurisdiction's margin requirements and international standards,[93] and the specific provisions of the foreign jurisdiction that govern: (i) The transactions subject to the foreign jurisdiction's margin requirements; (ii) the entities subject to the foreign jurisdiction's margin requirements; (iii) the methodologies for calculating the amounts of initial and variation margin; (iv) the process and standards for approving models for calculating initial and variation margin models; (v) the timing and manner in which initial and variation margin must be collected and/or paid; (vi) any threshold levels or amounts; (vii) risk management controls for the calculation of initial and variation margin; (viii) eligible collateral for initial and variation margin; (ix) the requirements of custodial arrangements, including rehypothecation and the segregation of margin; (x) documentation requirements relating to margin; and (xi) the cross-border application of the foreign jurisdiction's margin regime.[94]

In addition, the Commission would expect the applicant, at a minimum, to describe how the foreign jurisdiction's margin requirements addresses each of the above-referenced elements, and identify the specific legal and regulatory provisions that correspond to each element (and, if necessary, whether the relevant foreign jurisdiction's margin requirements do not address a particular element). Further, the applicant must describe the objectives of the foreign jurisdiction's margin requirements, the ability of the relevant regulatory authority or authorities to supervise and enforce compliance with the foreign jurisdiction's margin requirements, including the powers of the foreign regulatory authority or authorities to supervise, investigate, and discipline entities for compliance with the margin requirements and the ongoing efforts of the regulatory authority or authorities to detect, deter, and ensure compliance with the margin requirements. Finally, the applicant must furnish copies of the foreign jurisdiction's margin requirements (including an English translation of any foreign language document) and any other information and documentation that the Commission deems appropriate.[95]

In issuing a Comparability Determination, the Commission may impose any terms and conditions it deems appropriate.[96] In addition, the Proposed Rule would provide that the Commission may, on its own initiative, further condition, modify, suspend, terminate, or otherwise restrict a comparability determination in the Commission's discretion. This could result, for example, from a situation where, after the Commission issues a comparability determination, the basis of that determination ceases to be true. In this regard, the Commission would require an applicant to notify the Commission of any material changes to information submitted in support of a comparability determination (including, but not limited to, changes in the foreign jurisdiction's supervisory or regulatory regime) as the Commission's comparability determination may no longer be valid.[97]

The collection of information that is proposed by this rulemaking is necessary to implement sections 4s(e) of the CEA, which mandates that the Commission adopt rules establishing minimum initial and variation margin requirements for CSEs on all swaps that are not cleared by a registered derivatives clearing organization, and section 2(i) of the CEA, which provides that the provisions of the CEA relating to swaps that were enacted by Title VII of the Dodd-Frank Act (including any rule prescribed or regulation promulgated thereunder) apply to

[91] 7 U.S.C. 2(i).

[92] A CSE may apply for a comparability determination only if the uncleared swap activities of the CSE are directly supervised by the authorities administering the foreign regulatory framework for uncleared swaps. Also, a foreign regulatory agency may make a request for a comparability determination only if that agency has direct supervisory authority to administer the foreign regulatory framework for uncleared swaps in the requested foreign jurisdiction.

[93] *See* note 74, *supra,* for a discussion of the definition of ''international standards'' under the Proposed Rule. See also § 23.160(a)(3) of the Proposed Rule.

[94] *See* § 23.160(c)(2) of the Proposed Rule for submission requirements.

[95] *See* § 23.160(c)(2)(v) and (vi) of the Proposed Rule.

[96] The violation of such terms and conditions may constitute a violation of the Commission's margin requirements and/or result in the modification or revocation of the comparability determination.

[97] The Commission expects to impose this obligation as one of the conditions to the issuance of a comparability determination.

activities outside the United States that have a direct and significant connection with activities in, or effect on, commerce of the United States.[98] The information collection would be necessary for the Commission to consider whether the requirements of the foreign rules are comparable to the applicable requirements of the Commission's rules.

As noted above, any CSE who is eligible for substituted compliance may make a request for a comparability determination. Currently, there are approximately 102 CSEs provisionally registered with the Commission. The Commission further estimates that of the approximately 102 CSEs, approximately 61 CSEs would be subject to the Commission's margin rules as they are not subject to a Prudential Regulator. However, the Commission notes that any foreign regulatory agency that has direct supervisory authority over one or more CSEs and that is responsible to administer the relevant foreign jurisdiction's margin requirements may apply for a comparability determination. Further, once a comparability determination is made for a jurisdiction, it would apply for all entities or transactions in that jurisdiction to the extent provided in the determination, as approved by the Commission. The Commission estimates that it will receive requests for a comparability determination from 17 jurisdictions, consisting of the 16 jurisdictions within the G20, plus Switzerland,[99] and that each request would impose an average of 10 burden hours.

Based upon the above, the estimated hour burden for collection is calculated as follows:

Number of respondents: 17.

Frequency of collection: Once.

Estimated annual responses per registrant: 1.

Estimated aggregate number of annual responses: 17.

Estimated annual hour burden per registrant: 10 hours.

Estimated aggregate annual hour burden: 170 hours (17 registrants × 10 hours per registrant).

Information Collection Comments. The Commission invites the public and other Federal agencies to comment on any aspect of the reporting burdens discussed above. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Comments may be submitted directly to the Office of Information and Regulatory Affairs, by fax at (202) 395–6566 or by email at *OIRAsubmissions@omb.eop.gov*. Please provide the Commission with a copy of submitted comments so that all comments can be summarized and addressed in the final rule preamble. Refer to the **ADDRESSES** section of this notice of proposed rulemaking for comment submission instructions to the Commission. A copy of the supporting statements for the collections of information discussed above may be obtained by visiting *RegInfo.gov.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

C. Cost-Benefit Considerations

1. Introduction

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders.[100] Section 15(a) further specifies that the costs and benefits shall be evaluated in light of 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. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors.

In promulgating the Proposed Margin Rules,[101] the Commission considered the costs and benefits associated with its choices regarding the scope and extent to which it would apply its proposed margin requirements to uncleared swaps of a CSE, including those related to the setting of the material swap exposure for financial entities, and related substantive requirements, such as the determination of eligible collateral and acceptable custodial arrangements. In addition, in light of the fact that section 4s(e), by its terms, applies to uncleared swaps of all CSEs, regardless of the domicile of the CSE (or its counterparties), the costs and benefits discussed in the Proposed Margin Rules' **Federal Register** release relate both to the domestic and cross-border application of the margin rule.[102] The cost and benefit considerations (''CBC'') set out in this proposal are intended to augment the CBC set forth in the Proposed Margin Rules' **Federal Register** release and address cost and benefit considerations related to the Commission's choices regarding the extent to which it would recognize compliance with comparable foreign requirements as an alternative means of compliance with the Commission's margin rules (''substituted compliance'') and the extent to which it would exclude uncleared swaps from the Commission's margin rules. Further, in considering the relevant costs and benefits of the Proposed Margin Rules, the Commission used as its baseline the swaps market as it existed at the time of the Proposed Margin Rules' **Federal Register** release; because this Proposed Rule addresses the cross-border application of the Proposed Margin Rules, the Commission is using as its baseline the swaps market as it would operate once the Proposed Margin Rules were fully implemented.

As discussed in section I.B. above, in developing the proposed cross-border framework in the Proposed Rule, the

[98] Section 2(i) of the CEA provides that the provisions of the CEA relating to swaps that were enacted by Title VII of the Dodd-Frank Act (including any rule prescribed or regulation promulgated thereunder), shall not apply to activities outside the United States unless those activities (1) have a direct and significant connection with activities in, or effect on, commerce of the United States or (2) contravene such rules or regulations as the Commission may prescribe or promulgate as are necessary or appropriate to prevent the evasion of any provision of Title VII of the CEA.

[99] Because the Commission's proposed margin requirements are based on the BCBS–IOSCO framework and one of the factors that the Commission will consider in making its determination is the comparability to these international standards, the Commission estimates that in all likelihood, it will receive applications from all 16 jurisdictions within the G20, plus Switzerland.

[100] 7 U.S.C. 19(a).

[101] The Commission's Proposed Margin Rules are set forth in proposed §§ 23.150 through 23.159 of part 23 of the Commission's regulations, proposed as 17 CFR 23.150 through 23.159. *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 79 FR 59898 (Oct. 3, 2014).

[102] *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 79 FR 59920–59926 (Oct. 3, 2014).

Commission is mindful of the global and highly interconnected nature of the swaps market—and that risk exposures overseas can quickly manifest in the United States and pose substantial threat to the U.S. financial system. At the same time, the Commission also recognizes that competitive distortions and market inefficiencies can result—and the benefits of the BCBS–IOSCO framework lost—if due consideration is not given to comity principles. The Commission has also carefully considered the impact of its choices in determining whether (and, if so, under what circumstances) substituted compliance would be available or whether (and, if so, under what circumstances) swaps would be deemed excluded, including the effect of its choices on efficiency, competition, market integrity and transparency.

The Commission is aware of the potentially significant trade-offs inherent in its policy decisions. For instance, the Commission's choice not to exclude from its margin requirements certain foreign-facing swaps involving U.S. CSEs and non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person may make it more costly for such firms to conduct their swaps business, particularly in foreign jurisdictions, and put them at a competitive disadvantage relative to non-U.S. CSEs whose obligations under the relevant swap are not guaranteed by a U.S. person. It could also make foreign counterparties less willing to deal with U.S. CSEs and non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person. On the other hand, full application of the margin requirements to these CSEs may enhance the safety and soundness of these CSEs and consequently, the U.S. financial system. In addition, the extent, if any, to which either of the aforementioned disadvantages would arise depends on whether competitors of such CSEs must comply with comparable margin requirements. In developing the proposed cross-border framework in the Proposed Rule, the Commission has attempted to appropriately consider competing concerns in seeking to effectively address the risk posed to the safety and soundness of CSEs, while creating a workable framework that mitigates the potential for undue market distortions and that promotes global harmonization.

The Commission's consideration of the costs and benefits associated with the proposed framework is complicated by the fact that other jurisdictions may adopt requirements with different scope or on different timelines. Currently, no foreign jurisdiction has finalized rules for margin of uncleared swaps. However, the EU [103] and Japan [104] have proposed such rules, each of which are based on the BCBS–IOSCO framework.[105] The extent to which, if at all, foreign jurisdictions will follow the BCBS–IOSCO framework and the differences between the requirements implemented overseas and the Commission's margin requirements will affect the costs and benefits related to the Proposed Rule. Thus, for example, if a margin rule in a particular foreign jurisdiction is less rigorous than the Commission's margin rule, those CSEs (U.S. and non-U.S. CSEs) that are subject to the Commission's margin rule may be competitively disadvantaged relative to those dealers that are eligible for Exclusion from the Commission's margin rule for certain swaps or are outside the Commission's jurisdiction.[106]

In sum, given that foreign jurisdictions do not yet have in place their margin rules, it is not possible to fully evaluate the costs and benefits associated with the Proposed Rule, and in particular, the implications for the safety and soundness of CSEs and competition. However, to the extent that a foreign regime's margin requirements are comparable, any differences between the Commission's margin requirements and foreign margin requirements would be insignificant and, therefore, mitigate the potential for undue risk to the CSE and competitive distortions. However, if a foreign regime's margin requirements are not deemed comparable, this may put a CSE at a competitive disadvantage when competing with non-U.S. firms that are not registered with the Commission because these non-CFTC registered dealers would have a cost advantage that could affect their pricing terms to clients.

In the sections that follow, the Commission considers: (i) Costs and benefits associated with the proposed definition of U.S. person; (ii) the proposed framework for substituted compliance; (iii) the proposed exclusion from the margin rule; (iv) the submission of requests for a comparability determination; and (v) alternatives considered and the cost and benefit of such alternatives. Wherever reasonably feasible, the Commission has endeavored to quantify the costs and benefits of this proposed rulemaking. In a number of instances, the Commission currently lacks the data and information required to precisely estimate costs and benefits. Where it was not feasible to quantify (*e.g.,* because of the lack of accurate data or appropriate metrics), the Commission has endeavored to consider the costs and benefits of these rules in qualitative terms.

2. Proposed Rule

The Proposed Rule sets forth a definition of ''U.S. person,'' describing the circumstances under which substituted compliance or the exclusion would be available, and would establish a process for the submission of requests for a comparability determination. In addition to issues related to financial integrity of markets, competition and market distortions noted above, the U.S. person definition and comparability determination process entail monetary costs for CSEs and market participants because a market participant may have

[103] *See* European Banking Authority, European Securities and Markets Authority, and European Insurance and Occupational Pensions Authority, Consultation Paper on draft regulatory technical standards on risk-mitigation techniques for OTC-derivative contracts not cleared by a CCP under Article 11(15) of Regulation (EU) No 648/2012 (for the European Market Infrastructure Regulation) (April 14, 2014), *available at https://www.eba.europa.eu/documents/10180/655149/JC+CP+2014+03+%28CP+on+risk+mitigation+for+OTC+derivatives%29.pdf*, and Second Consultation Paper on draft regulatory technical standards on risk-mitigation techniques for OTC-derivative contracts not cleared by a CCP under Article 11(15) of Regulation (EU) No 648/2012 (for the European Market Infrastructure Regulation) (Jun. 10, 2015), *available at https://www.eba.europa.eu/documents/10180/1106136/JC-CP-2015-002+JC+CP+on+Risk+Management+Techniques+for+OTC+derivatives+.pdf.*

[104] *See* Financial Services Agency of Japan, draft amendments to the ''Cabinet Office Ordinance on Financial Instruments Business'' and ''Comprehensive Guidelines for Supervision'' with regard to margin requirements for non-centrally cleared derivatives (July 3, 2014). Available in Japanese at *http://www.fsa.go.jp/news/26/syouken/20140703-3.html.*

[105] *See* Margin Requirements for Non-centrally Cleared Derivatives, Sept. 2013, *available at http://www.bis.org/publ/bcbs261.pdf.* The Commission is not incorporating the details of the EU and Japanese proposals in this CBC, because they have not been adopted and would be subject to change upon adoption.

[106] As discussed in section I.B. above, in the interest of promoting global harmonization, the Commission has consulted and coordinated with the Prudential Regulators and foreign regulatory authorities. In addition, the Commission staff has participated in numerous bilateral and multilateral discussions with foreign regulatory authorities discussing national efforts to implement margin reform and the possibility of conflicts and overlaps between U.S. and foreign regulatory regimes. Although at this time foreign jurisdictions do not yet have their margin regimes in place, the Commission has participated in ongoing, collaborative discussions with regulatory authorities in the EU and Japan regarding their cross-border approaches to the margin rules, including the anticipated scope of application of margin requirements in their jurisdiction to cross-border swaps, their plans for recognizing foreign margin regimes, and their anticipated timelines. The Commission expects that these discussions will continue as it finalizes and then implements its margin rules, and as other jurisdictions develop their own margin rules and approaches to cross-border applications.

to expend resources to determine whether it (or its counterparty) is a U.S. person. A CSE seeking to rely on substituted compliance could incur costs in connection with the submission of a request for a comparability determination, although this would not be the case in circumstances where the relevant jurisdiction has itself attained a comparability finding from the Commission. In this section, we describe the most significant considerations that we have taken into account in formulating the Proposed Rule.

a. U.S. Person

Under the Proposed Rule, the term ''U.S. person'' would be defined so as to identify activities having a substantial nexus to the U.S. market because they are undertaken by individuals or entities organized or domiciled in the United States or because of other connections to the U.S. market. The definition is intended to identify those individuals and entities whose swap activities have a substantial nexus to U.S. markets even when they transact in swaps with a non-U.S. CSE. As noted in section II.B.1. above, this proposed definition generally follows the traditional, territorial approach to defining a U.S. person. The chief benefit of this territorial approach is that it is objective and clear—and the Commission believes that the industry has largely followed a similar definition of ''U.S. person'' included in the Guidance.

The Commission considered including the U.S. majority-ownership prong that was included in the Guidance (50% U.S. person ownership of a fund or other collective investment vehicle), but has determined not to propose it.[107] The Commission understands that unlike other corporate structures, certain types of funds, specifically fund-of-funds and master-feeder structures, would require an adviser or administrator to look through to other fund entities in the fund structure, in ascertaining whether a beneficial owner of the fund is a U.S. person. The Commission further understands that this may be difficult to determine in some cases. In addition, the Commission believes that other elements of the U.S. person definition would in many circumstances cover these funds as a ''U.S. person.''

Even if a non-U.S. fund with U.S. majority-ownership is treated as a non-U.S. person, such fund would be excluded from the Commission's margin rules only in limited circumstances (namely, when the fund trades with a non-U.S. CSE that is not a consolidated subsidiary of a U.S. entity or a U.S. branch of a non-U.S. CSE). Additionally, any excluded swaps would most likely be covered by another jurisdiction that adheres to the BCBS–IOSCO standards. The Commission anticipates that non-U.S. CSEs will generally be required, in their home jurisdiction, to collect margin from these non-U.S. funds.[108] Therefore, non-U.S. CSEs would generally be protected in the event of a default by a non-U.S. fund even if the uncleared swap with the non-U.S. fund falls within the Exclusion.[109] Accordingly, the Commission believes that treatment of non-U.S. funds with U.S. majority-ownership as non-U.S. persons will not have a substantial impact on the safety and soundness of CSEs or the stability of the U.S. financial system; at the same time, the Commission believes that excluding the majority-ownership prong would alleviate any burden associated with determining whether a fund qualifies as a U.S. person under this criterion.

As noted in section II.B.1. above, prong (6) (Proposed Rule § 23.160(a)(10)(vi)) of the proposed ''U.S. person'' definition would capture certain legal entities owned by one or more U.S. person(s) and for which such person(s) bear unlimited responsibility for the obligations and liabilities of the legal entity. In the case of the Guidance, the ''U.S. person'' definition would generally characterize a legal entity as a U.S. person if the entity were ''directly or indirectly majority-owned'' by one or more persons falling within the term ''U.S. person'' and such U.S. person(s) bears unlimited responsibility for the obligations and liabilities of the legal entity. Because this prong of the proposed definition of ''U.S. person'' is broader in scope, the Commission believes that this may result in more legal entities meeting the U.S. person definition. In addition, to the extent that this prong of the proposed definition of ''U.S. person'' expands the number of market participants that would be deemed to be a ''U.S. person,'' the Commission believes that the benefits that would have been provided to otherwise non-U.S. CSEs from being able to avail themselves of substituted compliance and the Exclusion would not be realized.

The proposed ''U.S. person'' definition does not include the prefatory phrase ''includes, but is not limited to'' that was included in the Guidance. The Commission believes that this prefatory phrase should not be included in the Proposed Rule in order to provide legal certainty regarding the application of U.S. margin requirements to cross-border swaps.

Finally, the Commission believes that the definition of ''U.S. person'' provides a clear and objective basis upon which to identify a U.S. person, and that identifying whether a counterparty is a ''U.S. person'' should be relatively straightforward because, as noted above, the Commission believes that a swap counterparty generally should be permitted to reasonably rely on its counterparty's written representation in determining whether the counterparty is within the definition of the term ''U.S. person.''

b. Availability of Substituted Compliance and Exclusion

i. Uncleared Swaps of U.S. CSEs or of Non-U.S. CSEs Whose Obligations Under the Relevant Swap Are Guaranteed by a U.S. Person

As set out in Table A to this release, under the Proposed Rule, the Commission's margin rules would generally apply to all uncleared swaps of U.S. CSEs. For U.S. CSEs, substituted compliance would only be available with respect to the requirement to post initial margin and only if the counterparty is a non-U.S. person (including a non-U.S. CSE) whose obligations under the uncleared swap are not guaranteed by a U.S. person. Uncleared swaps with U.S. CSEs would never qualify for the Exclusion. Under the Proposed Rule, non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person would receive the same treatment as U.S. CSEs.[110] The Commission believes

[107] The Commission's definition of the term ''U.S. person'' as used in the Guidance included a prong (iv) which covered ''any commodity pool, pooled account, or collective investment vehicle (whether or not it is organized or incorporated in the United States) of which a majority ownership is held, directly or indirectly, by a U.S. person(s).''

[108] At this time, we do not have information as to what portion of the funds that would have been covered by the U.S. majority-ownership prong are hedge funds.

[109] Further, as noted earlier, a non-U.S. CSE that can avail itself of the Exclusion would still be subject to the Commission's margin rules with respect to all uncleared swaps not meeting the criteria for the Exclusion, albeit with the possibility of substituted compliance. The Commission further believes that the possibility of a cascading event affecting U.S. counterparties and the U.S. market more broadly as a result of a default by the non-U.S. CSE would also be mitigated because the non-U.S. CSE would be subject to U.S. margin requirements (with the possibility of substituted compliance to the extent applicable) when entering into a swap with U.S. counterparties.

[110] As discussed in section II.B.2, under the Proposed Rule the Commission is defining a

Continued

that this result is appropriate because a swap of an entity guaranteed by that U.S. person will have economic and financial implications that are likely to be very similar to the economic and financial implications of a swap entered into directly by the U.S. guarantor, as discussed in section II.B.2. above.

The Commission understands that the Proposed Rule may place U.S. CSEs and non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person at a disadvantage when competing with either non-U.S. CSEs that are able to rely on the Exclusion or with non-CFTC registered dealers for foreign clients, though whether such a disadvantage exists would depend on whether these competitors are subject to comparable margin rules in other jurisdictions. For example, the ability of a non-U.S. CSE that is not guaranteed by a U.S. person (and that is not a Foreign Consolidated Subsidiary or a U.S. branch of a non-U.S. CSE) to rely on the Exclusion could allow it to gain a cost advantage over a U.S. CSE or a non-U.S. CSE that is guaranteed by a U.S. person and thus offer better pricing terms to foreign clients, unless it is subject to another jurisdiction's margin rules that are comparable. U.S. CSEs and non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person may also be at a disadvantage when competing for clients with non-U.S. CSEs that are able to rely on substituted compliance more broadly if the clients believe complying with the foreign jurisdiction's margin requirements would be less burdensome or costly than when transacting with a U.S. CSE under the Proposed Rule, as the amount posted by the non-U.S. counterparty would need to comply with U.S. margin requirements. However, the Commission believes that the requirement that the relevant foreign jurisdiction's margin requirements have comparable outcomes should operate to narrow any competitive disadvantage, thereby diminishing opportunities for regulatory arbitrage.[111]

In addition, because the Proposed Rule provides for limited substituted compliance for U.S. CSEs and non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person (relative to other CSEs), those CSEs may be subject to conflicting or duplicative regulations, and consequently, would incur costs associated with developing multiple sets of policies and procedures and operational infrastructures. The Commission recognizes that such costs would vary for firms depending on the nature and scope of the individual firm's business, and costs relative to other competitors would depend on whether the competitors are subject to other jurisdictions' margin rules. The Commission requests data from commenters to assist the Commission in considering the quantitative effect of the limited substituted compliance for U.S. CSEs and non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person.

On the other hand, the Commission believes that requiring U.S. CSEs and non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person to comply with its margin requirements would foster the stability of the U.S. financial markets. By their nature, U.S. CSEs and non-U.S. CSEs whose swap obligations are guaranteed by a U.S. person have a significant impact on the U.S. financial markets, and the Commission therefore has a strong interest in ensuring their viability. As discussed in section II.C.1. above, the Commission believes that requiring U.S. CSEs and non-U.S. CSEs whose swap obligations are guaranteed by a U.S. person to comply with the Commission's margin requirements, with only limited substituted compliance, is important to maintaining well-functioning U.S. financial markets and ensuring the sound risk management practices of key market participants in the U.S. swaps market.

ii. Uncleared Swaps of Non-U.S. CSEs Whose Obligations Under the Relevant Swap Are Not Guaranteed by a U.S. Person

As set out in Table A to this release, under the Proposed Rule, non-U.S. CSEs whose obligations under the relevant uncleared swap are not guaranteed by a U.S. person, including Foreign Consolidated Subsidiaries, are eligible for substituted compliance to a greater extent relative to U.S. CSEs or non-U.S. CSEs whose obligations under the relevant uncleared swap are guaranteed by a U.S. person. A subset of these non-U.S. CSEs may qualify for the Exclusion, as described in section II.C.3. above. As noted in section II.C.2., the Commission believes that the proposed approach is appropriate since a non-U.S. CSE whose swap obligations are not guaranteed by a U.S. person (including a Foreign Consolidated Subsidiary), may implicate equal or greater supervisory concerns on the part of a foreign regulator relative to the Commission's supervisory interests (in comparison to U.S. CSEs or non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person, because the Commission has a significant regulatory interest in uncleared swaps of these CSEs).

Substituted compliance would benefit such non-U.S. CSEs by allowing them to avoid conflicting or duplicative regulations and choose the most appropriate set of rules when transacting with each other. Furthermore, eligible non-U.S. CSEs could further benefit from developing one enterprise-wide set of compliance and operational infrastructures.[112] And

guarantee narrower than in the Guidance, and in doing so, the Commission has broadened the availability of substituted compliance and the Exclusion to certain non-U.S. CSEs that would not have the ability to avail themselves of these if the broader definition of guarantee used in the Guidance were used in the Proposed Rule instead of the narrower definition. However, the Commission believes that as a result of its decision to define certain non-U.S. CSEs as Foreign Consolidated Subsidiaries, some of these same non-U.S. CSEs that would have been able to avail themselves of substituted compliance and the Exclusion, as a result of the narrow definition of a guarantee, would not be eligible for the Exclusion (but would benefit from the full application of substituted compliance instead of a limited application). The costs and benefits related to substituted compliance and the Exclusion are set out in this section and below.

[111] The Commission notes that of the approximately 61 CSEs that would be subject to the Commission's margin rules, 21 are non-U.S. CSEs. Of those 21 non-U.S. CSEs, 20 are domiciled in jurisdictions that participated in the development of the BCBS–IOSCO framework. Although harmonization among these jurisdictions may mitigate some competitive disadvantages, the associated costs and benefits cannot be reasonably determined as no jurisdictions have finalized their margin rules.

[112] The Commission notes that the costs of developing the margin infrastructure needed to comply with Commission margin requirements in the context of cross-border transactions, as well as the costs of complying with the Commission's margin requirements more generally in the context of cross-border transactions, could vary significantly for different CSEs based on factors specific to each firm (*e.g.,* organizational structure, status as a U.S. CSE or non-U.S. CSE (including whether the firm is a Foreign Consolidated Subsidiary or a U.S. branch of a non-U.S. CSE), jurisdictions in which uncleared swaps activities are conducted, applicable margin requirements in the U.S. and other jurisdictions, the location and status of counterparties, existence of an appropriate MOU or similar arrangement with the relevant jurisdictions, existence of Comparability Determinations in the relevant jurisdictions and any conditions in such determinations, and firm policies and procedures for the posting and collection of margin). The Commission further notes that currently no foreign jurisdiction has finalized rules for margin of uncleared swaps. However, the EU and Japan have proposed such rules, each of which are based on the BCBS–IOSCO framework. Accordingly, the Commission lacks the data and information required to reasonably estimate costs related to developing the appropriate margin infrastructure or the costs of complying with

because substituted compliance is contingent on the Commission's determination that the relevant jurisdiction's margin rules are comparable, the potential for undue risk to the CSE and competitive distortions between those registrants that are eligible for substituted compliance and those that are not would be mitigated. However, if the foreign jurisdiction's margin requirements are not deemed comparable, these CSEs will be at a disadvantage to non-CFTC registered dealers when competing for client business.

iii. Exclusion for Uncleared Swaps of Non-U.S. CSEs Where Neither Counterparty's Obligations Under the Relevant Swap Are Guaranteed by a U.S. Person and Neither Counterparty Is a Foreign Consolidated Subsidiary Nor a U.S. Branch of a Non-U.S. CSE

As discussed in section II.C.3., under the Proposed Rule, the Commission would exclude from its margin rules uncleared swaps entered into by a non-U.S. CSE with a non-U.S. person counterparty (including a non-U.S. CSE), provided that neither counterparty's obligations under the relevant swap are guaranteed by a U.S. person and neither counterparty is a Foreign Consolidated Subsidiary nor a U.S. branch of a non-U.S. CSE. As discussed in section II.C.3. above, the Commission believes that it would be appropriate to tailor the application of margin requirements in the cross-border context, consistent with section 4s(e) of the CEA [113] and comity principles, so as to exclude this narrow class of uncleared swaps involving a non-U.S. CSE and a non-U.S. counterparty.

The Commission believes that such non-U.S. CSEs may benefit from the Exclusion because it allows them to avoid conflicting or duplicative regulations where a transaction would be subject to more than one uncleared swap margin regime. On the other hand, to the extent a non-U.S. CSE would be able to rely on the margin requirements of a foreign jurisdiction, as opposed to the Commission's margin requirements, and such other margin requirements are not comparable, the Exclusion could result in a less rigorous margin regime for such CSE. This, in turn, could create competitive disparities between non-U.S. CSEs relying on the Exclusion and other CSEs that are not eligible for the Exclusion. That is, the Exclusion could allow these non-U.S. CSEs to offer better pricing to their non-U.S. clients, which would give them a competitive advantage relative to those CSEs that are not eligible for the Exclusion (*e.g.,* U.S. CSEs, non-U.S. CSEs whose obligations under the relevant swap are not guaranteed by a U.S. person, or Foreign Consolidated Subsidiaries). However, whether these competitive effects occur will also depend on whether the relevant foreign jurisdiction has comparable margin rules. In addition, non-U.S. CSEs that are eligible for the Exclusion could be in a better position to compete with non-CFTC registered dealers in the relevant foreign jurisdiction for foreign clients.

As noted above, at this time, given that foreign jurisdictions do not yet have in place their margin regimes, it is not possible to fully evaluate the Proposed Rule's eventual implications for the safety and soundness of CSEs and competition. Assuming, however, for the sake of analysis that the relevant foreign jurisdiction does not have comparable margin requirements, the Commission preliminarily believes that the Exclusion would not result in a significant diminution in the safety and soundness of the non-U.S. CSE, as discussed in section II.C.3. above. This is based on several considerations. First, the potential adverse effect on a non-U.S. CSE would be substantially mitigated by the Commission's capital requirements.[114] Additionally, any excluded swaps would most likely be covered by another jurisdiction that adheres to the BCBS–IOSCO standards because the Commission believes that most swaps are currently undertaken in jurisdictions that already have agreed to adhere to the BCBS–IOSCO margin standards.

Further, a non-U.S. CSE that can avail itself of the Exclusion would still be subject to the Commission's margin rules with respect to all uncleared swaps not meeting the criteria for the Exclusion, albeit with the possibility of substituted compliance. The Commission further believes that the possibility of a cascading event affecting U.S. counterparties and the U.S. financial markets more broadly as a result of a default by the non-U.S. CSE would also be mitigated because the non-U.S. CSE would be subject to U.S. margin requirements (with the possibility of substituted compliance to the extent applicable) when entering into a swap with U.S. counterparties.

iv. Foreign Consolidated Subsidiaries

Under the Proposed Rule, substituted compliance is more broadly available to a Foreign Consolidated Subsidiary whose obligations under the relevant swap are not guaranteed by a U.S. person than a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person. Further, a Foreign Consolidated Subsidiary would be able to avail itself of substituted compliance to the same extent as other non-U.S. CSEs, but would not be eligible for the Exclusion. A Foreign Consolidated Subsidiary's financial position, operating results, and statement of cash flows are directly reflected in its ultimate U.S. parent entity's financial statements. Given the nature of a Foreign Consolidated Subsidiary's direct relationship to a U.S. person, the Commission believes that the uncleared swaps of Foreign Consolidated Subsidiaries should not be excluded from the margin requirements, as discussed in section II.C.3. above.

The unavailability of the Exclusion could disadvantage Foreign Consolidated Subsidiaries relative to other non-U.S. CSEs that would be eligible for the Exclusion (*i.e.,* non-U.S. CSEs where neither counterparty's obligations under the relevant swap are guaranteed by a U.S. person and neither counterparty is a Foreign Consolidated Subsidiary nor a U.S. branch of a non-U.S. CSE) or non-CFTC registered dealers within a foreign jurisdiction. Non-U.S. CSEs that rely on the Exclusion or non-CFTC registered dealers could realize a cost advantage over Foreign Consolidated Subsidiaries and thus have the potential to offer better pricing terms to foreign clients. The competitive disparity between non-U.S. CSEs that rely on the Exclusion and Foreign Consolidated Subsidiaries, however, may be somewhat mitigated to the extent that the relevant foreign jurisdiction implements the BCBS–IOSCO framework.

v. U.S. Branch of a Non-U.S. CSE

Under the Proposed Rule, the Exclusion from the margin rules would not be available to a U.S. branch of a non-U.S. CSE. The Commission believes that when a non-U.S. CSE conducts its swap activities within the United States through a branch or office located in the United States, it should be subject to U.S. margin requirements, but with the possibility of substituted compliance, consistent with comity principles. The Commission believes that the Proposed Rule's Exclusion should not be available in this case, because U.S. branches of non-U.S. CSEs are operating within the

the Commission's margin requirements generally in the context of cross-border transactions.

[113] Section 4s(e)(3)(A) of the CEA, 7 U.S.C. 6s(e)(3)(A). The section provides, among other things, that margin requirements ''be appropriate for the risks associated with the non-cleared swaps held as a swap dealer or major market participant.''

[114] *See* section II.A.1.

U.S. market and competing with U.S. CSEs for business, including from non-U.S. counterparties.

If a U.S. branch of a non-U.S. CSE were permitted to use the Exclusion it could be able to offer more competitive terms to non-U.S. clients than U.S. CSEs, and thereby gain an unwarranted advantage when dealing with non-U.S. clients relative to other CSEs operating within the United States (*i.e.,* U.S. CSEs). On the other hand, for the same reason, the Proposed Rule could put non-U.S. CSEs that conduct swaps business through their U.S. branches at a disadvantage relative to either non-U.S. CSEs that are eligible for the Exclusion or non-CFTC registered dealers that conduct swaps business overseas. However, to the extent that the U.S. branch of a non-U.S. CSE is able to rely on substituted compliance, the competitive disparities relative to those non-U.S. CSEs that are eligible for the Exclusion should be reduced to the extent that the relevant foreign jurisdiction implements BCBS–IOSCO framework standards.[115]

The unavailability of the Exclusion could also result in the U.S. branch of a non-U.S. CSE being subject to conflicting or duplicative margin requirements. However, the Commission believes that overall any resulting costs may not be significant to the extent that the U.S. branch is able to avail itself of substituted compliance in that jurisdiction.

c. Alternatives

The Commission believes that the Proposed Rule effectively addresses the risk posed to the safety and soundness of CSEs, while creating a workable framework that reduces the potential for undue market disruptions and promotes global harmonization by taking into account the interests of other jurisdictions and balancing those interests with the supervisory interests of the United States.

The Commission has determined not to propose the Guidance Approach because it believes that if the Guidance Approach were adopted, too many swaps would be excluded from the margin rules to ensure the safety and soundness of CSEs and the U.S. financial system. In particular, under the Guidance Approach, uncleared swaps between a non-U.S. CSE and a non-U.S. person whose uncleared swap obligations are not guaranteed by a U.S. person would be excluded from the Commission's margin rules without regard to whether the non-U.S CSE is guaranteed or its financial statements are consolidated with a U.S. parent entity under U.S. generally accepted accounting principles.

The Commission has also determined not to propose the Entity-Level Approach. On the one hand, the Entity-Level Approach (where the margin requirements would apply to all uncleared swaps of a CSE, with no possibility of any exclusion) is arguably appropriate because margin requirements are critical in ensuring the safety and soundness of a CSE and in supporting the stability of the U.S. financial markets. As a result of CSEs engaging in a level of uncleared swap activity that is significant enough to warrant U.S. registration, their uncleared swaps have a direct and significant nexus to the U.S. financial system, irrespective of whether their counterparty is a U.S. or non-U.S. entity. However, the Commission believes that the Entity-Level Approach does not adequately consider the relative supervisory interests of U.S. and foreign regulators.

d. Comparability Determinations

As noted in section II.D. above, any CSE who is eligible for substituted compliance may make a request for a comparability determination. Currently, there are approximately 102 CSEs provisionally registered with the Commission. The Commission further estimates that of the 102 CSEs that are registered, approximately 61 CSEs would be subject to the Commission's margin rules, as they are not supervised by a Prudential Regulator. However, the Commission notes that any foreign regulatory agency that has direct supervisory authority to administer the foreign regulatory framework for margin of uncleared swaps in the requested foreign jurisdiction may apply for a comparability determination. Further, once a comparability determination is made for a jurisdiction, it would apply for all entities or transactions in that jurisdiction to the extent provided in the determination, as approved by the Commission.

The Commission assumes that a CSE or foreign regulatory agency will apply for a comparability determination only if the anticipated benefits warrant the costs attendant to submission of a request for a comparability determination. Although there is uncertainty regarding the number of requests that would be made under the Proposed Rule, the Commission estimates that it would receive applications for comparability determinations from 17 jurisdictions representing 61 separate registrants, and that each request would impose an average of 10 burden hours per registrant.[116]

Based upon the above, the Commission estimates that the preparation and filing of submission requests for comparability determinations should take no more than 170 hours annually in the aggregate (17 registrants × 10 hours). The Commission further estimates that the total aggregate cost of preparing such submission requests would be $64,600, based on an estimated cost of $380 per hour for an in-house attorney.[117]

3. Section 15(a) Factors

As discussed above, the Proposed Rule is intended to apply the Proposed Margin Rules on a cross-border basis in a manner that effectively addresses risks to U.S. persons and the U.S. financial system, while mitigating the potential for conflicts and duplications that could lead to market distortions and undue competitive disparities. The discussion that follows supplements the related cost and benefit considerations addressed in the preceding section and addresses the overall effect of the Proposed Rule in terms of the factors set forth in section 15(a) of the CEA.

a. Protection of Market Participants and the Public

CEA section 15(a)(2)(A) requires the Commission to evaluate the costs and benefits of a proposed regulation in light of considerations of protection of market participants and the public. CEA section 4s(e)(2)(A) requires the Commission to develop rules designed to ensure the safety and soundness of CSEs and the U.S. financial system. In developing the Proposed Rule, the Commission's primary focus was on the relationship or trade-offs between the benefits associated with applying the Commission's margin requirement and the costs associated with extending substituted compliance or the

[115] Non-U.S. CSEs are also likely to conduct swaps business with U.S. clients from locations outside the United States; nevertheless, U.S. branches are likely to have greater U.S. client-orientation relative to such foreign operations.

[116] *See* note 99, *supra.*

[117] Although different registrants may choose to staff preparation of the comparability determination request with different personnel, Commission staff estimates that, on average, an initial request could be prepared and submitted with 10 hours of an in-house attorney's time. To estimate the hourly cost of an in-house attorney's attorney time, Commission staff reviewed data in SIFMA's Report on *Management and Professional Earnings in the Securities Industry 2013,* modified by Commission staff to account for an 1800-hour work-year and multiplied by a factor of 5.35 to account for firm size, employee benefits and overhead. Commission staff believes that use of a 5.35 multiplier here is appropriate because some persons may retain outside advisors to assist in making the determinations under the rules.

Exclusion. On the one hand, full application of the Commission's margin requirements would help to ensure the safety and soundness of CSEs and the U.S. financial system by reducing counterparty credit risk and the threat of contagion; on the other hand, extending substituted compliance or the Exclusion to CSEs would reduce the potential for conflicting or duplicative requirements, which would, in turn, reduce market distortions and promote global harmonization. Substituted compliance in particular should not reduce the safety and soundness benefit of the Proposed Rule because substituted compliance will not be available unless the Commission determines that foreign margin regulations are comparable to the Commission's margin regulations. Granting the Exclusion to certain CSEs should not significantly undermine these purposes, because other requirements and circumstances discussed above should mitigate the risk those CSEs pose to the U.S. financial system.

b. Efficiency, Competitiveness, and Financial Integrity

CEA section 15(a)(2)(B) requires the Commission to evaluate the costs and benefits of a proposed regulation in light of efficiency, competitiveness and financial integrity considerations.

i. Efficiency

The availability of substituted compliance to CSEs following comparable margin requirements in a foreign jurisdiction may incentivize global implementation of the BCBS–IOSCO framework. Greater harmonization across markets lessens the potential for conflicting or duplicative requirements, which, in turn, would promote greater operational efficiencies as a CSE would be able to avoid creating individualized compliance and operational infrastructures to account for the unique requirements of each jurisdiction in which it conducts swaps business. Also, to the extent that margin regimes across jurisdictions are comparable, substituted compliance should help to mitigate regulatory arbitrage.

ii. Competitiveness

Under the Proposed Rule, the availability of substituted compliance would turn primarily on the nature of the non-U.S. CSE's relationship to a U.S. person and the national status of the non-U.S. CSE's counterparty. For example, in the case of a non-U.S. CSE whose swap obligations are not guaranteed by a U.S. person, substituted compliance would be available for any swap with a counterparty that is not a U.S. CSE or a non-U.S. CSE whose swap obligations are guaranteed by a U.S. person. Further, under the Proposed Rule, an uncleared swap entered into by a non-U.S. CSE with a non-U.S. person counterparty (including a non-U.S. CSE) would be excluded from the Commission's margin rules, provided that neither counterparty's obligations under the relevant swap are guaranteed by a U.S. person and neither counterparty is a Foreign Consolidated Subsidiary nor a U.S. branch of a non-U.S. CSE.

The availability of substituted compliance and/or the Exclusion could create competitive disparities between those CSEs that are eligible for substituted compliance and/or the Exclusion relative to those that are not eligible. In addition, as the Exclusion is not provided to all CSEs, those that are not permitted to use the Exclusion may be at a competitive disadvantage when competing in foreign jurisdictions that do not have comparable margin rules to that of the Commission relative to non-CFTC registered dealers for foreign clients.[118] Because the Proposed Rule offers to U.S. CSEs (and non-U.S. CSEs with respect to swaps whose obligations are guaranteed by a U.S. person) only a minimal degree of substituted compliance and no Exclusion, these CSEs may be particularly impacted. As discussed in section II.C.1., however, the Commission believes that the Proposed Margin Rules should apply to the maximum degree to such CSEs in order to ensure the safety and soundness of U.S. CSEs (and U.S. guarantor) and the U.S. financial system. Furthermore, to the extent that that a relevant foreign jurisdiction's margin rules are comparable to that of the Commission's margin rules, such competitive disparities could be reduced.

iii. Financial Integrity of Markets

The safety and soundness of CSEs are critical to the financial integrity of markets. Further, as discussed in section II.A. above, margin serves as a first line of defense to protect a CSE as a whole in the event of a default by a counterparty. Together with capital, margin represents a key element in a CSE's overall risk management program, which ultimately mitigates the possibility of a systemic event.

At the same time, the Commission recognizes that a CSE's uncleared swaps with a particular counterparty may implicate the supervisory interests of foreign regulators, and it is important to calibrate the cross-border application of the margin requirements to mitigate, to the extent possible, consistent with the Commission's regulatory interests, the potential for conflict or duplication with other jurisdictions. Therefore, the Proposed Rule also allows for substituted compliance and an Exclusion in certain circumstances.

The Commission believes that the Proposed Rule strikes the right balance between the two competing considerations to ensure that substituted compliance and the Exclusion are not extended in a way that could pose substantial risk to the integrity of the U.S. financial system. Substituted compliance is predicated on the Commission's determination that the relevant foreign jurisdiction has comparable margin rules; if the Commission does not find a foreign jurisdiction's rules comparable, the CSE would then need to comply with the Commission's rules. Even in instances where the Exclusion would be available, the Commission has taken into account that the risk to the integrity of the financial markets would be mitigated by the Commission's expectation that: (1) The Proposed Margin Rules would cover many of the swaps of the non-U.S. CSEs (eligible for the Exclusion) with other counterparties, namely, all U.S. counterparties; (2) the Exclusion would be limited to a narrow set of swaps by non-U.S. CSEs; (3) the capital requirements would apply on an entity-level basis to all CSEs; and (4) the excluded swaps will most likely be covered by another foreign regulator's margin rules that are based on the BCBS–IOSCO framework.

c. Price Discovery

CEA section 15(a)(2)(C) requires the Commission to evaluate the costs and benefits of a proposed regulation in light of price discovery considerations. The Commission generally believes that substituted compliance, by reducing the potential for conflicting or duplicative regulations, could reduce impediments to transact uncleared swaps on a cross-border basis. This, in turn, may enhance liquidity as more market participants would be willing to enter into uncleared swaps, thereby possibly improving price discovery—and ultimately reducing market fragmentation. Alternatively, if substituted compliance or the Exclusion were not made available, it would

[118] The Commission notes, however, that of the approximately 61 CSEs that would be subject to the Commission's margin rules, 21 are non-U.S. CSEs. Of those 21 non-U.S. CSEs, 20 are domiciled in jurisdictions that participated in the development of the BCBS–IOSCO framework, which may mitigate possible regulatory arbitrage between these dealers.

incentivize CSEs to consider setting up their swap operations outside the Commission's jurisdiction, and as a result, increase the potential for market fragmentation.

d. Sound Risk Management Practices

CEA section 15(a)(2)(D) requires the Commission to evaluate the costs and benefits of a proposed regulation in light of sound risk management practices. Margin is a critical element of a firm's sound risk management program that, among other things, can prevent the accumulation of counterparty credit risk. As international regulators and the Commission harmonize their margin regulations for uncleared swaps, market participants may be able to manage their risk more effectively on an enterprise-wide basis. On the other hand, to the extent that a CSE relies on the Exclusion for eligible swaps and the relevant foreign jurisdiction does not have comparable margin requirements, the Proposed Rule could lead to weaker risk management practices.

e. Other Public Interest Considerations

CEA section 15(a)(2)(E) requires the Commission to evaluate the costs and benefits of a proposed regulation in light of other public interest considerations. The Commission has not identified any additional public interest considerations related to the costs and benefits of the Proposed Rule.

4. General Request for Comment

The Commission requests comment on all aspects of the costs and benefits relating to the cross-border application of the Proposed Rule, including the nature and extent of the costs and benefits discussed above and any other costs and benefits that could result from adoption of the Proposed Rule. Commenters are encouraged to discuss the costs and benefits to U.S. CSEs and non-U.S. CSEs covered by the Proposed Rule, as well as any costs and benefits to other market participants, the swap markets, or the general public, and to the extent such costs and benefits can be quantified, monetary and other estimates thereof. The Commission requests that commenters provide any data or other information that would be useful in estimating the quantifiable costs and benefits of this rulemaking. Among other things, commenters may wish to submit comments on the following questions:

1. Are the Commission's assumptions about the costs and benefits of the Proposed Rule accurate? If not, please explain and provide any data or other information that you have quantifying or qualifying the costs and benefits of the Proposed Rule.

2. Did the Commission consider all of the appropriate costs and benefits related to the Proposed Rule? If not, what additional costs and benefits should the Commission consider? Please explain why these additional costs and benefits should be considered and provide any data or other information that you have quantifying or qualifying the costs and benefits of these additional costs of the Proposed Rule.

3. Please provide any data or other information relating to costs associated with the definition of ''U.S. person'' in the Proposed Rule, and in particular, as the proposed definition relates to the definition of ''U.S. person'' that was included in the Guidance.

4. Will allowing substituted compliance or the Exclusion for swaps between certain categories of non-U.S. persons lead to fragmentation (*e.g.,* creating separate or multiple swap markets) of the liquidity in swaps markets for uncleared swaps to the detriment of price discovery? Is swap market fragmentation detrimental to various market participants when there is post-trade price transparency of swaps? Commenters are encouraged to quantify when practicable. Does the Proposed Rule have any significant effects on price discovery? Indeed, to what extent are the impacts on price discovery the result of other requirements, such as the margin for uncleared swaps or the trade execution mandate, and not the Proposed Rule per se?

List of Subjects in 17 CFR Part 23

Swaps, Swap dealers, Major swap participants, Capital and margin requirements.

For the reasons discussed in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR chapter I as set forth below:

PART 23—SWAP DEALERS AND MAJOR SWAP PARTICIPANTS

■ 1. The authority citation for part 23 is revised to read as follows:

Authority: 7 U.S.C. 1a, 2, 6, 6a, 6b, 6b-1, 6c, 6p, 6r, 6s, 6t, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21.

Section 23.160 also issued under 7 U.S.C. 2(i); Sec. 721(b), Pub. L. 111–203, 124 Stat. 1641 (2010).

■ 2. Add subpart E to part 23 to read as follows:

Subpart E—Capital and Margin Requirements for Swap Dealers and Major Swap Participants

Sec.

23.100–23.149 [Reserved]
23.150–23.159 [Reserved]
23.160 Cross-border application.
23.161–23.199 [Reserved]

Subpart E—Capital and Margin Requirements for Swap Dealers and Major Swap Participants

§§ 23.100–23.149 [Reserved]

§§ 23.150–23.159 [Reserved]

§ 23.160 Cross-border application.

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

(1) *Foreign Consolidated Subsidiary* means a non-U.S. CSE in which an ultimate parent entity that is a U.S. person has a controlling financial interest, in accordance with U.S. GAAP, such that the U.S. ultimate parent entity includes the non-U.S. CSE's operating results, financial position and statement of cash flows in the U.S. ultimate parent entity's consolidated financial statements, in accordance with U.S. GAAP.

(2) *Guarantee* means an arrangement pursuant to which one party to a swap transaction with a non-U.S. person counterparty has rights of recourse against a U.S. person, with respect to the non-U.S. person counterparty's obligations under the swap transaction. For these purposes, a party to a swap transaction has rights of recourse against a U.S. person if the party has a conditional or unconditional legally enforceable right to receive or otherwise collect, in whole or in part, payments from the U.S. person in connection with the non-U.S. person counterparty's obligations under the swap.

(3) *International standards* means the margin policy framework for non-cleared, bilateral derivatives issued by the Basel Committee on Banking Supervision and the International Organization of Securities in September 2013, as subsequently updated, revised, or otherwise amended, or any other international standards, principles or guidance relating to margin requirements for non-cleared, bilateral derivatives that the Commission may in the future recognize, to the extent that they are consistent with United States law (including the margin requirements in the Commodity Exchange Act).

(4) *Non-U.S. CSE* means a covered swap entity that is not a U.S. person. The term ''non-U.S. CSE'' includes a ''Foreign Consolidated Subsidiary'' or a U.S. branch of a non-U.S. CSE.

(5) *Non-U.S. person* means any person that is not a U.S. person.

(6) *Ultimate parent entity* means the parent entity in a consolidated group in which none of the other entities in the

consolidated group has a controlling interest, in accordance with U.S. GAAP.

(7) *United States* means the United States of America, its territories and possessions, any State of the United States, and the District of Columbia.

(8) *U.S. CSE* means a covered swap entity that is a U.S. person.

(9) *U.S. GAAP* means U.S. generally accepted accounting principles.

(10) *U.S. person* means:

(i) A natural person who is a resident of the United States;

(ii) An estate of a decedent who was a resident of the United States at the time of death;

(iii) A corporation, partnership, limited liability company, business or other trust, association, joint-stock company, fund or any form of entity similar to any of the foregoing (other than an entity described in paragraph (a)(10)(iv) or (v) of this section) (a ''legal entity''), in each case that is organized or incorporated under the laws of the United States or having its principal place of business in the United States, including any branch of such legal entity;

(iv) A pension plan for the employees, officers or principals of a legal entity described in paragraph (a)(10)(iii) of this section, unless the pension plan is primarily for foreign employees of such entity;

(v) A trust governed by the laws of a state or other jurisdiction in the United States, if a court within the United States is able to exercise primary supervision over the administration of the trust;

(vi) A legal entity (other than a limited liability company, limited liability partnership or similar entity where all of the owners of the entity have limited liability) that is owned by one or more persons described in paragraphs (a)(10)(i) through (v) of this section and for which such person(s) bears unlimited responsibility for the obligations and liabilities of the legal entity, including any branch of the legal entity; or

(vii) An individual account or joint account (discretionary or not) where the beneficial owner (or one of the beneficial owners in the case of a joint account) is a person described in paragraphs (a)(10)(i) through (vi) of this section.

(b) *Applicability of margin requirements*—(1) *Uncleared swaps of U.S. CSEs or Non-U.S. CSEs whose obligations under the relevant swap are guaranteed by a U.S. person*—(i) *Applicability of U.S. margin requirements; availability of substituted compliance for requirement to post initial margin.* With respect to each uncleared swap entered into by a U.S. CSE or a non-U.S. CSE whose obligations under the swap are guaranteed by a U.S. person, the U.S. CSE or non-U.S. CSE whose obligations under the swap are guaranteed by a U.S. person shall comply with the requirements of §§ 23.150 through 23.159, provided that the U.S. CSE or non-U.S. CSE whose obligations under the swap are guaranteed by a U.S. person may satisfy its requirement to post initial margin to certain counterparties to the extent provided in paragraph (b)(1)(ii) of this section.

(ii) *Compliance with foreign initial margin collection requirement.* A covered swap entity that is covered by paragraph (b)(1)(i) of this section may satisfy its requirement to post initial margin under this part by posting initial margin in the form and amount, and at such times, that its counterparty is required to collect initial margin pursuant to a foreign jurisdiction's margin requirements, but only to the extent that:

(A) The counterparty is neither a U.S. person nor a non-U.S. person whose obligations under the relevant swap are guaranteed by a U.S. person;

(B) The counterparty is subject to such foreign jurisdiction's margin requirements; and

(C) The Commission has issued a comparability determination under paragraph (c) of this section (''Comparability Determination'') with respect to such foreign jurisdiction's requirements regarding the posting of initial margin by the covered swap entity (that is covered in paragraph (b)(1) of this section).

(2) *Uncleared swaps of Non-U.S. CSEs whose obligations under the relevant swap are not guaranteed by a U.S. person*—(i) *Applicability of U.S. margin requirements except where an exclusion applies; Availability of substituted compliance.* With respect to each uncleared swap entered into by a non-U.S. CSE whose obligations under the relevant swap are not guaranteed by a U.S. person, the non-U.S. CSE shall comply with the requirements of §§ 23.150 through 23.159 except to the extent that an exclusion is available under paragraph (b)(2)(ii) of this section, provided that a non-U.S. CSE whose obligations under the relevant swap are not guaranteed by a U.S. person may satisfy its margin requirements under this part to the extent provided in paragraphs (b)(2)(iii) and (iv) of this section.

(ii) *Exclusion.* A non-U.S. CSE shall not be required to comply with the requirements of §§ 23.150 through 23.159 with respect to each uncleared swap it enters into to the extent:

(A) The non-U.S. CSE's obligations under the relevant swap are not guaranteed by a U.S. person;

(B) The non-U.S. CSE is not a U.S. branch of a non-U.S. CSE; and

(C) The non-U.S. CSE is not a Foreign Consolidated Subsidiary with a non-U.S. person counterparty (excluding a Foreign Consolidated Subsidiary or the U.S. branch of a non-U.S. CSE), whose obligations under the relevant swap are not guaranteed by a U.S. person.

(iii) *Availability of substituted compliance where the counterparty is not a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person.* Except to the extent that an exclusion is available under paragraph (b)(2)(ii) of this section, with respect to each uncleared swap entered into by a non-U.S. CSE whose obligations under the relevant swap are not guaranteed by a U.S. person with a counterparty (except where the counterparty is either a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person), the non-U.S. CSE whose obligations under the relevant swap are not guaranteed by a U.S. person may satisfy margin requirements under this part by complying with the margin requirements of a foreign jurisdiction to which such non-U.S. CSE (whose obligations under the relevant swap are not guaranteed by a U.S. person) is subject, but only to the extent that the Commission has issued a Comparability Determination under paragraph (c) of this section for such foreign jurisdiction.

(iv) *Availability of substituted compliance where the counterparty is a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person.* With respect to each uncleared swap entered into by a non-U.S. CSE whose obligations under the relevant swap are not guaranteed by a U.S. person with a counterparty that is a U.S. CSE or a non-U.S. CSE whose obligations under the relevant swap are guaranteed by a U.S. person, the non-U.S. CSE (whose obligations under the relevant swap are not guaranteed by a U.S. person) may satisfy its requirement to collect initial margin under this part by collecting initial margin in the form and amount, and at such times and under such arrangements, that the non-U.S. CSE (whose obligations under the relevant swap are not guaranteed by a U.S. Person) is required to collect initial margin pursuant to a foreign jurisdiction's margin requirements, provided that:

(A) The non-U.S. CSE (whose obligations under the relevant swap are not guaranteed by a U.S. person) is subject to the foreign jurisdiction's regulatory requirements; and

(B) The Commission has issued a Comparability Determination with respect to such foreign jurisdiction's margin requirements.

(c) *Comparability determinations*—(1) *Eligibility requirements.* The following persons may, either individually or collectively, request a Comparability Determination with respect to some or all of the Commission's margin requirements:

(i) A covered swap entity that is eligible for substituted compliance under this section; or

(ii) A foreign regulatory authority that has direct supervisory authority over one or more covered swap entities and that is responsible for administering the relevant foreign jurisdiction's margin requirements.

(2) *Submission requirements.* Persons requesting a Comparability Determination should provide the Commission (either by hard copy or electronically):

(i) A description of the objectives of the relevant foreign jurisdiction's margin requirements;

(ii) A description of how the relevant foreign jurisdiction's margin requirements address, at minimum, each of the following elements of the Commission's margin requirements. Such description should identify the specific legal and regulatory provisions that correspond to each element and, if necessary, whether the relevant foreign jurisdiction's margin requirements do not address a particular element:

(A) The transactions subject to the foreign jurisdiction's margin requirements;

(B) The entities subject to the foreign jurisdiction's margin requirements;

(C) The methodologies for calculating the amounts of initial and variation margin;

(D) The process and standards for approving models for calculating initial and variation margin models;

(E) The timing and manner in which initial and variation margin must be collected and/or paid;

(F) Any threshold levels or amounts;

(G) Risk management controls for the calculation of initial and variation margin;

(H) Eligible collateral for initial and variation margin;

(I) The requirements of custodial arrangements, including rehypothecation and the segregation of margin;

(J) Documentation requirements relating to margin; and

(K) The cross-border application of the foreign jurisdiction's margin regime.

(iii) A description of the differences between the relevant foreign jurisdiction's margin requirements and the International Standards;

(iv) A description of the ability of the relevant foreign regulatory authority or authorities to supervise and enforce compliance with the relevant foreign jurisdiction's margin requirements. Such description should discuss the powers of the foreign regulatory authority or authorities to supervise, investigate, and discipline entities for compliance with the margin requirements and the ongoing efforts of the regulatory authority or authorities to detect, deter, and ensure compliance with the margin requirements; and

(v) Copies of the foreign jurisdiction's margin requirements (including an English translation of any foreign language document);

(vi) Any other information and documentation that the Commission deems appropriate.

(3) *Standard of review.* The Commission will issue a Comparability Determination to the extent that it determines that some or all of the relevant foreign jurisdiction's margin requirements are comparable to the Commission's corresponding margin requirements. In determining whether the requirements are comparable, the Commission will consider all relevant factors, including:

(i) The scope and objectives of the relevant foreign jurisdiction's margin requirements;

(ii) How the relevant foreign jurisdiction's margin requirements compare to the International Standards;

(iii) Whether the relevant foreign jurisdiction's margin requirements achieve comparable outcomes to the Commission's corresponding margin requirements;

(iv) The ability of the relevant regulatory authority or authorities to supervise and enforce compliance with the relevant foreign jurisdiction's margin requirements; and

(v) Any other facts and circumstances the Commission deems relevant.

(4) *Reliance.* Any covered swap entity that, in accordance with a Comparability Determination, complies with a foreign jurisdiction's margin requirements would be deemed to be in compliance with the Commission's corresponding margin requirements. Accordingly, the failure of such a covered swap entity to comply with the foreign jurisdiction's margin requirements may constitute a violation of the Commission's margin requirements. All covered swap entities, regardless of whether they rely on a Comparability Determination, remain subject to the Commission's examination and enforcement authority.

(5) *Conditions.* In issuing a Comparability Determination, the Commission may impose any terms and conditions it deems appropriate. The violation of such terms and conditions may constitute a violation of the Commission's margin requirements and/or result in the modification or revocation of the Comparability Determination.

(6) *Modifications.* The Commission reserves the right to further condition, modify, suspend, terminate or otherwise restrict a Comparability Determination in the Commission's discretion.

(7) *Delegation of authority.* The Commission hereby delegates to the Director of the Division of Swap Dealer and Intermediary Oversight, or such other employee or employees as the Director may designate from time to time, the authority to request information and/or documentation in connection with the Commission's issuance of a Comparability Determination.

§§ 23.161—23.199 [Reserved]

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

TABLE A—APPLICATION OF THE PROPOSED RULE [1 2 3]

CSE	Counterparty	Proposed approach
U.S. CSE or Non-U.S. CSE (including U.S. branch of a non-U.S. CSE and a Foreign Consolidated Subsidiary ("FCS")) whose obligations under the relevant swap *are* guaranteed by a U.S. person.	• U.S. person (including U.S. CSE). • Non-U.S. person (including non-U.S. CSE, FCS, and U.S. branch of a non-U.S. CSE) whose obligations under the relevant swap are guaranteed by a U.S. person.	U.S. (All).

TABLE A—APPLICATION OF THE PROPOSED RULE [1] [2] [3]—Continued

CSE	Counterparty	Proposed approach
	• Non-U.S. person (including non-U.S. CSE, FCS and U.S. branch of a non-U.S. CSE) whose obligations under the relevant swap are not guaranteed by a U.S. person.	U.S. (Initial Margin collected by CSE in column 1). Substituted Compliance (Initial Margin posted by CSE in column 1). U.S. (Variation Margin).
FCS whose obligations under the relevant swap *are not* guaranteed by a U.S. person or U.S. branch of a non-U.S. CSE whose obligations under the relevant swap *are not* guaranteed by a U.S. person.	• U.S. CSE. • Non-U.S. CSE (including U.S. branch of a non-U.S. CSE and FCS) whose obligations under the relevant swap are guaranteed by a U.S. person. • U.S. person (except as noted above for a CSE). • Non-U.S. person whose obligations under the swap are guaranteed by a U.S. person (except a non-U.S. CSE, U.S. branch of a non-U.S. CSE, and FCS whose obligations are guaranteed, as noted above). • Non-U.S. person (including non-U.S. CSE, U.S. branch of a non-U.S. CSE, and a FCS) whose obligations under the relevant swap are not guaranteed by a U.S. person.	U.S. (Initial Margin posted by CSE in column 1). Substituted Compliance (Initial Margin collected by CSE in column 1). U.S. (Variation Margin). Substituted Compliance (All).
Non-U.S. CSE (that is not a FCS or a U.S. branch of a non-U.S. CSE) whose obligations under the relevant swap *are not* guaranteed by a U.S. person.	• U.S. CSE. • Non-U.S. CSE (including U.S. branch of a non-U.S. CSE and FCS) whose obligations under the swap are guaranteed by a U.S. person. • U.S. person (except as noted above for a CSE). • Non-U.S. person whose obligations under the swap are guaranteed by a U.S. person (except a non-U.S. CSE whose obligations are guaranteed, as noted above). • U.S. branch of a Non-U.S. CSE or FCS, in each case whose obligations under the relevant swap are not guaranteed by a U.S. person.	U.S. (Initial Margin posted by CSE in column 1). Substituted Compliance (Initial Margin collected by CSE in column 1). U.S. (Variation Margin). Substituted Compliance (All).
	• Non-U.S. person (including a non-U.S. CSE, but not a FCS or a U.S. branch of a non-U.S. CSE) whose obligations under the relevant swap are not guaranteed by a U.S. person.	Excluded.

[1] This table should be read in conjunction with the rest of the preamble and the text of the Proposed Rule.

[2] The term "U.S. person" is defined in § 23.160(a)(10) of the Proposed Rule. A "non-U.S. person" is any person that is not a "U.S. person." The term swap means an uncleared swap and is defined in § 23.151 of the Proposed Margin Rules. *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 79 FR 59898 (Oct. 3, 2014).

[3] As used in this table, the term "Foreign Consolidated Subsidiary" or "FCS" refers to a non-U.S. CSE in which an ultimate parent entity that is a U.S. person has a controlling financial interest, in accordance with U.S. GAAP, such that the U.S. ultimate parent entity includes the non-U.S. CSE's operating results, financial position and statement of cash flows in the U.S. ultimate parent entity's consolidated financial statements, in accordance with U.S. GAAP. The term "ultimate parent entity" means the parent entity in a consolidated group in which none of the other entities in the consolidated group has a controlling interest, in accordance with U.S. GAAP.

Issued in Washington, DC, on July 2, 2015, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

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

Appendices to Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants—Cross-Border Application of the Margin Requirements—Commission Voting Summary, Chairman's Statement, and Commissioners' Statements

Appendix 1—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Wetjen, Bowen, and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Statement of Chairman Timothy G. Massad

Today the Commission voted unanimously to issue a proposal on the cross-border application of our previously proposed rules on margin for uncleared swaps. I thank my fellow Commissioners for their work and input on this proposal, and I also want to thank our staff for their hard work.

The proposed rule on margin for uncleared swaps, which we issued last fall, is one of the most important rules for the regulation of the over-the-counter swaps market.

That is because there will always be a large part of the swaps market that is not cleared through central counterparties. Although we are mandating clearing for certain swaps, we should not mandate clearing for all swaps. Some products are not appropriate for such

a mandate because of their risk or liquidity characteristics.

Margin can be an effective tool for addressing counterparty credit risk arising from uncleared swaps. Our rule will make sure that registered swap dealers post and collect margin in their transactions with other registered swap dealers and financial institutions that are above certain thresholds. That helps lower the risk to the financial system and the overall economy. I also note that the requirements do not apply to commercial end users.

We saw what happened in 2008 when there was a build-up of excessive risk in bilateral swaps. That risk intensified and accelerated the financial crisis like gasoline poured on a fire. And that crisis cost our economy eight million jobs and untold suffering for American families.

Moreover, we saw how that risk could be created offshore, outside our borders, but still jeopardize our financial stability and our economy.

The excessive swap risk taken on by AIG was initiated from its overseas operation. In order to prevent the failure of AIG, our government had to commit over $180 billion.

We got all that money back, but that is a painful example of why the cross-border application of the margin rule is important.

The proposal we are issuing today addresses the possibility that risk created offshore can flow back into the U.S. And so it applies to activities of non-U.S. swap dealers that are registered with us. At the same time, our proposal recognizes the importance of harmonizing rules with other jurisdictions.

If a transaction by an offshore swap dealer is guaranteed by a U.S. person, such as the parent of the dealer, the risk of that transaction can flow back into the U.S. But the same can occur even if the transaction is not guaranteed by the U.S. parent. Our proposal addresses that. By doing so, I believe our proposal is a good way to address the risk that can arise from uncleared swaps in that situation.

The proposal draws a line as to when we should take this offshore risk into account that is both reasonable and clear. The line we are proposing is this: If the financial results and position of the non-U.S. swap dealer are consolidated in the financial statements of the U.S. parent, then we should take that into account, whether or not there is an explicit guarantee.

This is how the proposal works: U.S. swap dealers would be required to comply with the rule in all their transactions, but in their transactions with certain non-U.S. counterparties, they would be entitled to substituted compliance with respect to margin they post, but not the margin they collect. Non-U.S. swap dealers whose swap obligations are guaranteed by a U.S. person would be treated the same way. Substituted compliance would be available in the case of the laws of those jurisdictions which we have deemed comparable.

For non-U.S. swap dealers registered with us, whose obligations are not guaranteed by a U.S. person, they must still comply, but they would be entitled to substituted compliance to a greater extent. Generally, they could avail themselves of full substituted compliance unless the counterparty was a U.S. swap dealer or a swap dealer guaranteed by a U.S. person. And, transactions between a non-U.S. swap dealer (but not conducted through its U.S. branch) and a non-U.S. counterparty would be excluded from the margin rules, if neither party's obligations under the relevant swap are guaranteed by a U.S. person nor consolidated in the financial statements of its U.S. parent.

Limiting the exclusion from our rule to only those transactions where neither party is guaranteed or consolidated with a U.S. person helps address the concern that there is risk to the U.S. even if there is no explicit guarantee.

Lastly, when foreign banks conduct their swaps business within the U.S. through their branches located in the U.S., in direct competition with U.S. swap dealers, the exclusion would not apply. However, U.S. branches would be eligible for substituted compliance, which would reduce the potential for conflicts with foreign jurisdictions.

The broad scope of substituted compliance recognizes that we must work together with other jurisdictions to regulate this market, and we should design our rules to avoid conflict and duplication as much as possible. And the proposal may reduce competitive disparities that would otherwise result from different sets of rules applying to swap dealers engaged in essentially the same activity.

The proposal we are making today is very similar to the approach proposed last fall by the prudential regulators. That is appropriate, because the law requires us and the prudential regulators to harmonize our margin rules as much as possible. It also makes sense when you look at the composition of the registered swap dealers. There are approximately 100 swap dealers registered with us. Approximately 40 of those will be subject to the margin rules of the prudential regulators, while approximately 60 will be subject to our rules. About two thirds of those 60 swap dealers that will be subject to our margin rule have affiliates who will be subject to the margin rules of the prudential regulators. For example, of the approximately 60 swap dealers subject to our margin rules, over half are subsidiaries of just five major U.S. bank holding companies. Each of those large bank holding companies has other subsidiaries that are, subject to the margin rules of the prudential regulators. Therefore, if our margin rules are substantially different from the margin rules of the prudential regulators, then we have created incentives for firms to move activity from one entity to another solely to take advantage of potential differences in the rules. That is an outcome we should try very hard to avoid.

We also wish to coordinate our rules with the margin rules of other jurisdictions. That is why our proposal today provides for substituted compliance. In addition, at my direction, our staff is actively engaged with their counterparts in other jurisdictions to try to harmonize the rules as much as possible. Although much work remains to be done, and the Commission must take final action, I am hopeful that our final rules will be similar on many critical issues to those currently being developed in other major jurisdictions.

I would also like to say a word about our Cross-Border Guidance, which discussed how the Commission would generally apply Dodd-Frank requirements to cross-border swap activities. In doing so, the Commission recognized that the market is complex and dynamic and that a flexible approach is necessary. As stated in the Guidance, ''the Commission will continue to follow developments as foreign regulatory regimes and the global swaps market continue to evolve. In this regard, the Commission will periodically review this Guidance in light of future developments.'' That is essentially what we are doing here. With each area of our rules, the implications of cross-border transactions for our policy objectives may vary. Margin for uncleared swaps is intended to protect the safety and soundness of swap dealers and ultimately, to ensure the stability of the U.S. financial system. Therefore, it is appropriate to take into account whether that risk flows back into the United States by virtue of a guarantee by a U.S. person, or financial consolidation with a U.S. person. But the approach we are proposing today for margin may not be appropriate with respect to other areas of regulation—such as swaps reporting or trading.

In conclusion, I believe the approach we are proposing today combines the best elements of the various approaches proposed last fall. It strikes the right balance between the Commission's supervisory interest in ensuring the safety and soundness of registered swap dealers and the need to recognize principles of international comity and reduce the potential for conflict with foreign regulatory requirements.

Appendix 3—Statement of Commissioner Mark P. Wetjen

Today's release lays out a proposed framework for the application of the Commission's margin rules to un-cleared swaps (the ''Margin Rule'') in cross-border transactions. Interestingly, the release states that there was no consensus among those who filed comments in response to the Commission's Advance Notice of Proposed Rulemaking (''ANPR'') last fall, which laid out three alternative, cross-border approaches: The Guidance Approach, the Prudential Regulators' Approach, and the Entity Approach. To the extent, therefore, that the release was designed to identify a consensus view concerning which of these three approaches was best, it failed.

The comment letters, however, provided a great deal of useful discussion that has aided the Commission's thinking about the extra-territorial application of its rules. Ultimately, the agency was guided by those comments to propose today an approach that is essentially an entity approach, but because of more availability of substituted compliance, appears most similar to the Prudential Regulators' Approach in terms of its practical implementation.

I am comfortable supporting today's release, but for the reasons discussed below,

continue to harbor some doubts as to whether we have selected the approach that best balances the Commission's interests in protecting the financial system and U.S. taxpayers, meeting its statutory mandate to preserve an appropriate competitive landscape for participants in the global swaps market, and adopting policies whose costs to those affected do not exceed their benefits.[1]

The Commission's Responsibilities Regarding the Margin Rule

To begin, it is important to understand the scope of the Commission's responsibilities with respect to implementing and enforcing the Margin Rule. As was made plain by the proposal seeking comment on the Margin Rule released last fall, the rulemaking is one of the most important component parts of the risk-focused requirements under Title VII of Dodd-Frank. The statute divides up responsibilities for implementing and enforcing the Margin Rule among this Commission, the U.S. prudential regulators, and the Securities and Exchange Commission. Those responsibilities are weighty, requiring, among others, the review and approval of margin methodologies submitted by the covered swap entities under each authority's jurisdiction.

As of today, five U.S. bank holding companies regulated by the Board of Governors of the Federal Reserve System (the ''Board'') have 17 U.S. registered swap dealers that would fall exclusively within the CFTC's jurisdiction for margin purposes. These same five U.S. bank holding companies have 15 non-U.S. registered swap dealers that would fall exclusively within the CFTC's jurisdiction for margin purposes (the ''U.S. Foreign-Affiliate Dealers''). That is a total of 32 registered swap dealers that the commission would have to oversee, supervise, and enforce compliance with respect to the Margin Rule.

There are another three non-U.S. parent entities regulated by the Board, which altogether have four entities registered with the Commission as swap dealers, due to the level of swap-dealing activity they engage in with U.S. counterparties (''Non-U.S. Dealers''). There are only three non-U.S. registered swap dealers that do not have a parent entity regulated by the Board and that would fall exclusively within the CFTC's jurisdiction for margin purposes (the ''Truly Foreign Dealers''), or just a fraction of the number of firms that are either based in the U.S. or controlled by a U.S. regulated parent. This brings to 39 the total number of swap dealers whose un-cleared swap activities would be subjected to the Commission's Margin Rule.

The Commission's regulatory interests in each of these categories of registered swap dealers is different, notwithstanding the fact the Commission has responsibility over all of them. In most respects, the Commission (and other U.S. policymakers and swap-market stakeholders) should be primarily concerned about the U.S. Foreign-Affiliate Dealers when thinking through and developing a cross-border framework to determine when these entities should follow U.S. law. This statement is based on the fact that concerns about risk importation into the U.S. are much lower, relatively speaking, when it comes to the activities of the Non-U.S. Dealers and Truly Foreign Dealers (none of the Non-U.S. Dealers or Truly Foreign Dealers would appear to meet the control test under the prudential regulators' September 2014 margin rule proposal). Instead, these latter categories of swap dealers raise different issues related to the Commission's mandates to enhance market integrity and promote fair competition.[2]

Appropriately, when Non-U.S. Dealers and Truly Foreign Dealers face other non-U.S. counterparties, they are excluded from having to comply with the Margin Rule under the proposal, so long as neither the registered swap dealer's nor its counterparty's obligations benefit from a guarantee by a U.S. person. Under the Guidance Approach, these Non-U.S. Dealers and Truly Foreign Dealers would be excluded from the Margin Rule as well, so long as neither the swap dealer's nor its counterparty's obligations benefit from a guarantee by a U.S. person.

I review the scope and weight of these responsibilities here because the context to deciding how much supervisory responsibilities to assert over the cross-border swap activities of entities located outside of the U.S. is important, both in understanding the practical implications of claiming those responsibilities as well as the potential effect on international comity. The review of the different categories of swap-dealer registrants also makes it clear to me that to pursue the Entity Approach without allowing substituted compliance, as some commenters suggested, is neither necessary for the Commission to meet its statutory responsibilities nor advisable, not to mention impractical.

When the Commission voted on the ANPR, I noted the potential benefits of the proposal set forth by the Prudential Regulators' Approach, which would effectively apply the margin rule as an entity-level rule with certain exclusions for foreign swap activities. At that time, however, I expressed my view that applying the margin rule as a transaction-level requirement under the Guidance Approach was the better option. In part, that view was shaped by the practical reality that it would be difficult for the Commission to meet its challenge to supervise U.S. swap dealers' compliance with the margin rule, let alone the activities of the U.S. Foreign-Affiliate Dealers and Truly Foreign Dealers.

Policy Advantages of Today's Proposal

As it relates to the Truly Foreign Dealers, compliance obligations under today's proposal would be effectively the same as under the cross-border guidance, so presumably no new burdens or competitive considerations would be created here for those firms (as discussed above). Additionally, as it relates to the U.S. Foreign-Affiliate Dealers (some of which have affiliates not supervised by the commission and engaged in swap activities), today's proposal could dis-incentivize firms from moving swap activity transacted by an affiliated entity regulated by a U.S. prudential regulator, into the U.S. Foreign-Affiliate Dealer. Such a market response is conceivable given the fact there could be different compliance obligations under the proposal as compared to the Guidance Approach depending on whether the U.S. Foreign-Affiliate Dealer is a Foreign Consolidated Subsidiary, and whether the dealer's un-cleared swap is supported by a guarantee. Presumably, there is swap activity of some of these U.S. Foreign-Affiliate Dealers that would be required to comply with the Margin Rule under today's proposal, that would not have been subjected to the Margin Rule under the Guidance Approach.

U.S. domestic regulators should not knowingly create an opportunity for affiliates within a U.S. bank holding company to move swap activity from one affiliate to another for no other reason than to avoid application of U.S. law (even if there are legitimate policy reasons that U.S. law would not apply). Indeed, this is why the Dodd-Frank Act requires the relevant agencies implementing the Margin Rule to coordinate their efforts as closely as possible. Knowingly allowing such a result also would be inconsistent with the Commission's statutory duty to promote fair competition.[3]

Similarly, the Commission should be careful to avoid adopting a significantly different cross-border approach from the U.S. prudential regulators if it would incentivize affiliates of U.S. Foreign-Affiliate Dealers to move their swap activity to the U.S. Foreign-Affiliate Dealer in order to exploit the relative dearth of resources available to the Commission for supervising and enforcing compliance. The CFTC currently is under-staffed. Meeting the challenge to monitor compliance with the complex and technical requirements of the Margin Rule as it applies to the swap activity conducted by U.S. Foreign-Affiliate Dealers today would be difficult. A cross-border approach that is substantively similar to the Prudential Regulators' Approach may facilitate the Commission in meeting its supervisory challenge.

Relatedly, I am also cognizant of market efforts to develop a standard initial-margin methodology for un-cleared swaps, which I believe would be supported by the hybrid approach set forth in today's proposal. I am in favor of these efforts because the use of a standard initial margin methodology has the potential to reduce dispute burdens by using a common approach for reconciliation, promote the efficient use of limited market resources, and enhance fairness and transparency in the global OTC derivatives markets. As such, the Commission should, if possible, avoid adopting a cross-border approach that would discourage the development of a standard initial-margin methodology, or would otherwise encourage the development of different margin methodologies across affiliated entities and/or the broader marketplace. This outcome

[1] *See* 7 U.S.C. 19(a).

[2] *See* section 3(b) of the Commodity Exchange Act (''CEA''), 7 U.S.C. 5(b).

[3] *See* section 3(b) of the CEA, 7 U.S.C. 5(b).

would complicate the jobs of all supervisory authorities involved, perhaps especially the U.S. prudential regulators.

Policy Advantages of the Guidance Approach

Generally speaking, the Commission in adopting its cross-border guidance intended to strike a reasonable balance in assuring that the swaps markets were brought under the new regulatory regime as directed by Congress and consistent with section 2(i) of the CEA.[4] We should not depart from those important policy judgments without a compelling reason to do so.

One advantage of the Guidance Approach, therefore, is that it would harmonize the Commission's own cross-border policies as they related to both cleared and un-cleared swap activity. Because many firms under the Commission's jurisdiction have incurred significant costs by building systems and practices designed to follow the Commission's cross-border guidance, overall costs to registered swap dealers might be lower if the Guidance Approach were adopted, which obviously is relevant to the Commission's mandate to consider the benefits and costs of its policies. But of course, with harmony of the Commission's cross-border policies comes disharmony with the U.S. prudential regulators.

Another advantage to the Guidance Approach is that it provides a more elegant way for U.S. Foreign-Affiliate Dealers, Non-U.S. Dealers and Truly Foreign Dealers to comply with their regulatory obligations when the Commission has made a substituted-compliance determination regarding another jurisdiction's margin requirements. Under the Guidance Approach, an affected swap dealer's obligations to post margin and collect margin would follow the same law or regulation of another jurisdiction if the Commission had made such a substituted-compliance determination; which is to say, margin payments going in both directions would follow the same set of rules. This outcome has the added benefit of being consistent with the Basel Committee on Banking Supervision's (''BCBS'') and the Board of the International Organization of Securities Commissions' (''IOSCO'') final margin policy framework for margin requirements for non-centrally cleared derivatives (the ''BCBS–IOSCO Framework''), which states that when a transaction is subject to two sets of rules, the regulators should endeavor to harmonize their rules to the extent possible.[5]

Given the relatively broad agreement among key jurisdictions about how the global framework for margin requirements ought to be structured, such a result should be an acceptable way to address any remaining concerns about risk from overseas activity transferring back to the U.S. Again, those concerns primarily would arise from the un-cleared swap activities of the U.S. Foreign-Affiliate Dealers. The proposal, on the other hand, would require a non-U.S. covered swap entity guaranteed by a U.S. person to follow U.S. initial margin rules, but only permit substituted compliance for the *posting* of initial margin when such non-U.S. covered swap entity trades with a non-U.S. counterparty.

In this scenario, it would be possible for two separate laws to apply to the same transaction. Under this framework, I question whether market participants engaging in un-cleared swaps would have the necessary legal certainty as to which margin requirements they would face. While this framework is proposed ostensibly to help ensure the safety and soundness of covered swap entities and to support the stability of the U.S. financial markets, these goals arguably will be accomplished only if the framework is workable. The Guidance Approach would arguably provide greater certainty as to the law applicable to a particular transaction, and render the Commission's policy more consistent with the BCBS–IOSCO Framework.[6]

To that end, I look forward to hearing additional comments on whether a swap between a non-U.S. covered swap entity and a non-U.S. counterparty should receive substituted compliance for the entire swap, rather than subject the swap to both U.S. and foreign margin requirements. Ideally, such comments would give the Commission a better understanding of the feasibility of designing systems to assist the covered swap entity comply with two separate margin requirements for the same transaction.

To the degree that the Commission should be concerned about deferring to other regulators to supervise the posting and collecting of margin for un-cleared swaps—as it would in the wake of a substituted-compliance determination—context again is important to remember here. As mentioned, there is relatively broad agreement among key jurisdictions about how the global framework for margin requirements should be structured, as a result of the issuance of the BCBS–IOSCO Framework. It's equally important to remember that the Commission's capital rule is treated as an entity-level rule under the Commission's cross-border guidance.[7] As I stated when the Commission released its proposal for the Margin Rule, credit risks not addressed through the Margin Rule could be addressed, at least in part, through indirect capital requirements at the holding company level, and direct capital requirements at the registrant level for those swap dealers relying on substituted compliance (or otherwise).

Yet another advantage to the Guidance Approach is that it might better avoid further diminishments to liquidity that the marketplace has experienced recently, as well as better avoid regulatory market fragmentation that materialized after the Commission's new swap-execution framework went into effect. Several commenters expressed strong concerns that the Entity Approach could further fragment the swaps markets and impair liquidity, promote regulatory arbitrage, and place the foreign affiliates of U.S. entities at a competitive disadvantage beyond the circumstances they face in the cleared swap environment under the Commission cross-border guidance. I have recognized and spoken about market fragmentation for years, and so do not take lightly such concerns being raised again in this context.

Clarifications of the Commission's Definition of ''Guarantee'' and ''U.S. Person''

The proposal includes two important clarifications for market participants that I would like to acknowledge. First, I am supportive of the proposed removal of the U.S. majority-ownership prong from the U.S. person definition. For certain types of funds, it is extremely difficult for advisors or administrators to accurately determine whether, and how many of, the beneficial owners of fund entities within the fund structure are U.S. persons. Given this complexity and the other elements of the U.S. person definition that would capture those funds that have a substantial nexus to the U.S. markets, I believe this exclusion is necessary and appropriate. I also support the release's proposed definition of ''guarantee''. This clearer definition will help market participants better identify those transactions that raise or implicate greater supervisory interest by the Commission.

Conclusion

The questions asked in this proposal are intended to solicit comment in hopes of further clarifying the most appropriate way for the Commission to meet its regulatory objectives as well as finding more consensus on the important issues raised in the release. As discussed above, I am open to the approach taken in this proposal and recognize its merits. I look forward to seeing whether comments filed in response to today's release can further build the case for the Commission adopting the proposal, rather than the Guidance Approach.

Appendix 4—Concurring Statement of Commissioner Sharon Y. Bowen

I'm pleased to support this new proposed rule on cross-border application of uncleared margin requirements for swap dealers and major swap participants. Margin requirements for uncleared swaps, needless to say, are a core piece of the new regulatory regime we are establishing as required by the Dodd-Frank Wall Street Reform and Consumer Protection Act.

It is imperative that we get all aspects of our margin requirements right, and that includes getting the cross-border element of the requirements right. The swaps market is a global one—the market has organically evolved to rely on the ability of U.S. entities to trade with European entities as a matter of course. It is incumbent on us that our rules not severely restrict this flow of commerce, just as it is incumbent on us that our rules provide rigorous regulations on this market for the protection of investors, consumers, and the broader financial system.

[4] *See* section 2(i) of the CEA, 7 U.S.C. 2(i).

[5] See BCBS and IOSCO, Margin requirements for non-centrally cleared derivatives (Sept. 2013) at 22, available at *http://www.bis.org/publ/bcbs261.pdf*. The BCBS–IOSCO Framework also provides that regulators should recognize the equivalence and comparability of their respective rules and apply only one set of rules to the transaction.

[6] *See id.*

[7] *See* Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations, 78 FR 45292 (July 26, 2013).

To that end, I look forward to receiving comments on this proposal from a wide swath of stakeholders, from market participants to financial reform advocates. I hope we will receive comments on whether this rule is workable, whether it is sufficiently robust, and what changes would make the rule more effective on both of those metrics.

Appendix 5—Statement of Commissioner J. Christopher Giancarlo

The Commission's proposal for the cross-border application of margin requirements for uncleared swaps is a highly complicated labyrinth. I look forward to the jolt to U.S. economic growth that will occur in the 3rd quarter of 2015 as a result of the thousands of billable hours that will be expended by lawyers and other professionals, who will have to read, interpret and respond to this tangled regulatory construct.

I have many concerns and questions regarding the proposal, including:

1. The shift from the transaction-level approach set forth in the July 2013 Cross-Border Interpretive Guidance and Policy Statement [1] (''Guidance'') to a hybrid approach and what this means for the status of the Guidance moving forward;

2. the revised definitions of ''U.S. person'' (defined for the first time in an actual Commission rule) and ''guarantee'' and how these new terms will be interpreted and applied by market participants across their entire global operations;

3. the scope of when substituted compliance is allowed; and

4. the practical implications of permitting substituted compliance, but disallowing the exclusion from CFTC margin requirements (''Exclusion'') for non-U.S. covered swap entities (''CSEs'') who qualify as Foreign Consolidated Subsidiaries.

My concerns extend to the standards set forth for determining comparability. An appropriate framework for the cross-border application of margin requirements for uncleared swaps is essential if we are to preserve the global nature of the swaps market. Congress recognized this when it instructed the CFTC, the SEC and the prudential regulators to ''coordinate with foreign regulatory authorities on the establishment of consistent international standards with respect to the regulation . . . of swaps.'' [2] Towards that end, representatives of more than 20 regulatory authorities, including the CFTC, participated in consultations with the Basel Committee on Banking Supervision (''BCBS'') and the Board of the International Organization of Securities Commissions (''IOSCO''), which resulted in the issuance of a final BCBS–IOSCO framework in September 2013 that establishes minimum margin standards for uncleared swaps (''BCBS–IOSCO framework'').[3]

Element seven of the BCBS–IOSCO framework discusses the cross-border application of margin requirements and stresses the importance of developing consistent requirements across jurisdictions to ensure that implementation at a national jurisdictional level is appropriately interactive:

> that is, that each national jurisdiction's rule is territorially complementary such that (i) regulatory arbitrage opportunities are limited, (ii) a level playing field is maintained, (iii) there is no application of duplicative or conflicting margin requirements to the same transaction or activity, and (iv) there is substantial certainty as to which national jurisdiction's rules apply. When a transaction is subject to two sets of rules (duplicative requirements), the home and the host regulators should endeavor to (1) harmonize the rules to the extent possible or (2) apply only one set of rules, by recognizing the equivalence and comparability of their respective rules.[4]

Regulatory authorities in major financial centers continue to collaborate in the development of their rules and I commend CFTC staff for their continued dialogue with fellow domestic and foreign regulators. Nevertheless, there are bound to be differences across jurisdictions in the final rule sets that are ultimately adopted. Comparability determinations allowing for substituted compliance with the margin requirements of foreign jurisdictions will be essential to achieving a workable cross-border framework. I am concerned that the standards for making comparability determinations outlined in the Commission's proposal may be too restrictive.

The Commission states that it will employ an outcome-based comparability standard focusing on whether the margin requirements in a foreign jurisdiction achieve the same regulatory objectives as the CFTC's margin requirements and will not require specific rules identical to the Commission's rules. The Commission states further, however, that it will make its outcome-based determinations on an element-by-element basis that will include, but not be limited to, analyzing: (i) The transactions subject to the foreign jurisdiction's margin requirements; (ii) the entities subject to the foreign jurisdiction's margin requirements; (iii) the methodologies for calculating the amounts of initial and variation margin; (iv) the process and standards for approving models for calculating initial and variation margin models; (v) the timing and manner in which initial and variation margin must be collected and/or paid; (vi) any threshold levels or amount; (vii) risk management controls for the calculation of initial and variation margin; (viii) eligible collateral for initial and variation margin; (ix) the requirements of custodial arrangements, including rehypothecation and segregation of margin; (x) documentation requirements relating to margin; and (xi) the cross-border application of the foreign jurisdiction's margin regime.

As proposed, the Commission will not be assessing whether the foreign authority's margin regime as a whole meets the broad regulatory objectives of requiring margin for uncleared swaps.[5] Rather, in looking at each element (and any other factor not included in the foregoing list) the Commission may determine that a foreign regime is comparable as to some elements, but not others, in which case substituted compliance might be allowed, for example, with respect to the methodologies for calculating initial and variation margin, but not for the eligible collateral.

Depending on how it is put into practice, this element-by-element approach may be difficult to distinguish from the rule-by-rule analysis the Commission claims to eschew. We have seen this before when the Commission made its comparability determinations for certain foreign countries regarding certain transaction-level requirements for swap dealers and major swap participants.[6] There, the Commission made its determinations on a ''requirement-by-requirement'' basis, rather than on the basis of the foreign regime as a whole.[7] Former Commissioner Scott O'Malia observed in that instance that this was a ''rule-by-rule'' analysis, which was contrary to the recommendations of the OTC Derivatives Regulators Group and afforded only limited substituted compliance relief.[8] Will our ''element-by-element'' analysis be any different than the ''requirement-by-requirement'' method the Commission employed then?

I fear that the proposed element-by-element approach will be outcome-based in name only. In a perfect world all G–20 countries will adopt comparable margin requirements, but we cannot let the perfect be the enemy of the good. For substituted compliance to work, we must focus on broad objectives, not specific requirements.

I am also troubled by the provision of the proposed rule that would not permit swaps executed ''through or by'' a U.S. branch of a non-U.S. CSE to qualify for the Exclusion for non-U.S. CSEs who qualify as Foreign Consolidated Subsidiaries. Under the proposal, uncleared swaps entered into by a non-U.S. CSE with a non-U.S. person counterparty (purely foreign-to-foreign swaps), where neither counterparty is a Foreign Consolidated Subsidiary or guaranteed by a U.S. person, would be excluded from the Commission's margin rules. The Exclusion is not available, however, if the swap is executed ''through or by'' the U.S. branch of a non-U.S. CSE.[9] The

[1] Interpretive Guidance and Policy Statement Regarding Compliance With Certain Swap Regulations, 78 FR 45292 (Jul. 26, 2013).

[2] 15 U.S.C. 8325(a) (added by section 752 of the Dodd-Frank Act).

[3] *See* Margin Requirements for Non-centrally Cleared Derivatives (Sep. 2013), *available at http://www.bis.org/publ/bcbs261.pdf*, revised Mar. 2015, *available at http://www.bis.org/bcbs/publ/d317.pdf*.

[4] *Id.* at 23.

[5] The regulatory objectives of requiring margin for uncleared swaps, as stated in the Dodd-Frank Act, are to help insure the safety and soundness of the swap dealer or major swap participant, the financial integrity of the markets and the stability of the U.S. financial system. Section 4s(e)(3)(A), (C), 7 U.S.C. 6s(e)(3)(A), (C).

[6] *See, e.g.,* Comparability Determination for the European Union: Certain Transaction-Level Requirements, 78 FR 78878 (Dec. 27, 2013).

[7] *Id.* at 78881.

[8] *Id.* at 78889.

[9] I note that the ''through or by'' language appears in the preamble to the rule, not the rule text.

request for comment following this discussion asks how the Commission should determine whether a swap is executed ''through or by'' a U.S. branch and suggests using the same analysis used in the Commission's Volcker Rule, which required that personnel that ''arrange, negotiate, or execute'' a purchase or sale conducted under the exemption for trading activity of a foreign banking entity must be located outside the U.S.[10]

Prior to its appearance in the Commission's final Volcker Rule this concept appeared in a hastily issued, November 2013 Staff Advisory 13–69 (sometimes referred to in the industry as the ''elevator rule'') that imposed swaps transaction rules on trades between non-U.S. persons whenever anyone on U.S. soil ''arranged, negotiated, or executed'' the trade.[11] The effective date of this Staff Advisory has been delayed four times.[12] As I have stated before, the elevator rule is causing many overseas trading firms to consider cutting off all activity with U.S.-based trade support personnel to avoid subjecting themselves to the CFTC's flawed swaps trading rules. The Staff Advisory, if it goes into effect, will jeopardize the role of bank sales personnel in U.S. financial centers like Boston, Charlotte, Chicago, New Jersey and New York. It will likely have a ripple effect on technology staff supporting U.S. electronic trading systems, along with the thousands of jobs tied to the vendors who provide food services, office support, custodial services and transportation for the U.S. financial series industry. With this proposal, rather than recognizing the myriad of problematic issues arising from the Staff Advisory, the Commission is proposing to expand its scope from trading rules to margin rules.

Despite my many questions and concerns, I support issuing the proposed rule only so that the public may provide thorough analysis and thoughtful comment. My vote to issue the proposal for public comment should not signal, however, my agreement with it. I look forward to reviewing public comment.

[FR Doc. 2015–16718 Filed 7–13–15; 8:45 am]

BILLING CODE 6351–01–P

[10] *See* Prohibitions and Restrictions on Proprietary Trading and Certain Interests in, and Relationships With, Hedge Funds and Private Equity Funds, 79 FR 5808, 5927 & n.1526 (Jan. 31, 2014).

[11] CFTC Staff Advisory No. 13–69 (Nov. 14, 2013), *available at http://www.cftc.gov/ucm/groups/public/@lrlettergeneral/documents/letter/13-69.pdf.*

[12] CFTC Letter No. 14–140, Extension of No-Action Relief: Transaction-Level Requirements for Non-U.S. Swap Dealers (Nov. 14, 2014), *available at http://www.cftc.gov/ucm/groups/public/@lrlettergeneral/documents/letter/14-140.pdf.*

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Federal Register

Vol. 80, No. 134

Tuesday, July 14, 2015

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FEDERAL REGISTER PAGES AND DATE, JULY

37529–37920 1
37921–38390 2
38391–38612 6
38613–38912 7
38913–39376 8
39377–39668 9
39669–39940 10
39941–40894 13
40895–41408 14

CFR PARTS AFFECTED DURING JULY

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:
13699 37529
Administrative Orders:
1 37921

5 CFR

532 40895
Proposed Rules:
1600 39974
1601 39974
1651 39974
1653 39975
Ch. XXII 38019

7 CFR

929 37531
932 37533
4279 39377
4287 39377
Proposed Rules:
986 38021
1211 37555

9 CFR

94 ..... 37923, 37935
112 39669

10 CFR

430 ..... 37953, 37954
Proposed Rules:
Ch. II 38019
Ch. III 38019
Ch. IX 38019
429 ..... 39486, 39644
430 ..... 39644, 40938
431 ..... 38032, 39486
1703 39389

12 CFR

600 40896
Proposed Rules:
Ch. I 39390
Ch. II 39390
Ch. III 39390
327 40838
701 37898
723 37898
741 37898

14 CFR

33 38913
39 ..... 38391, 38613, 38615, 38617, 39941, 39943, 40897, 40899
Proposed Rules:
39 ..... 38033, 38036, 38038, 38406, 38408, 38656, 38990, 38992, 39392, 39394, 40942, 40947, 40949

15 CFR

736 39950
740 39950
744 39950
748 39950
774 39950

16 CFR

Proposed Rules:
313 38410
1112 38041
1233 38041

17 CFR

231 37536
232 37537
241 37536
271 37536
275 37538
276 37536
Proposed Rules:
23 41376
229 41144
240 ..... 38995, 00000
249 41144
274 41144
275 38050
279 38050

18 CFR

Proposed Rules:
284 39719
342 39010

19 CFR

201 39377
206 39377
208 39377
213 39377
214 39377
215 39377
216 39377
217 39377
218 39377
219 39377
220 39377
221 39377
222 39377
223 39377
224 39377
225 39377
226 39377
227 39377
228 39377
229 39377
230 39377
231 39377
232 39377
233 39377
234 39377
235 39377
236 39377
237 39377
238 39377
239 39377

240....39377
241....39377
242....39377
243....39377
244....39377
245....39377
246....39377
247....39377
248....39377
249....39377
250....39377
251....39377
252....39377
253....39377
254....39377
255....39377
256....39377
257....39377
258....39377
259....39377
260....39377
261....39377
262....39377
263....39377
264....39377
265....39377
266....39377
267....39377
268....39377
269....39377
270....39377
271....39377
272....39377
273....39377
274....39377
275....39377
276....39377
277....39377
278....39377
279....39377
280....39377
281....39377
282....39377
283....39377
284....39377
285....39377
286....39377
287....39377
288....39377
289....39377
290....39377
291....39377
292....39377
293....39377
294....39377
295....39377
296....39377
297....39377
298....39377
299....39377

20 CFR

404....37970
416....37970

21 CFR

11....39675
20....38915
101....39675
310....38915
314....38915
600....38915
601....37971
610....37971
680....37971
Proposed Rules:
601....38145
1100....37555
1140....37555
1143....37555

22 CFR

121....37974
Proposed Rules:
171....40951

23 CFR

650....41350

24 CFR

Proposed Rules:
203....38410

25 CFR

83....37538, 37862

26 CFR

1....38940, 38941
54....41318
Proposed Rules:
1....39397
301....39397
602....39397

27 CFR

Proposed Rules:
9....38147

28 CFR

527....38620
571....38622
Proposed Rules:
506....38658
810....39400

29 CFR

18....37539
2519....41318
2590....41318
Proposed Rules:
541....38516

31 CFR

591....39676
Proposed Rules:
22....39977
315....37539
353....37539
360....37539

32 CFR

323....39381

33 CFR

100....38394, 38397, 39382
117....39382, 39383, 39683
147....40903
165....37540, 37542, 37545, 37976, 37978, 37980, 37982, 38623, 38941, 38943, 38944, 38946, 39383, 39384, 39386, 39686, 39688, 39689, 39691, 39694, 39957, 39960, 39961
Proposed Rules:
117....38417
165....37562, 39400, 39403

34 CFR

Proposed Rules:
668....39608
682....39608
685....39608

36 CFR

Proposed Rules:
7....39985
13....39988

38 CFR

Proposed Rules:
4....39011

39 CFR

Proposed Rules:
957....37565
961....37567
966....37567

40 CFR

52....37985, 38400, 38403, 38625, 38951, 38959, 38966, 38969, 39696, 39961, 39966, 39968, 39970, 40905, 40909, 40911, 40913, 40915, 40917
60....38628
70....40922
80....38284
81....39970
180....37547, 38976, 38981
257....37988
262....37992
761....37994
Proposed Rules:
9....40138
22....40138
52....38152, 38419, 38423, 39020, 40952, 40954, 40955
85....40138
86....40138
87....37758
600....40138
704....38153
1033....40138
1036....40138
1037....40138
1039....40138
1042....40138
1043....40138
1065....40138
1066....40138
1068....37758, 40138

41 CFR

301....37995
302....37995
303....37995
304....37995
305....37995
306....37995
307....37995
308....37995
309....37995
310....37995
Proposed Rules:
102–177....39719

42 CFR

480....40923
482....40923
Proposed Rules:
88....39720
409....39840
410....39200
412....39200
413....37808
416....39200
419....39200
424....39840
484....39840
510....41198

43 CFR

Proposed Rules:
47....39991
48....39991
3160....40768
3170....40768

44 CFR

64....37996

45 CFR

147....41318
155....38652

46 CFR

503....37997
Proposed Rules:
501....38153
502....38153

47 CFR

1....38653, 38812
2....38812
15....37551
17....37552
20....38653
25....38812
27....38812
54....40923
74....38812
76....38001
78....38812
79....39698
80....38812
87....38812
90....38812
97....38812
101....38812
Proposed Rules:
2....38316
8....38424
15....38316
69....40956
73....38158, 40957
74....38158
79....39722
80....38316
90....38316
97....38316
101....38316

48 CFR

Ch. 1....38292, 38313
1....38293, 38306, 40968
2....38293
3....38293
4....38293, 40968
5....38307
6....38293
7....38293
8....38293, 40968
9....38293, 38309
10....38293
12....38293, 38311
13....38293, 38311
15....38293, 38312
16....38293
17....38293, 40968
18....38311
19....38293

22 .....38293, 38307, 40968
25.....38293
28.....38293
30.....38293
42.....38293
50.....38293
52 .....38293, 38306, 38309, 38312, 40968
53.....38293

49 CFR

219.....38654
390.....37553

Proposed Rules:

190.....39916
191.....39916
192.....39916
195.....39916
199.....39916
512.....40138
523.....40138
534.....40138
535.....40138
537.....40138
538.....40138
1201.....39021
1241.....39045
1242.....39045
1243.....39045
1244.....39045
1245.....39045
1246.....39045
1247.....39045
1248.....39045

50 CFR

21.....38013
300.....38986
622 .....38015, 39715, 40936
635.....38016
660.....39716
679.....38017

Proposed Rules:

17.....37568
219.....39542
224.....40969
648.....39731
679.....39734, 40988

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List July 9, 2015

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